

Biotech Daily

Friday June 4, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.49 percent on Friday June 4, 2021, with the ASX200 up 35.3 points to 7,295.4 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, 13 fell and five traded unchanged. All three Big Caps were up.

Prescient was the best on no news, up four cents or 30.8 percent to 17 cents, with 33.2 million shares traded. Antisense climbed 15.8 percent; Actinogen improved 11.5 percent; Telix was up 7.6 percent; Dimerix rose 6.7 percent; Next Science was up 5.6 percent; Paradigm and Universal Biosensors improved more than four percent; Medical Developments and Patrys were up more than three percent; Kazia, LBT, Polynovo and Pro Medicus rose more than two percent; Avita, Clinuvel, Cochlear, CSL, Cyclopharm, Genetic Signatures and Resmed were up more than one percent; with Nanosonics, Neuren, Proteomics and Volpara up by less than one percent.

Uscom led the falls, down two cents or 11.1 percent to 16 cents, with 381,546 shares traded. Amplia lost six percent; Immutep and Osprey were down five percent or more; Optiscan fell 4.9 percent; Alterity was down 3.45 percent; Resonance retreated 2.6 percent; Compumedics, Imugene, Orthocell and Pharmaxis were down more than one percent; with Mesoblast and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: UNIVERSAL BIOSENSORS

By TIM BOREHAM

ASX code: UBI (Chess Depositary Instruments)

Share price: 61.5 cents; Market cap: \$109.2 million; Shares on issue: 177,621,854

Financials (March quarter 2021): revenue \$1.55 million (up 200%), operating loss of \$2.41 million (previously a \$3.3 million deficit), cash of \$20.7 million (down 12%)

Chief executive: John Sharman

Board*: Craig Coleman (chairman), David Hoey, Judith Smith

* Marshall Heinberg resigned on March 17, 2021

Identifiable major shareholders: Vibernum Funds (Craig Coleman) 15.3%, JM Financial 12.4%, Jencay 11.7%

Almost a year into his reign at the sensor monitoring group, Universal Biosensors chief John Sharman doesn't hold back about the company's ability to disappoint investors over the last decade, despite big-ticket deals with industry giants Johnson & Johnson (Lifescan) and Siemens.

His blunt assessment: "I've seen plenty of corporate disasters over my journey, but none with such great technology and opportunity that has delivered almost nothing."

Ouch!

Whether this critique is totally fair or not, clear evidence is emerging of an uptick in fortunes under the reign of Mr Sharman, who ran fellow ASX-listed device play Medical Developments for a decade.

When he clocked on, Universal derived most of its (modest) revenue from providing its Xprecia Stride blood coagulation monitoring strips to Siemens (for warfarin users).

In September 2019, the company bought back the coagulation rights from Siemens, for \$15 million.

In September 2018, Lifescan exercised its option to buy the rights to Universal's blood glucose monitoring platform for \$44.6 million, a disappointing deal that sent the share-price crashing.

Using its core electrochemical platform, Universal has now launched a potentially lucrative wine testing device and is also confident of a simple test for cancer biomarkers, hormones (for fertility testing) and veterinary glucose testing.

The back story

The Universal Biosensors story is based on its proprietary handheld electro-chemical sensing system, devised by a team led by CSIRO electro-chemist Dr Alistair Hodges. The company listed in December 2006 after raising \$22 million at 50 cents apiece.

For reasons lost in the mists of time, the company is incorporated in Joe Biden's home state of Delaware but is not listed in the US. Still, the company has to file all those ponderous Securities and Exchange Commission disclosures that use archaic fonts and terminology and go on for pages and pages ... and pages.

Similar to the cartridge and printer model, the company derived annuity revenue from both the hand-held device (the printer) and the single use disposable strips.

Ten billion blood and coagulation tests have been carried out, so there's no issue with the tech being verified.

