11 October 2023

CXBLADDER TEST VOLUMES RESILIENT IN THE FACE OF HEADWINDS

DUNEDIN, New Zealand – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) announces test volumes processed at its laboratories in the second quarter of the 2024 financial year (Q2 24) fell 12% to 8,525 from 9,704 in the prior quarter (Q1 24) amid the reorganization of our US operations and publicity on the Medicare coverage determinations.

However, the volume of tests processed in Q2 24 represents an 8% increase on the 7,864 tests processed in the same quarter of the prior year (Q2 23). The reorganization, detailed in the company's Q1 24 investor update also released today, weighed on sales activity in August and early September.

Meanwhile, volumes were also impacted by some uncertainty among physicians and healthcare providers over Cxbladder's coverage status following the Medicare non-coverage determination in June by Novitas and then its July withdrawal. These effects were exacerbated by the normal July holiday season lull.

Tests processed in our US laboratory were 7,335 tests in Q2 24, a 15% decrease on the 8,627 tests in Q1 24. The figure represents a 9% increase on the 6,699 tests processed in Q2 23. The number of unique ordering clinicians in the US fell 7% through the quarter to 1,147 but is up 17.3% on the 978 clinicians who ordered tests in Q2 23.

Asia Pacific volumes in Q2 24 were 1,190 up 10% on the 1,077 tests processed in Q1 24, and up 2% on the 1,165 tests processed in Q2 23 with the quarter-on-quarter increase largely reflecting an increase in test volumes associated with clinical studies in the region.

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

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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 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.

PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

OCTOBER 23

INSIDE

LETTER FROM THE CEO

BUILDING RESILIENCE AMID CHANGE

Dear Shareholders,
The second quarter of the 2024 financial year was one of significant challenge and change for Pacific Edge. Despite this operating environment, Cxbladder throughput was 8,525 tests for the quarter, which is down 12% on prior quarter, but still our third highest quarter and an increase of 8% over the same quarter in the prior year.

We started the quarter with Novitas, our Medicare Administrative Contractor, finalizing 'Genetic testing for oncology' (L39365) as 'future effective', a move that was set to end Medicare coverage of our tests.

However, following pressure from Pacific Edge, peer companies, industry partners, healthcare providers and the clinical community, the determination was withdrawn, and a new, albeit unchanged draft (DL39365), was released for public review and comment in line with statutorily regulated procedures.

This very welcome decision returned Pacific Edge to a condition we have endured for much of the last year. We remain a covered benefit by Medicare and continue to receive reimbursement for our tests. Yet once again we are having to make the case that Cxbladder is medically reasonable and necessary despite historical coverage from Novitas clearly indicating that this is the case. With uncertainty over whether our message will be heard, and uncertainty regarding when the determination will be finalized, there is naturally uncertainty regarding how long Medicare coverage will continue.

Notwithstanding the strength of our existing clinical evidence, the strength of our written arguments to Novitas, and the strong support we have received from the most significant organizations in the US urology community (see page 5), the risks of a non-coverage decision are now more elevated than we assessed for much of the last year.

> **"Our operations are now configured to ride out a non-coverage determination..."**

In response we have restructured our business (see page 4) to reduce our cash burn. This contrasts with our prior focus on top line revenue growth. The approach we have taken is in line with our communications to investors at the Annual Shareholder Meeting in July. Our operations are now configured to ride out a non-coverage determination and regain Medicare coverage relying on our existing capital reserves.

We now have a smaller sales force. Each team member has a larger territory, where the focus is on territory profitability, not throughput growth alone. The team is adopting refined value-based messaging to healthcare providers and clinicians emphasizing that the greatest clinical and economic value of Cxbladder is realized if the tests are protocolized in the clinical pathway to safely avoid or defer cystoscopies and imaging for hematuria evaluation or bladder cancer surveillance (see page 4).

We are supporting this change by better equipping the team with marketing collateral and digital technologies to ensure that clinicians - having determined the clinical utility of Cxbladder for themselves - elect to protocolize our tests systematically on every eligible patient type. We are also seeking to facilitate this decision by offering a seamless ordering and results delivery experience.

We continue our evidence generation activities with a focus on the end points required for inclusion of Cxbladder in the clinical guidelines of the American Urological Association (AUA) and the National Comprehensive Cancer Network (NCCN). Guideline inclusion, as we have noted before, remains the most effective strategy to entrench coverage of our tests (see page 8).

