



# Biotech Daily

Friday November 24, 2023

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.17 percent on Friday November 24, 2023, with the ASX200 up 11.6 points to 7,040.8 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and three were untraded.

Universal Biosensors was the best on no news, up five cents or 26.3 percent to 24 cents, with 371,679 shares traded; followed by 4D Medical, up 18.6 percent to 92.5 cents with 3.9 million shares traded.

Impedimed improved 12.5 percent; Prescient climbed 7.35 percent; Pharmaxis was up 6.7 percent; Alcidion rose 5.8 percent; Cyclopharm and Nova Eye were up more than three percent; Imugene, Volpara and Telix rose more than two percent; Immutep and Polynovo were up more than one percent; with Clinuvel, CSL, Nanosonics, Neuren and Resmed up by less than one percent.

Patrys led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 8.5 million shares traded. Proteomics lost 5.7 percent; Actinogen, Cynata, Micro-X and SDI fell four percent or more; Emvision, Next Science and Opthea were down more than three percent; Atomo, Mesoblast and Paradigm shed more than two percent; Antisense and Avita were down more than one percent; with Cochlear and Pro Medicus down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: OPTISCAN](#)

**By TIM BOREHAM**

**ASX code:** OIL

**Share price:** 9.5 cents; **Shares on issue:** 835,140,803; **Market cap:** \$79.3 million

**Chief executive officer:** Prof Camile Farah

**Board:** Robert Cooke (chair), Prof Farah, Karen Borg, Ron Song, Sean Gardiner

**Financials (year to June 30, 2023):** revenue \$1.68 million (up 66%), loss of \$4.35 million (previous deficit \$4.23 million)

**September 2023 quarter:** customer receipts \$190,000, cash outflows \$1.62 million, cash \$15.73 million (post \$16.7 million capital raising) quarters of available funding: 9.7

**Major shareholders:** Peters Investments (24.1%), Orchard Capital 18.6%, Ibsen Pty Ltd (former director Ian Mann) 5.2%

Having viewed too many medical soapies, your columnist is relieved that robots are rapidly replacing surgeons in the (literally) hands-on aspect of the role.

Why? In shows such as ER and Grey's Anatomy, the knife wielders are more obsessed with their love lives than getting the excisions right.

In real life, the hands of older surgeons are also shakier than they once were – in the operating theatre as well as on the golf course. In contrast, robots have hands that won't move a millimetre out of place for the whole procedure, as well 'minds' that are undistracted by tawdry affairs with interns.

Surgical robots are a key growth avenue for the ASX-listed Optiscan, a leader in an imaging technique called confocal laser endo-microscopy (CLE). A potential replacement for biopsies, CLE enables clinicians obtain a live, or 'in-vivo', three-dimensional (3-D) microscopic digital image of tissue with a hand-held device.

"We are trying to shift the pathology work flow from being a manual analogue outdated procedure to bringing the pathologist and the surgeon into the operating theatre where they make decisions using our platform," says Optiscan chief Prof Camile Farah.

### **Not the endo the story ...**

Optiscan has developed Invivage, a hand-held pen-like device for digital biopsies that harnesses confocal laser endo-microscopy (CLE) to produce high-resolution images.

Invivage shows surgeons individual human cells, magnified 1,000 times and conveyed via a single optical fibre, placed directly on the tissue.

Surgeons and pathologists can make real-time decisions during surgery, in a fraction of the time it takes to get a verdict on a biopsy from the laboratory. The surgeon knows immediately whether further excision is required or - just as importantly - whether the suspect mass is benign.

The device is relevant for open surgery, notable for lumpectomies (breast surgery) but the company is also developing a flexible version to assist surgeons in laparoscopic (keyhole) surgeries.

In the US, procedures such as lumpectomies and proctectomies (rectal surgery) increasingly are being carried out by robots. Optiscan's probes enable the real-time imaging of the suspect area to be conveyed to the surgeon, who guides the robot via a joystick.

### **But biopsies be gone ...**

Physical biopsies have been around for more than a century but remain the standard-of-care for determining diseases.

A biopsy involves removing a small piece of tissue, also known as human flesh or the suspected growth, with the sample analysed under a microscope.

Biopsies can be notoriously painful and result in side effects such as bleeding, infection and even accidental damage to adjacent organs.

They also take precious time and often turn out to be unnecessary.

### **Muddling along**

Optiscan has a tangled history marked by regular management upheavals and missed deadlines.