Mr Sharman was CEO of Medical Developments for 10 years, having previously run the nuclear imaging company Cyclopharm. He became involved with Universal Biosensors via Max Johnston, who was president of Johnson & Johnson's Asia Pacific operations and a Medical Developments director.

"He was the one signing the cheques and liked the technology," he says.

From micromolar to picomolar

Mr Sharman says the platform's applications have been limited to so-called micromolar level detection, which rules out many health applications.

In a deal with Lubris Biopharma, the company has secured technology that increases detection by one million times, to picomolar level. The secret sauce is an anti-fouling agent called Lubricin, which Mr Sharman describes as a "supersonic magnifying glass".

When applied to electro-chemicals in bio-assays, the coating overcomes the issue of electrode surface fouling. The upshot is that the company can expand into the oncology, women's health and wine testing applications.

Mr Sharman says the ensuing clarity is like comparing the functionality of an old camera to that of a mobile phone.

"Lubricin makes us the Tesla or Apple versus Kodak. It puts us at the forefront of handheld detection."

Early cancer detection with a pin prick

In the cancer space, Universal is targeting a test for the Tn antigen, which is expressed in at least 10 carcinomas including breast lung, prostate, bladder and colorectal.

Developed in conjunction with Swinburne, Deakin and Wollongong universities, the sensor detects the early warning sign of a carcinoma.

Apart from early diagnosis, Mr Sharman says the simple test has the potential as a tool for physicians to test the progression of cancer from stage one to stage three. It can also map the efficacy of a therapy.

Perhaps the most promising use is as an easy ongoing home test for cancer patients in remission.

Mr Sharman says a typical regimen currently is twice-yearly tests for the first two years, and then one test annually, thereafter, but the Universal Biosensors Tn test could be carried out weekly, increasing the chances of early detections of recurring carcinomas.

Mr Sharman notes that 131 million cancer patients are in remission, with 78 million of these recovering from carcinomas. With 122 million blood cell count tests done each year, the remission market alone is worth \$17 billion a year.

According to one study, 90 percent of patients with recurring bladder cancer had detectable levels of Tn antigen.

Mr Sharman acknowledges that while the regulatory pathway would be similar to that pursued for the blood and coagulation monitoring, the hurdles are not to be sneezed at.

A fertile source of revenue

For the purpose of fertility procedures, the patient's oestrogen and progesterone levels have to be just right to maximize the chances of procreation.

The two million patients undergoing in-vitro fertilization (IVF) procedures a year need to undergo half a dozen 'blood draw' tests to determine the optimal levels of the blood tests.

"That's a \$2 billion a year industry just for the blood tests," Mr Sharman says.

The company is being advised by Prof Michael Cooper, a leading Australian fertility expert.

I'll drink to that

Universal's clear and present revenue opportunity lies not with human health but human happiness: testing wine batches during production.

While winemakers pride themselves on their artisan abilities, the truth is that the process involves more chemistry than a petro-chemical plant.

"The artists hate the chemistry but need it to create the art," Mr Sharman says. "The winemaker doesn't want to be a chemist, but the chemist wants to be a winemaker."

Vignerons need to test separately for levels of free sulphur, malic acid, glucose and fructose, acetic acids and total acids. Universal Biosensors is already marketing its device, Sentia, to test for sulphur levels and hopes to expand to four tests by the end of 2020.

Traditionally, each assay takes 20 to 30 minutes, with the testers scurrying between barrel barn and lab to test and manually record each batch.

"We will do it inside a minute, in an idiot-proof fashion," Mr Sharman says.

Indeed, Mr Sharman kindly whipped out his kit and uncapped a minibar-sized bottle of Jacobs Creek cab say, to demonstrate that that's indeed the case.

Crucially, the test can be carried out for one tenth (or perhaps even one twentieth) of the cost of the current tests, which involve beakers and other paraphernalia. Having launched Sentia in early March, Universal claims sales of 800 devices and 100,000 strips, which "in a Covid-infected world is a very good result", and with a string of country-based distribution deals, the company cites access to 14,000 winemakers.

