



Biotech Daily

Tuesday September 19, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 5%; IMUGENE DOWN 10%**
- * **OPTISCAN MICROSCOPE 'COMPARABLE' FOR BREAST CANCER MARGINS**
- * **IMAGION RECEIVES \$3.5m FEDERAL R&D TAX INCENTIVE**
- * **ACRUX, DASH TERMINATE TESTOSTERONE DEAL**
- * **IMPEDIMED: 'CGI, ISS OPPOSE SPILL'**
- * **HERAMED EGM 26% OPPOSE 12m BROKER OPTIONS**
- * **ONCOSIL TO LOSE DIRECTOR BRIAN LEEDMAN**
- * **HEXIMA APPOINTS PHILLIP HAINS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.47 percent on Tuesday September 19, 2023 with the ASX200 down 33.8 points to 7,196.6 points.

Six of the Biotech Daily Top 40 stocks were up, 22 fell, nine traded unchanged and three were untraded.

Antisense was the best, up 0.3 cents or 4.55 percent to 6.9 cents, with 1.1 million shares traded.

Cyclopharm climbed 3.75 percent; Emvision, Nanosonics and Neuren rose more than two percent; Cochlear was up 1.1 percent; with Pro Medicus up by 0.5 percent.

Imugene led the falls, down 0.6 cents or 10.2 percent to 5.3 cents, with 62.1 million shares traded.

Paradigm lost 9.4 percent; Atomo and Next Science were down more than seven percent; Universal Biosensors shed 6.1 percent; 4D Medical, Actinogen, Opthea, Pharmaxis and Resonance were down more than five percent; Prescient fell 4.6 percent; Clinuvel was down 3.2 percent; Avita, Dimerix, Genetic Signatures, Kazia, Polynovo and Starpharma shed two percent or more; Immutep, Medical Developments, Mesoblast and Telix were down more than one percent; with CSL and Resmed down by less than one percent.

OPTISCAN IMAGING

Optiscan says interim results from a 50-patient study show its confocal microscope is “comparable” to histopathology when imaging breast cancer margins.

In 2018, Optiscan said it began the first part of the trial of its confocal laser endomicroscope to assess the surgical margin in patients undergoing breast cancer conservation surgery (BD: Oct 15, 2018).

In 2021, the company said it completed recruitment for its breast cancer margin assessment trial, imaging 42 breast cancer lumpectomy samples and 38-patient cavity shaves (BD: Nov 12, 2021).

Today, Optiscan said the imaging stage of the study, at the Royal Melbourne hospital, examined 50 patients and 59 distinct tumors, with ex-vivo inter-operative imaging performed on all fresh tumors, and a further 12 patients with 15 distinct tumors undergoing imaging after tissue fixation and processing in the pathology laboratory.

Optiscan said that the initial data examining the correlation between its confocal laser endomicroscopic imaging and that of conventional histopathology had shown “excellent correlation” between its real-time, confocal laser endomicroscopic technology and traditional histological analysis.

The company said that its technology could “provide images comparable to conventional histopathology for determination of presence of cancer and for determination of tumor involvement in surgical margins”.

“This was possible in all 15 resected tumors which underwent fixation, with final diagnoses including invasive lobular carcinoma and invasive carcinoma,” Optiscan said.

Optiscan said its probe “could identify and differentiate healthy marginal tissue from cancer-involved margins in each case that was identified on gross sectioning and on final definitive histopathology”.

The company said that the assessment of fresh tissue “produced excellent imaging quality and fixation did not negatively affect quality of image”.

Optiscan said that following the ex-vivo study results it would conduct an intra-operative, in-vivo imaging study to assess the device in the hands of surgeons for the development of a clinical user case and future US Food and Drug Administration submissions.

Optiscan chief executive officer Dr Camile Farah said that “the strong correlation and concordance of Optiscan technology to histopathology provides another strong indication for the utility of our unique digital [confocal laser endomicroscopic] technology in breast surgery, as an adjunct in supporting clinical decision-making in the operating theatre in the context of breast cancer margin analysis”.

“Additionally, it paves the way for an ex-vivo approach to assess fresh or fixed tissue with standalone in-vitro diagnostic platforms which we are developing,” Dr Farah said.

“Breast conserving surgery is a complex challenge for health systems, with over 175,000 lumpectomies performed in the US alone and evidence revealing a re-excision rate of up-to 35 percent,” Dr Farah said.

Optiscan said it would report further analysis and findings by the end of the year.