The company was founded in 1994 as an arm of Circadian (now Opthea), based on technology invented by Peter Delaney who was working with the CSIRO, and listed on the ASX 1997, with a star-studded board including Dr Alan Finkel, later the nation's chief scientific officer, along with Vision Systems' and Biota's Dr Jim Fox.

In 2002, Optiscan started selling an early version of the device for gastro-intestinal surgery, via a partnership with Japan's Pentax (which finally cottoned on that film cameras had about as bright a future as nightmen and blacksmiths).

In 2007, Optiscan formed a collaboration with German optics house Carl Zeiss Meditec (CZM), which exclusive rights to Optiscan's neurosurgery, ear, nose, throat and spine applications. Under the tie-up, Optiscan sells the units to Carl Zeiss, which will then market them under its own name (Convivo).

Optiscan derives modest revenues from both this alliance and Viewnvivo, a miniaturised handheld probe used for research purposes by universities and big pharma.

Along with a string of chairs and CEOs, Mr Delaney led the company until 2016, when he was succeeded by Scotsman and sports administrator Archie Fraser in 2016. He resigned in January 2018, to be replaced by executive chair Darren Lurie.

At one stage Mr Delaney became chief technology officer, but in a farcical turn of events he quit the role amid a shareholder challenge, only to be reinstated.

A Perth-based oral physician and pathologist, Prof Farah was appointed in December 2021 with a remit to move the company to developing its own hardware and digital software tools.

## **Best breast results**

On September 19 this year, the company reported the interim results of a current trial at the Royal Melbourne Hospital, which assesses the efficacy of Invivage compared with traditional histology (microscope examination of cells) for breast cancer.

An ex-vivo analysis of 15 tumours in 12 patients, post-surgery, showed an “excellent correlation between Optiscan’s real-time CLE test and traditional histological analysis”. Prof Farah describes the preliminary results as “quite spectacular”.

“We are still continuing with analysis and might have another update by the end of this year,” he says.

In effect, the imaging was after the fact. In the next stage, the patient will be imaged during surgery, enabling better assessment of whether all the tumor has been excised.

“The difference is it is the surgeon doing the imaging and making the decisions,” Prof Farah says. “The first study was all about ‘let’s see if we can do this’ and, clearly, we can.”

Disturbingly, one-third of breast cancer lumpectomy patients still have cancerous cells in the surgical bed and must return for a wider resection. Optiscan’s ‘platform’ approach means its technology has broad live microscopic imaging applications, including in pathology, life science research and vet clinics.

“Oncology makes sense for us as a starting point, because it’s a huge addressable market with numerous clinical issues to solve,” Prof Farah says.

The ex-vivo trial was a non-inferiority exercise, which means Optiscan merely had to prove the device was no less accurate than the current standard of care.

## **Tackling the FDA first**

Optiscan is focused on securing regulatory approval with the US Food and Drug Administration (FDA), followed by the Australian and European gatekeepers.

It’s expected the breast cancer data will support the FDA application, under the de novo (new device) route.

In August 2022, the company submitted the device for oral cancer screening, under the 510(k) predicate device channel. But the agency told the company to take the novel route.

Still, Prof Farah describes the FDA process as straightforward, relative to the “very difficult” European pathway and says the amount of further work required depends on the claims the company chooses to pursue.

“If it’s about diagnostic accuracy the [FDA] will want US data, but if it’s about just imaging ability maybe they will accept well-designed studies in jurisdictions such as Australia.”

## **March of the robots**

Prof Farah notes that da Vinci, the robot made by the world’s largest robotics company Intuitive Surgical, is widely used in prostate and head and neck cancers and is now becoming deployed in lumpectomies.

“There are about 50 other robotic players coming in to the market in the US and China, to challenge da Vinci,” Dr Farah says.

Currently, the standard method of assessing whether all of a tumor has been resected is called digital palpation. That’s a fancy term for surgeons feeling around the margin of the tumour with their fingers, to check for any remaining hard bits.

The robots do not use their fingers, but are guided by the probe that monitors in real time.

“You can miniaturize this probe and embed it either with a robot, or adjacent to a robot,” Prof Farah says.

“It provides so much more flexibility across the board.”

Prof Farah says Optiscan’s probe can be adjusted to the tumor type and skill levels of the surgeon, as well as the type of robot.

“With all our devices we would like to be as ‘agnostic’ as possible, so we can supply as many players as possible.”

## **A.I. and tele-pathology**

In January this year, the company signed a deal with Canada’s Prolucid Technologies, an artificial intelligence (AI) leader.

The compact involves the parties developing AI algorithms to enable immediate clinical decision making, focusing on oral cancer in the first instance.

Optiscan retains all intellectual property and no royalties are payable.

