

30 April 2024



CLINICAL UTILITY OF CXBLADDER TO HEADLINE AT AUA 2024

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) released a routine marketing communication this morning to investors, customers, and the media on its activities at the American Urological Association (AUA) Annual Meeting on May 3 - 6 to promote the results of its STRATA¹ study. These activities had been previously described in our Q4 24 Investor Update released on 9 April, 2024.

Pacific Edge incorrectly stated in a footnote of this morning's marketing communication that the information contained in it was 'material', and is issuing this communication to the NZX and ASX as a correction. Pacific Edge has already corrected the statement in a revised marketing email. Pacific Edge maintains the view that the information is not material as defined by the NZX listing rules since the results of the study and the AUA's interest in it were disclosed in the company's Q4 24 Investor Update.

Notably, in the Q4 24 Investor Update the company disclosed that the abstract of the study had been accepted as a podium presentation at the AUA and that a manuscript on the study requested by the AUA for publication in the issue of the Journal of Urology that will coincide with the AUA Annual Meeting was in the final stages of peer-review. The peer-review process has since been completed and the manuscript is confirmed to be published.

For more information:

Investors:

Dr Peter Meintjes
Chief Executive
Pacific Edge
P: +64 22 032 1263

Media:

Richard Inder
The Project
P: +64 21 645 643

OVERVIEW

Pacific Edge: www.pacifiedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

Cxbladder: www.cxbladder.com

Cxbladder is a urine-based genomic biomarker test optimized for the detection and surveillance of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous

¹ Safe Testing of Risk for AsymptomaTic microhematuria

ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder has been trusted by over 4,400 US urologists in the diagnosis and management of more than 100,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 75% of the population via public healthcare and all residents have the option of buying the test online.



NOTE: PEB HAS NOT RELEASED THIS UPDATE TO THE NZX OR ASX AS PER LISTING RULES.¹

Clinical Utility of Cxbladder to Headline at AUA 2024

A ground-breaking study demonstrating the clinical utility of Cxbladder is to be the centrepiece of cancer diagnostics company Pacific Edge's (NZX, ASX: PEB) activities at the 2024 American Urological Association (AUA) Annual Meeting to be held May 3 – 6 in San Antonio, Texas.

The AUA Annual Meeting represents a unique opportunity for Pacific Edge to highlight the findings of the new STRATA study and drive the adoption of Cxbladder tests. The conference, now in its 119th year, is the largest and most influential event in the US and global urological calendar, and is expected to attract over 10,000 urologists, urologic oncologists, researchers, educators, advanced practice providers, and other healthcare professionals from across North America and around the world.

STRATA, the first ever randomized controlled trial of a urine biomarker for hematuria evaluation, demonstrates Cxbladder Triage can help clinicians to safely and more effectively risk-stratify low risk hematuria patients when compared to AUA guidelines. It provides the strongest clinical utility evidence yet for inclusion of Cxbladder products in a future update to the hematuria guidelines.

The STRATA study will be presented on the podium by Dr Yair Lotan, Professor of Urology at UT Southwestern. The presentation is scheduled during a session covering advances in bladder cancer care on the morning of the first day of the conference (Friday May 3).

STRATA will also be published in the prestigious Journal of Urology on the same day and will be promoted as “practice changing research” by the AUA and the Journal of Urology in the lead up to, during, and after the event. A link to the paper is provided below (and will only become active at the commencement of the podium presentation at 10:40am Friday May 3 CDT). A selection of published comments by key reviewers of the paper will also be made available following the event.

Referencing the clinical utility of the test, authors of the paper led by Dr Lotan, said in an abstract to the study that Cxbladder Triage “can help reduce the burden of unnecessary cystoscopies... resulting in less patient morbidity and discomfort, improved access to care, and reduced environmental impact”.

The study showed clinicians in the test arm of the STRATA study, who could use information generated by a Cxbladder Triage test to help them determine the intensity of a patient workup, undertook 59% fewer cystoscopies than those clinicians in the control arm of the study who could not use the information from the Cxbladder test.

With the STRATA podium presentation providing a focal point for discussion throughout the event, Pacific Edge will be hosting a booth in the main hall alongside a range of other targeted activities through which the team will engage with customers and other attendees.

This year Pacific Edge will sponsor a tabletop session during the Urological Society for American Veterans (USAV) sub-meeting. This meeting will be attended by urologists working within Veterans Affairs (VA) facilities and is of particular importance as the company progresses its DRIVE and microDRIVE studies, both focused on VA patient cohorts.

Further detail on scheduled sessions at AUA 2024:

- 10:40am - 10:50 AM, Friday May 3 (CDT): Podium presentation - A Multicentre Prospective Randomized Trial Comparing Cxbladder Triage to Cystoscopy in Patients with Microhematuria.
- 10:00am - 2:30 PM Sunday May 5 (CDT): USAV Tabletop Session (Grant Hyatt, Texas Ballroom C).

Pacific Edge’s CEO, Dr. Peter Meintjes says: “The invitation to present the results of STRATA as practice changing research at AUA 2024, the world's most important meeting of urologists, reflects its first of a kind status and the potential for Cxbladder tests to redefine the standard of care. Going forward,

patients presenting with microhematuria with a negative Cxbladder test, can be treated as AUA low risk, safely reducing the need for cystoscopy allowing urology teams to focus their time and clinical resources on those that need it the most, while reducing the burden of invasive testing on patients.

"STRATA provides the strongest case yet for AUA hematuria guidelines inclusion. Additionally, we will use the paper as the basis of a reconsideration request to Novitas² regarding 'Genetic Testing for Oncology' local coverage determination (DL 39365)."

[View](#) the STRATA study published in the Journal of Urology. Please note that this link will become active at the commencement of the AUA podium presentation: 10:40am Friday May 3 (CDT).

¹ PEB has not released the information contained in this update to the NZX and ASX as it regards it to be immaterial, as defined in the NZX Listing Rules and Section 231 of the FMC Act.

² Novitas, the Medicare Administrative Contractor with responsibility for Pacific Edge's US laboratory, is currently reviewing Pacific Edge's submissions on DL39365 and those of industry, the urological community and healthcare payers. Novitas must withdraw or finalize the draft determination by 26 July 2024.