Optiscan was unchanged at 7.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has received \$3,534,712 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

Imagion said that the rebate related to research and development expenditure for the year to December 31, 2022.

Imagion was unchanged at 1.4 cents with 2.5 million shares traded.

ACRUX

Acrux and Dash Pharmaceuticals say they mutually agreed to terminate the agreement for the commercialization of Acrux's generic testosterone topical solution in the US.

In 2021, Acrux said the US Food and Drug Administration approved its generic version of the Grand Rapids, Michigan-based Perrigo's 30mg/1.5mL testosterone topical solution; and later that year, said that the Upper Saddle River, New Jersey-based Dash Pharmaceuticals had begun US marketing of the solution (BD: Jan 17, Aug 26, 2021).

Acrux managing-director Michael Kotsanis told Biotech Daily the product was "a generic of Perrigo's Testosterone Topical Solution ... in effect a generic of Axiron".

In 2017, Acrux said it and Eli Lilly terminated the Axiron licence, effectively ending US sales, with Biotech Daily calculating that Eli Lilly had received more than \$US810.8 million (\$A1,260.6 million) in revenue from Axiron sales at that time (BD: Sep 6, 2017).

Mr Kotsanis said the FDA required a testosterone trial which would cost "hundreds of millions of dollars" and sales had fallen following the launch of generic versions of Axiron. Today, the company said that due to "the continued decline in the testosterone market the product is no longer commercially viable for the companies to continue commercialization and will be withdrawn from sale as inventory is depleted".

Acrux said it would retain exclusive ownership of all related rights and intellectual property associated with the product, and the termination would not have a material impact on its revenue or expenses.

Acrux fell 0.2 cents or 4.65 percent to 4.1 cents.

IMPEDIMED

Impedimed says proxy advisors CGI Glass Lewis and ISS advise investors to vote against all extraordinary general meeting resolutions in favor of a spill motion.

In July and August, Impedimed said it had received a section 249D notice from Acadia Park Pty Ltd calling for the removal of chair Donald Williams and directors Amit Patel, David Anderson and Daniel Sharp to be replaced by McGregor Grant, Christine Emmanuel-Donnelly, Andrew Grant and Janelle Delaney (BD: Jul 31, Aug 3, 2023).

Today, Impedimed said that CGI and ISS were "independent proxy advisers" and neither had engaged with Impedimed [or any associate] in making their determination".

Impedimed said the general meeting would take place on September 28, 2023.

Impedimed was unchanged at 17.5 cents with 1.3 million shares traded.

HERAMED

Heramed says that 25.65 percent of its extraordinary general meeting voted against the issue of 12,000,000 broker options to Clarity Capital Advisors Pty Ltd.

Heramed said that 34,090,896 votes (74.35%) supported the issue of the options exercisable at 12 cents each by July 20, 2026, with 11,763,649 votes (25.65%) against.

The company said that 14.96 percent of votes opposed the issue of placement shares and options, 6.65 percent opposed the issue of 7,500,000 options, exercisable at 9.75 cents each by December 31, 2025, pending performance hurdles to chair Dr Ron Weinberger, with the amendment to the HMDAL options opposed by 4.04 percent.

In July, Heramed raised \$2.58 million at 7.0 cents a share (BD: Jul 12, 2023)

According to its most recent filing, Heramed had 242,657,048 shares on issue, meaning the opposition to the broker options amounted to 4.85 percent of the company, not sufficient to requisition extraordinary general meetings.

Heramed was unchanged at 6.3 cents.

[ONCOSIL MEDICAL](#)

Oncosil says non-executive director Brian Leedman will retire at its annual general meeting.

Last year, Oncosil said it appointed Mr Leedman as a non-executive director, and that he founded Resapp Diagnostics and co-founded Oncosil Medical (BD: Sep 15, 2022).

Today, Mr Leedman said: "It has been a privilege to have finally served on the board of the company that I co-founded back in 2013."

"Following the recent departure of the previous chairman, I too feel it is time for me to give the newly appointed directors the opportunity to drive the future direction of the company and I wish them all the best in taking the company forward," Mr Leedman said.

Oncosil fell 0.1 cents or 9.1 percent to one cent.

[HEXIMA](#)

Hexima says it appointed Phillip Hains as a non-executive director on September 18, 2023.

Hexima said Mr Hains was an accountant with more than 30 years' experience and had "served the needs of a number of company boards, committees and management".

Hexima was untraded at 2.2 cents.