The devices sell for just under \$2,000, with a per-strip cost of \$3.50, and with more 100 million tests a year, wine testing turns over \$US850 million (\$A1.1 billion) annually.

"Getting to somewhere between 15 percent and 30 percent [market share] feels right, but we could get to 40 percent," Mr Sharman says.

The company is using the Coldstream Hills winery, formerly owned by wine critic James Halliday and now in the hands of Treasury Wine Estates, as a test site. During harvest and bottling time, the Yarra Valley winery has to hire a person for six weeks carry out 1,400 sulphur tests across 40 bins (barrels).

Don't forget the animals

Another promising sideline is with the veterinary market for glucose (diabetes) testing. The story here is that while Lifescan bought the human glucose testing business, it has no interest in the cats-and-dogs side and was happy to cede the tech to the company.

The vet glucose testing market is worth \$200 million and growing at around 11 percent a year. The key driver? An astonishing 50 percent of US companion dogs are obese and - yes - they resemble their owners.

Mr Sharman notes the market is already serviced by two key providers, but they have clunky products. If Universal can penetrate 10 percent of the market, that's \$20 million of annual revenue.

"We are just going to come to market with a cheaper, faster, better mouse trap," he says. "The company has just got to get the tech back and dust off the cobwebs. Some tinkering needs to be done to the meter and to the algorithms to accommodate for dogs and cats rather than humans."

The company expects to launch the vet product by the end of 2022.

Financials and performance

Universal Biosensors recorded revenue of just over \$1.5 million in the March quarter of 2021, with turnover derived mainly from coagulation testing with a splash of wine as well. In the year to December 2020 the company turned over \$3.2 million, down 54 percent and lost \$7.6 million compared with a \$4.8 million shortfall previously.

Mr Sharman says the company is "working hard" to achieve consistent monthly break even by the June half of 2022.

Thanks to the Johnson & Johnson Lifescan deal, Universal Biosensors has \$24 million of cash. It also has no debt, having repaid an (expensive) \$15 million loan to Athyrium Opportunities Fund in late 2018.

Ostensibly, there's no good reason for the company to be US-incorporated - it's more trouble than it's worth - but with \$US25 million tax losses crystallized in the corporate structure the arrangement won't unwind in a hurry. (For all intents and purposes the company is headquartered in Melbourne's suburban Rowville, where it makes the strips).

Over time, Universal Biosensors shares have traded between a peak of \$2.00 in January and a low of 14 cents in mid-March last year. For a while, the shares traded well below net cash backing ascribing a negative value to the company's technologies.

Dr Boreham's diagnosis:

Universal Biosensors' headline ambition is to have between 10 and 12 sensors on market, including six in wine and three in fertility. And with coagulation back in its own hands, the company is confident of increasing overall revenue to \$20 million a year.

The way we see it is that wine testing will uncork handy short-term revenues, while the cancer testing offers the most capacious upside.

On the vino side, winemakers tend to stick to tradition even though their way of doing things might not be the most effective. But most of them fell out of love with the romance of cork when Stelvin closures (screw caps) proved to be far more effective at preventing wine spoilage.

While Mr Sharman was at Medical Developments, the company increased market valuation from \$7 million to up-to \$770 million. "Universal Biosensors has the potential to outstrip that, if we get it right," he says.

Firstly, though, management needs to re-engage with jaded shareholders. But the stock's circa 300 percent bounce over the last year shows they are starting to groove to the jungle drums of opportunity.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He didn't drink the remaining Jacobs Creek because it was (a) Jacobs Creek and (b) 10am, not 11am.

EXOPHARM

Exopharm says that Russia's Patent Office has granted a patent covering its ligand-based exosome affinity purification (Leap) technology.

Exopharm said that the patent, titled 'Methods and compositions for purification or isolation of microvesicles and exosomes', would protect its intellectual property until December 22, 2037.