Finally, just as the quarter closed, the US Food and Drug Administration (FDA) has proposed rule changes that could see Cxbladder falling under its oversight and regulated as a medical device. We highlight our views on the relevance of this development in the context of the complex history and legal challenges associated with the various ebbs and flows on this topic over the last couple of decades on page 7.

Ngā mihi nui,

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

RESILIENT THROUGHPUT DESPITE HEADWINDS

Test volumes processed at Pacific Edge's laboratories in the second quarter of the 2024 financial year (Q2 24) fell 12% to 8,525 from 9,704 in the prior quarter (Q1 24) amid the reorganization of our US operations and publicity on the Medicare coverage determinations. The volume of tests processed in Q2 24 represents an 8% increase on the 7,864 tests processed in the same quarter of the prior year (Q2 23).

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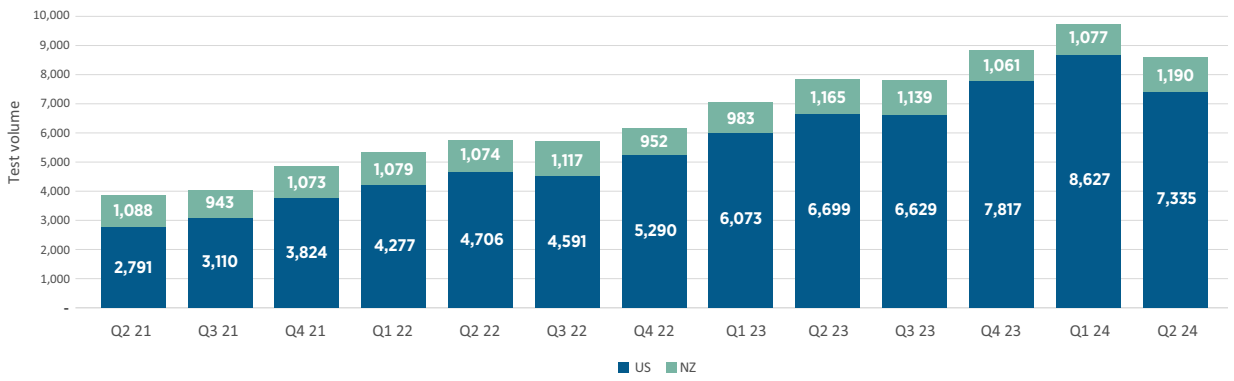
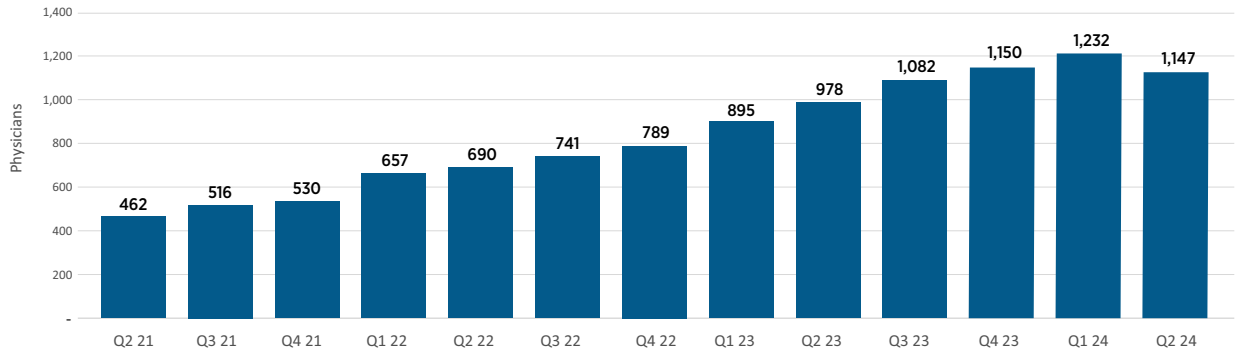
TOTAL TEST VOLUMES: GROUP



UNIQUE ORDERING CLINICIANS: US



NATIONAL SALES MEETING

SELLING THE VALUE OF CXBLADDER

'Cxbladder can help reduce the number of unnecessary procedures in your office and prioritize patients that need further investigations.' That was the focal point of new messaging to clinicians introduced at our US national sales meeting held in Denver in the middle of September.