The initial focus is on developing a tele-pathology platform enabling quality slide-free, biopsy-free imaging in remote geographies: in effect an artificial pathologist.

The pathology images can be downloaded and viewed by the clinician or pathologist in real time - and it doesn't matter whether the parties are in the same location or even country.

"We are trying to create a digital platform for the exchange of information and images, similar to what happened in radiology," Prof Farah says.

In mid-August, the parties announced they had completed a key technical milestone pertaining to ensuring the platform is secure and scalable across all health systems.

## **Finances and performance**

In July this year, Optiscan completed a \$16.7 million rights issue at eight cents a share.

The raising was supported by the two largest and long-time shareholders, Bob Peters' Peters Investment and the Singapore based Orchard Capital.

Both parties partially underwrote the raising and subscribed for their full allocation of \$6.95 million and \$2.68 million of shares respectively.

The company says the dough will fund its activities for the next three years "and cover off on all research and development and product development stages".

In the year to June 2023, Optiscan chalked up revenue of \$1.68 million, \$378,000 from Viewnivo sales. The company also pocketed \$737,570 in Federal Research and Development Tax Incentives.

Optiscan shares have declined from 15 cents in late October 2022, to a record low of seven cents on October 24 2023. The stock peaked at 44 cents in late April 2021.

## **Dr Boreham's diagnosis:**

Optiscan is suffering the common ailment of an ailing share valuation that seemingly goes against the grain of its clinical progress.

When we last covered the stock way back in 2017 - and apologies for the neglect - the shares were worth 9.0 cents for a \$38 million market cap

"We know there needs to be some significant needle-moving events," Prof Farah says.

"We expect 2024 will show the results of our hard work for the last couple of years, in terms of making that significant transformation."

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never had an endoscopy but is often scrutinized under the microscope and told to have a good look at himself.***

## ISLAND PHARMACEUTICALS

Island says it has dosed the first of 24 healthy volunteers in its single-ascending dose study of its ISLA-101 for dengue virus and other mosquito-borne diseases.

Earlier this month, Island said it had started screening healthy participants for its three-cohort, single-ascending dose trial of ISLA-101 (BD: Nov 13, 2023).

Today, Island executive chair Paul MacLeman told Biotech Daily that the first three cohorts would be treated fasted and then the last cohort, dosed at the highest dose of ISLA-101, would be treated again, following a meal.

The company said the study, conducted by Scientia Clinical Research in Sydney, would ensure that doses could “safely achieve blood concentrations of ISLA-101 that are predicted to be effective against the dengue virus”.

Island said it expected results in “early 2024” and that the study would inform a phase IIa clinical trial.

Island chief executive officer Dr David Foster said the company was “delighted to see the start of this study with the dosing of our first subject”.

“This news represents a critical step in our journey towards our ‘Peach’ clinical trial and progressing ISLA-101 toward approval as a much-needed treatment for dengue fever and other mosquito-borne diseases,” Dr Foster said.

Island was up 0.3 cents or 3.9 percent to eight cents.

## RHYTHM BIOSCIENCES

Rhythm says a Baker Institute study has identified five blood biomarkers that identified lung cancer with “85 percent sensitivity and 90 percent specificity” ( $p \leq 0.00001$ ).

Last year, Rhythm said that it had appointed Melbourne’s Baker Institute for a proof-of-concept study for a second unnamed cancer program using its cancer diagnostic platform (BD: Dec 15, 2022).

Today, the company said the feasibility immune-assay study assessed 17 biomarkers in 70 lung cancer patients and 71 healthy volunteers and found a five-biomarker combination that exhibited “an effective correlation with various stages of lung cancer”.

Rhythm said the “research use only” feasibility study identified the combination of biomarkers which could distinguish between lung cancer patients and healthy control volunteers.

The company said that the results warranted confirmation in a larger population and justified the continuation and advancement of the project.

Rhythm said once verified the results would support investment in a research and development program to develop, validate and clinically evaluate the performance of the biomarkers, as well as translate the results “into a commercially scalable, proprietary blood test to detect lung cancer when it is most responsive to potentially curative treatments”.

The company said that lung cancer was “the leading cause of cancer-related deaths worldwide, primarily because most people present when the stage is too advanced to offer any reasonable chance of cure”.

Rhythm said that in 2022, about 14,529 Australians were diagnosed with lung cancer, and more than 8,606 died from the disease.

The company said that the five-year survival rate for lung cancer was low, at about 22 percent and there was “a clear need to improve the diagnostic tools for screening in detecting early-stage lung cancer”.