The company said the patent covered the core technology that enabled the exosome extraction and purification needed to manufacture exosome-based medications at clinical and pharmaceutical grade and scale.

Exopharm chief executive officer and Leap co-inventor Dr Ian Dixon said that "for the first time, our broad claims around the novel use of chromatography for exosome purification have been granted at the country-level".

"These claims are the same we are actively progressing in key markets across North America, Europe and Asia," Dr Dixon said.

Exopharm was up three cents or 5.3 percent to 60 cents.

CRESO PHARMA

Creso says it has appointed Route2 Pharm as the distributor of its marijuana-based Cannaqix and Cannadol for Ecuador, extending to 14 countries in total.

In February, Creso said the Lahore, Punjab-based Route2 had agreed to minimum orders up-to CHF1.71 million (\$A2.48 million) for its Cannaqix 10, Cannaqix 50 and Cannadol products in the first year of the three-year agreement for distribution in Pakistan, the Philippines, and other markets (BD: Feb 15, 2021).

Today, the company said the agreement in association with Lahore, Punjab-based Highnoon Laboratories would follow similar material terms.

Creso fell one cent or 5.6 percent to 17 cents with 63.1 million shares traded.

RESONANCE HEALTH

Resonance says chief executive officer Alison Laws "unfortunately had to tender her resignation ... due to unplanned personal family obligations".

Resonance said Ms Laws joined the company in 2017 and was appointed chief executive officer in February 2018 and "during her tenure the company has achieved growth in sales volumes, revenues, cash at bank, and profitability".

The company said it had invited Ms Laws to provide consultancy services to it when her personal circumstances permit to which she had, in-principle, accepted.

Resonance said it expected Ms Laws to leave in "early July".

Resonance chairperson Dr Martin Blake said that Ms Laws had been "a highly effective and successful chief executive officer".

"Alison has earned the respect of the industry and the board of directors for her work ethic, and her management and business development skills," Dr Blake said.

"We wish Alison the best in the coming months," Dr Blake said.

The company said it has appointed director Mitchell Wells as an executive director, effective immediately until further notice.

Biotech Daily wishes Ms Laws and her family all the best.

Resonance fell half a cent or 2.6 percent to 19 cents with 3.1 million shares traded.

POLYNOVO

Polynovo says it has appointed accountant Andrew Lumsden as a non-executive director, effective from today.

Polynovo said Mr Lumsden had experience in governance, mergers and acquisitions, taxation, investor relations and strategic planning.

The company said Mr Lumsden was currently Wellcom Group's chief operating officer and was previously a senior audit manager at Pricewaterhousecoopers in the UK and Australia.

Polynovo said Mr Lumsden held a Master of Arts from Edinburgh's Heriot-Watt University. Polynovo was up six cents or 2.3 percent to \$2.68 with 1.1 million shares traded.

ACRUX

Acrux says it has appointed Don Brumley as a non-executive director, replacing Norman Gray.

Acrux said that Mr Brumley had been a partner at Ernst & Young Oceania for 30 years and had experience in initial public offers, transactions and audit.

The company said that Mr Gray had been a director since 2019 and resigned, effective from today.

Acrux was up half a cent or 3.7 percent to 14 cents.

OVENTUS MEDICAL

Oventus says it has appointed John Cox as its chief operating officer, with Jim Hunter as the acting chief financial officer, replacing Dan Parry.

Oventus said Mr Parry would "pursue another opportunity".

The company said Mr Cox had more than 30 years of experience in the medical technology sector which included experience in sleep and related technology marketing and operations.

Oventus said Mr Cox was previously the chief executive officer at Somnera Inc and USGI Medical chief operating officer, and was currently the co-founder and chair of Retraction. The company said Mr Cox held a Bachelor of Arts and Master of Business Administration from the Charlottesville-based University of Virginia.

Oventus said Mr Hunter had more than 30 years of experience and has previously led companies as head of finance through its growth stage and transformation.

Oventus was up half a cent or 4.55 percent to 11.5 cents.