Across several sessions the Medical Affairs Team linked Cxbladder utility pathways to existing American Urological Association (AUA) guidelines to drive the adoption of our tests.

For clinicians using Cxbladder Detect this means that they can safely rule out 78 of every 100 patients presenting with microhematuria from receiving cystoscopy and imaging procedures when compared to following the AUA guidelines without Cxbladder Detect.

For clinicians using Cxbladder Monitor this means that they can safely reduce the number of post-surgery cystoscopies by 50%, and also continue to non-invasively monitor patients that may have recurrent disease after guidelines no longer recommend invasive monitoring procedures.

This creates benefits to patients who present with comorbidities that elevate the procedural risks of cystoscopies and delivers the clinical benefits of not missing any serious disease. It is also economically beneficial to healthcare payers, enabling them to minimize unnecessary procedures, and make more efficient use of staff time and facilities (see page 7).

Alongside these key messages – we highlighted the investments we are making to drive the integration of Cxbladder into EMRs and online customer portals as part of our effort to deliver an improved customer experience with seamless test ordering and results delivery.

The sessions were enthusiastically received by the team, amid recognition that they are better positioned than they ever have been to capitalize on the opportunities our test offers.

RESTRUCTURE & INVESTMENT

CHARTING A COURSE TO ENTRENCHED COVERAGE

Guided by the principles we set out at our Annual Shareholders' Meeting in July we have completed the strategic restructure we flagged for our US and Asia Pacific operations.

With this smaller organization, we will continue to focus on growth from Account Executives in larger territories, from national accounts and capitated systems and from global market opportunities. In the event of an adverse Medicare coverage determination, we are also positioned to make further changes while continuing to pursue a course to regain coverage within our existing reserves.

In practical terms this has seen a reduction in the number of US sales territories from 29 to 17 and a reduction of the US sales regions from three to two. In the Asia Pacific our renewed focus is on growth markets in Australia and Southeast Asia. This approach recognizes that the primary opportunity for growth in New Zealand would be from a national contract with Te Whatu Ora that may take some time to develop.

We continue to invest in enhancing our sales capability (see above) and to amplify our clinical development program within the urology and oncology communities, supporting our efforts to see the inclusion of our tests in clinical guidelines.

Alongside this we have stepped up our investment in clinical studies with the CREDIBLE clinical study (see page 8).

Guideline inclusion, an expanding portfolio of evidence supporting the clinical utility of our tests, and strong medical communications are the best way to entrench coverage. In the event of an adverse Medicare local coverage determination, they are also the best strategies to ensure we follow the fastest route to regaining coverage.

Finally, we are driving improvements in the performance and efficiency of our operations with the continuing drive towards digitalization. This includes efforts to:

- improve the customer experience and data provenance to our lab with integrations into our customers' Electronic Medical Records (EMR) systems,
- create a customer portal for managing test requests, test results and documentation required for establishing medical necessity, and
- the ability to electronically manage patient recruitment, patient data, monitor clinical study sites and analyze data for clinical and research applications.

MEDICARE COVERAGE

A PERSUASIVE CASE – NOW TO THE VERDICT

Pacific Edge is confident we have made the best possible legal and clinical arguments for Cxbladder to retain Medicare coverage during the open public meetings and the written comment period for the draft Local Coverage Determination (LCD) 'Genetic testing for oncology' (DL39365).

Our representations to Novitas were strongly supported by the leading professional societies in urology - the American Urological Association (AUA), the Large Urology Group Practice Association (LUGPA) and the American Association of Clinical Urologists (AACU) – and by our industry partners, the Coalition for 21st Century Medicine (C21), the American Clinical Laboratory Association (ACLA) and by many other key urologic opinion leaders.

Together we highlighted the shortcomings in the MAC's evidentiary review to justify the non-coverage decision and the sharp contrast with its earlier reliance on the same evidence to cover our tests. We also highlighted the flaws in the conception of the LCD and particularly the unprecedented approach of outsourcing Medicare biomarker coverage decisions to three external databases[1].