Rhythm fell half a cent or 2.8 percent to 17.5 cents.

## ONCOSIL MEDICAL

Oncosil says its device for locally advanced pancreatic cancer has been approved as an appropriate treatment by the Tel Aviv, Israel-based insurer Clalit General Health Services. In January, Oncosil said that the first commercial patient had been treated with its pancreatic cancer radiation device in the Middle East, at Tel Aviv's Wolfson Medical Centre (BD: Jan 31, 2023).

Today, the company said the approval meant that Clalit General Health Services had given its clients clearance to use the device and it was "a necessary first step ahead of Clalit potentially creating any reimbursement schedule for patients using the ... device". Oncosil managing-director Nigel Lange said the development was "the achievement of yet another milestone in our ongoing efforts to enter the Israeli market".

"While Clalit's approval letter does not currently have any reimbursement ramifications, it provides further unambiguous evidence that key players in the Israeli health services sector have come to appreciate the role our unique device can play in the treatment of Israeli patients with a poor prognosis from cancer of the pancreas," Mr Lange said. Oncosil was up 0.1 cents or 12.5 percent to 0.9 cents with 1.1 million shares traded.

## EPSILON HEALTHCARE

Epsilon deputy chair Alan Beasley has told Biotech Daily that the extraordinary general meeting he requisitioned to remove the other two directors will go ahead as planned. Yesterday, in an announcement to the ASX "approved for release by the majority of the board of directors", Epsilon said the requisition had not followed "due processes" and cited Section 203D of the Corporations Act 2001 which required a minimum of two months' notice, writing to the director(s) concerned and other conditions.

Mr Beasley said that this was a cursory understanding of the provisions and he had legal advice that the extraordinary general meeting would go ahead as planned on December 22, 2023 including the resolutions to replace directors.

On Tuesday, Epsilon (then The Hydroponics Co) founder Mr Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing "the governance of the board" (BD: Nov 21, 2023).

Epsilon fell 0.2 cents or 6.7 percent to 2.8 cents.

## BOD AUSTRALIA

Bod says it has requested a trading halt "pending an announcement ... regarding the outcome of the capital raise and overall financial position of the company".

Earlier this month, Bod said it had "firm commitments" to raise \$2.05 million in a placement at 3.0 cents a share, and would pay its directors shares, in lieu of cash, subject to shareholder approval (BD: Nov 8, 2023).

At that time, the company said its Malaysia partner Antah Healthcare had committed \$1.1 million to the raise, and after the placement would hold 14.9 percent of the company.

In an announcement to the ASX on Tuesday titled 'Capital Raise Update', Bod said it had delayed the settlement of the first tranche of the placement due to an "administrative delay in the transfer of funds from outside Australia".

At that time, the company said Antah Healthcare required Monetary Authority of Singapore approval to transfer the funds, and that it had confirmed to Bod that it had been advised that approval was a "formality and will occur imminently".

Trading will resume November 28, 2023, or on an earlier announcement.

Bod last traded at 2.4 cents.



## [MONASH UNIVERSITY](#)

Monash University says it will offer a Master of Technology, Commercialization and Business for science technology engineering and mathematics (STEM) graduates. Monash said that the degree would be offered as coursework for graduates who had completed a four-year honors degree or higher qualification in a STEM discipline.

The University said that full-time students would complete the degree in one academic year of two semesters, with a part-time study option available.

Monash said that the course combined foundation units from the Monash Master of Business portfolio with specialist units in technology commercialization.

The University said the “capstone technology commercialization project” extending across the two semesters, would equip students to “gain real-world experience in conducting a formal, structured business consultancy engagement to assist leading researchers from academia and industry progress their innovations towards the market”.

Master of Technology, Commercialization and Business course director Prof Iain Cooke said the course began “with the perspective that typical STEM honors graduates are smart, capable and enthusiastic about science, but not all want to pursue increasingly focused research careers”.

“We aim to efficiently equip these graduates with the extra knowledge and skills to help them move swiftly beyond the academic laboratory and enter exciting and rewarding roles in science-related business and business-related science,” Prof Cooke said.

“The new course strikes a balance between content and skills-focused teaching and open-ended experiential learning,” Prof Cooke said.

“We take the view that someone who has completed a strong STEM honors degree could probably teach themselves just about anything, if they are motivated to do so ... [but] some subjects, especially those from an unfamiliar discipline, are best mastered quickly when taught by experts in a conventional pedagogical setting,” Prof Cooke said.

More information about the Master of Technology Commercialisation and Business degree is at: <https://bit.ly/3MZgRkN>.