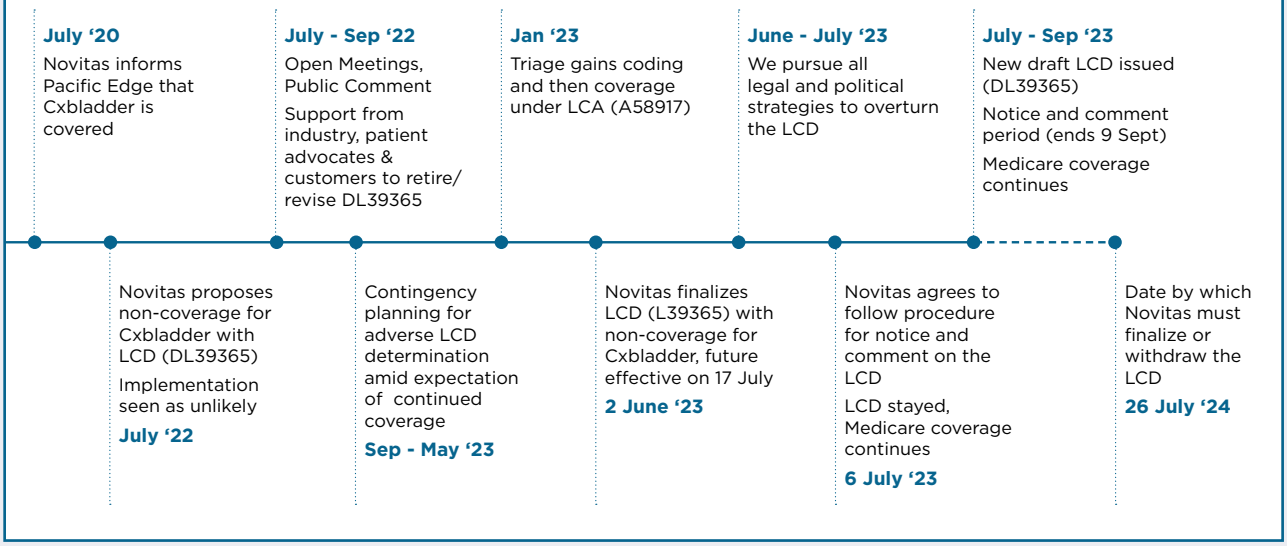
We followed up these public submissions with written comments to Novitas including a point-by-point rebuttal of Novitas' review of the Cxbladder clinical evidence. Meanwhile a 'who's who' of US key opinion leaders in urology, including numerous guidelines committee members, wrote an independent editorial commenting on the impact of Novitas' approach. This editorial has been accepted for publication in the journal "Bladder Cancer" and covers the importance of urine biomarkers with specific reference to Cxbladder and their optimal usage in hematuria evaluation and recurrence monitoring.

The submission period ended on 9 September and now Novitas must consider and respond publicly to all of the comments presented during the notice and comment period.

Novitas has given no indication on when it is likely to finalize the LCD, but it is statutorily required to do so (or withdraw the LCD) within 365 days of the original publication date. An LCD becomes effective 45 days after it is finalized.

The presentations given at the open meetings and details of written submissions are available on our website: https://www.pacificedgedx.com/investors/presentations/

PAST AND FUTURE: PACIFIC EDGE'S MEDICARE JOURNEY



[1] The draft LCDs outsources coverage decisions to three knowledge bases to determine coverage, rather than the MAC. They are Clinical Genome Resource (ClinGen); National Comprehensive Cancer Network (NCCN); Oncology Knowledge Base (OncoKB) knowledge bases.

KAISER PERMANENTE

A STRONG SUPPORTER

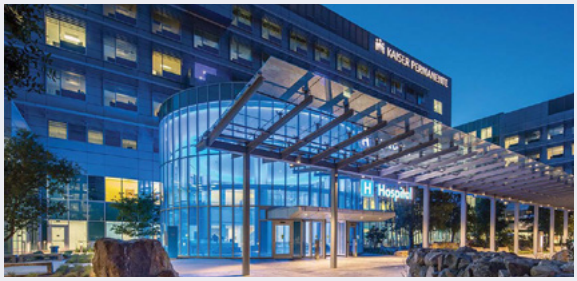
Our arguments for continued Medicare coverage of Cxbladder were significantly bolstered by the release of unpublished non-peer-reviewed data from Kaiser Permanente.

The real world evidence was documented in a letter to Novitas from the AUA, LUGPA and AACU and highlighted the role Cxbladder has played in substantially reducing the number of cystoscopies Kaiser undertakes each year. Kaiser is the largest capitated system in the USA covering more than 12.5 million lives.

The Kaiser data has also been submitted as an abstract to the Society for Urologic Oncology (SUO), and, if accepted, would form the basis for a poster presentation of that evidence at the SUO Meeting to be held between 28 November and 1 December this year.

The data illustrates how Cxbladder Triage safely excluded 78% of Kaiser patients presenting with hematuria from a cystoscopy. It also shows similarly positive results for Cxbladder Monitor for Kaiser patients under surveillance for the recurrence of bladder cancer. Notably the study disclosed, for the first time, that Kaiser undertakes approximately 25,000 cystoscopies each year in Southern California, the first region in the Kaiser system to roll out Cxbladder. While not all of these cystoscopies are for hematuria evaluation or monitoring for bladder cancer recurrence, the new Cxbladder clinical pathways for Triage and Monitor are expected to impact this number dramatically and simultaneously drive down patient wait times.

In addition to supporting our Medicare case, the study demonstrates the depth of support we have earned from our years of partnership with Kaiser and provides further detail regarding the size of the initial Kaiser opportunity. We continue to work with Kaiser to revise our commercial agreement in regard to scaling the deployment of Cxbladder through its Health Connect EMR, in a model that is expected to link pricing to volume.



DETECT+

DETECT+ CLEARS FIRST COMMERCIALIZATION HURDLE

Pacific Edge was notified in late September that Detect+ was included in the latest CPT coding schedule release by the AMA with code 0420U.

Consequently, Pacific Edge has completed the first of the three requirements for reimbursement: coding, coverage and pricing. Our Market Access Team will continue to work on pricing, targeting June 2024 for inclusion in the Clinical Lab Fee Schedule potentially effective January 2025.

Concurrently, we will seek to obtain Medicare coverage, but this timeline is dependent on the quality of the clinical evidence to support the use of the test. The groundbreaking Lotan et al (2023)[2] study delivered compelling evidence of the test's analytical validity. We are now looking forward to the results of DRIVE, AUSSIE, microDRIVE and the pooled analysis of these studies to deliver evidence of clinical validity.

We expect our new CREDIBLE study (see page 8) to deliver evidence of the test's clinical utility. We will seek a coverage decision as we gain new clinical validity or utility data.

[2] Lotan et al., (2022). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.

CXBLADDER ECONOMICS

MAKING THE ECONOMIC CASE TO HEALTHCARE INSTITUTIONS AND PAYERS

New health economic modelling shows routine use of Cxbladder Detect offers healthcare payers substantial savings for the evaluation and treatment of patients presenting to clinicians with hematuria.

A budget impact model for Cxbladder Detect, developed by Pacific Edge and authors from the Mayo Clinic and Germany's Coreva using national average data, has demonstrated median savings of $521.94 in direct costs per patient annually.

> **"This study shows... that doing the right thing for the patient is also cost effective for the health system payers."**

An abstract was submitted to the Western Section of the American Urological Association (WSAUA) conference and accepted as a poster where it was presented in Lake Tahoe in early October. It has also been submitted to the Society for Urologic Oncology (SUO). A manuscript for peer-reviewed publication has been submitted and is under review.

The model compares the AUA guidelines as a Standard of Care pathway to a Cxbladder clinical pathway. Hematuria patients in the Standard of Care pathway are stratified in line with AUA guidelines based on clinical factors into low risk, intermediate risk and high risk, while patients in the Cxbladder clinical pathway are risk stratified into AUA high risk (Detect positive) and AUA low risk (Detect negative).

The authors noted this cost saving strengthens the argument on the clinical value of deferring or avoiding cystoscopies and imaging, sparing thousands of patients these unnecessary procedures.

"This study shows for the first time that doing the right thing for the patient is also cost effective for the health system payers," says Pacific Edge Senior Medical Director Daniel Shoskes, who is a co-author of the study and Emeritus Professor of Urology at the Cleveland Clinic.

"Furthermore, this model does not account for indirect savings and other opportunities such as decreased waiting time for appointments and procedures, the cost and inconvenience for patients of coming in for unnecessary visits, and the environmental impact of eliminating the carbon footprint and medical waste from unnecessary medical procedures."

We note the original abstract presented to the WSAUA incorrectly states that the savings were $1,524 per patient.

CLINICAL STUDIES MARK NEW MILESTONES

New study 'CREDIBLE' commencing, microDRIVE opens, STRATA analysis continues and DRIVE moves closer to completion.

Pacific Edge is commencing a new study for demonstrating the clinical utility of Cxbladder Detect⁺ in hematuria evaluation The study CREDIBLE (**C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria) will follow at the conclusion of our microDRIVE study. CREDIBLE is a randomized, controlled study that will compare patients in the control arm risk stratified by AUA Standard of Care guidelines into high, intermediate and low risk with patients in the test arm risk stratified by Cxbladder Detect and managed as AUA high risk (Detect⁺ positive) and AUA low risk (Detect⁺ negative).

The clinical validation of Detect⁺ is now also in full swing.

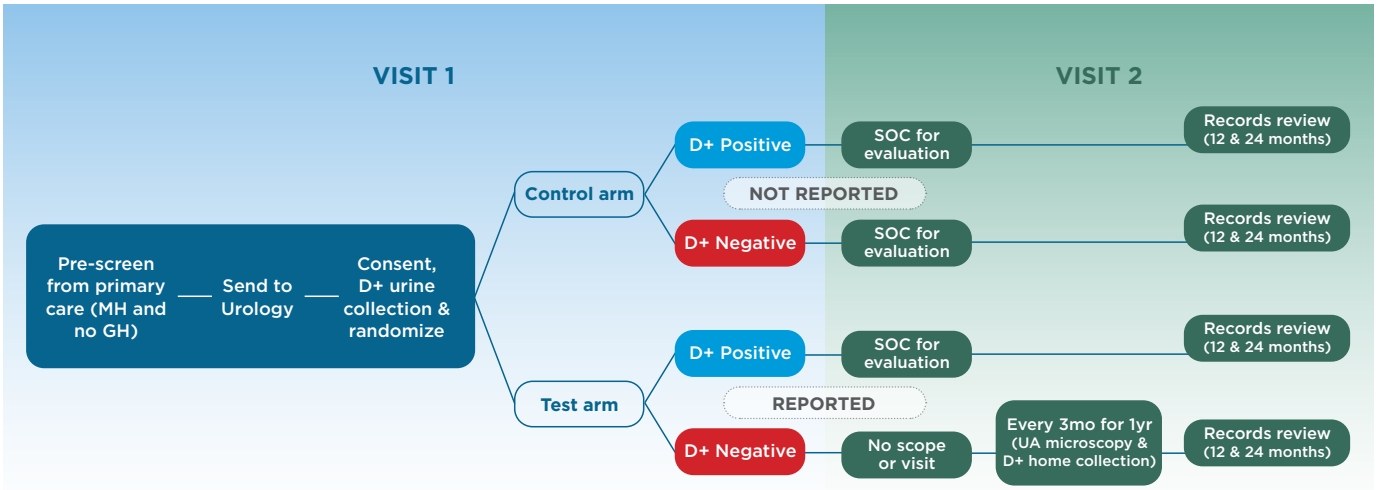
The primary endpoint for the study will compare the number of cystoscopies between the test and control arms. The number of tumors in each arm will be collected and analyzed as part of the secondary outcomes of the study.

The expectation is that the number of tumors would not be significantly different between the test and control arms, while the number of cystoscopies will be significantly reduced in the test arm compared to the control arm. We are targeting the completion of CREDIBLE in mid 2026 with the goal of publication in late 2026.

The clinical validation of Detect⁺ is now also in full swing with microDRIVE. We have completed contracting, the Institutional Review Board (IRB) has approved the study, and the first patients are expected to be recruited within the next month. This study is the first of its kind for Pacific Edge, as the primary contracted VA site will enroll patients from any VA site across the entire United States, acting in a similar fashion to a contract research organization (CRO) to dramatically reduce the total enrolment time. The entire study will be supported digitally, vastly improving our ability to monitor data quality, perform interim analyses, final analyses and product publications.

Meanwhile, since announcing the successful conclusion of STRATA (**S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**) the data analysis of the study is well underway. When concluded, this analysis will determine if there is a statistically significant difference in the proportion of patients that receive a cystoscopy between the control arm (no Cxbladder used) and the experimental arm (Cxbladder Triage result used to inform cystoscopy) for patients presenting with a mix of gross and microhematuria.

CREDIBLE PROTOCOL



Endpoints

- Count of cytoscopies on each arm
- Count of tumors found on each arm or per scope
- Count of tumors at FU when no cytoscopy occurs on test arm

EVIDENCE GENERATION

CLINICAL STUDY PROGRAM STATUS

STUDY	GOAL	POPULATION AND USE	STATUS
STRATA (**S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**)	• CU for Triage • CU for Detect⁺ (retrospective)	• Microhematuria • Risk stratification	- Enrolment is now closed with a total of 554 including 131 low risk patients Follow up will continue until Q3 2024. - Data monitoring is underway and expected to be completed Q1 2024
DRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV for Detect⁺ • CV for Triage and within a Veterans' cohort • Data for pooled-analysis	• Micro and gross hematuria • Risk stratification	- Enrolment total is 648 across 11 US sites and in line with target - Enrolment is expected to close late 2023 with follow up continuing until Q2 2024
AUSSIE (**A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia)	• CV of Detect⁺ with an Australian cohort • Data for pooled analysis	• Micro and gross hematuria • Risk stratification	- Target enrolment: 600 patients across three Australian sites - Enrolment commenced August 2023 and 7 subjects are enrolled to date
microDRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV of Detect⁺ • Data for pooled analysis	• Microhematuria • Detection	- Projected to start recruitment Oct 2023 as a network study across al VAMCs coordinated from a single US VA site - Target is 1000 patients and 50 tumor confirmed - Last patient in: March/April 2024
POOLED ANALYSIS	• CV of Detect⁺	• Microhematuria • Risk stratification	- Microhematuria patients from DRIVE, AUSSIE, STRATA and microDRIVE will be pooled and performance determined - The projected analysis is Q3-2025
LOBSTER (**LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence)	• CV of Monitor/ Monitor⁺	• Surveillance • Risk stratification	- Target enrollment is 426 subjects across 10 sites (US, Australia) - Enrolment is now 126 subjects
CREDIBLE (**C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria) - A randomized, controlled, clinical utility study for hematuria evaluation	• CU of Detect⁺	• Microhematuria • Risk stratification	- Target enrollment is 1000 subjects with an interim analysis at 600 to determine if the primary objective has been addressed - Due to commence late 2024

**Dates are calendar year not financial years*

Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication.

Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication.

Analytical validity (AV) - Evidence a test is repeatable in the lab for a given indication and population.

Visit the Pacific Edge website to learn more about the strategic rationale for our studies.

INTERNATIONAL

CXBLADDER LIVE IN THE PHILIPPINES

Cxbladder is now live in the Philippines following the signing of a distribution agreement with a local partner Hi-Precision Diagnostics (HPD), one of the country's largest medical laboratories, in June.

HPD's sales team numbers more than 50+ people nationally and the company has more than 70 sites across the country providing strong exposure of Cxbladder to the 900+ urologists practicing in the Philippines.

The agreement with HPD builds on similar agreements signed in Latin America, Vietnam, and Israel. In each case, Pacific Edge initiates logistical test shipments, works on any country specific registration or market access requirements, translates marketing material with our partners as necessary, and updates our billing processes. In all cases, our Distribution Partners have exclusive sales and marketing rights and are expected to drive the integration of Cxbladder into local standards of care by leveraging their strong relationships with clinicians and Pacific Edge's peer-reviewed and published clinical evidence.

REGULATION

FDA SIGNALS LDT REGULATION

The U.S. Food and Drug Administration (FDA) has released for public comment proposed rule changes that seek to have Laboratory Developed Tests (LDTs) such as Cxbladder regulated as medical devices under the US Federal Food, Drug, and Cosmetic Act.

There have been multiple attempts by the FDA to regulate LDTs over the last several decades or to assert the narrative that they have the right to do so, but this is strongly opposed by several major lobby groups, and numerous legal challenges are expected.

Pacific Edge continues to invest in systems and processes that will position the company to comply with the FDA or any other relevant regulatory body to enable uninterrupted clinical testing operations. Pacific Edge intends to keep shareholders updated about relevant regulatory milestones related to the FDA and other relevant agencies and/or standards as we achieve them.

ABOUT US

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