PacificEdge

INVESTOR UPDATE

OCTOBER 2025

INSIDE

LETTER FROM THE CEO

Medicare reimbursement conversation shifting in our favor

Dear Shareholders,

Pacific Edge has closed out 1H 26 confident that we have definitively shifted the conversation on Medicare reimbursement for Cxbladder. We have also further positioned the company for a faster path to profitability once the value of our tests is fully recognized through positive coverage policy in an LCD by Medicare.

The company has achieved three significant milestones demonstrating this progress.

Firstly, Novitas, our Medicare Administrative Contractor has announced its intention to convene a panel of experts called a Contractor Advisory Committee (CAC) to "to discuss evidence for the use of urine-based biomarkers in patients with microhematuria." The CAC is tentatively scheduled for February 19, 2026 at 6pm ET and demonstrates that Novitas recognizes the importance of the AUA's update to the 2025 Microhematuria Guideline and understands the strength of the evidence supporting our tests (see page 5).

"... timeframes of the appeals process are protracted, and we do not expect these efforts to begin contributing to revenue until the second half of this financial year."

Secondly, the US Centers for Medicare & Medicaid Services (CMS) recommended a reimbursement rate of US$1,328 for Cxbladder Triage Plus — a price that is US$568 or 75% above the US$760 price of our existing tests (Triage, Detect and Monitor) — materially enhancing our US growth prospects once we have achieved Medicare coverage for Triage Plus (see page 7).

Additionally, just after the quarter closed, our DRIVE Study, which demonstrates the clinical validity of Cxbladder Triage Plus in a veterans' population, was accepted for publication in the Journal of Urologic Oncology[1]. This publication provides the clinical validation evidence necessary for us to formally request Novitas to also consider coverage for Triage Plus (see page 8).

Novitas' indication that it will convene the CAC next year does impact the Medicare coverage timeline we signaled at our annual meeting in August. However, the rigor in this process demonstrates an increased understanding of the strength of our evidence and the value of our tests, given the inclusion of Cxbladder Triage in the AUA Guideline.

This delay is a source of immense frustration for the company, but we expect to navigate it. Having not reviewed new evidence for our tests since September 2023, our Medicare coverage status has simply not kept pace with the cadence of evidence nor the weight of clinical opinion, including the endorsement of the AUA, the world's premier urological professional society.

The consequences of this continue to drag on the operational performance of Pacific Edge, as the volumes we report today signal (see page 3). Novitas' actions during the establishment and finalization of the LCD — and the consequent administrative burden this imposes on clinicians, patients and the healthcare payers — represents a significant operating barrier to delivering the best patient care.

Overcoming this hurdle isn't a question of *if*, but *when* — and we are pursuing every avenue to deliver the value established through our clinical studies. The most productive route outside the formal reconsideration process is ongoing dialogue with the Coverage and Analysis Group at CMS and the Medicare appeals process (see page 6).

Since the non-coverage determination took effect in April, we have continued to seek reimbursement for Cxbladder Triage on the grounds that Guideline recommended tests are medically reasonable and necessary and therefore eligible for reimbursement under the US Social Security Act.

While initial claims for Triage tests have been denied as expected, we have filed appeals for a substantial portion of these claims and expect to have them heard by an Administrative Law Judge (ALJ). Given the strength of the new evidence from 2024 (STRATA) and 2025 (AUA Microhematuria Guideline) that was not considered during the establishment of the LCD, Pacific Edge sees a high probability of success on appeal.

[1] Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.

However, statutory timeframes of the appeals process are protracted, and we do not expect these efforts to begin contributing to revenue until the second half of this financial year.

Outside the US, demand remains encouraging. We have meanwhile strengthened our balance sheet with the completion during the quarter of a capital raise that secured $20.7[1] million in new equity. These funds give us the ability to navigate the US reimbursement environment, maintain our commercial footprint and continue to advance our clinical evidence program that — as the past year has demonstrated beyond doubt — is at the foundation of our shareholder value creation.

Looking ahead, operating discipline remains a priority, with close attention to sales force productivity and cost control to ensure careful capital management.

We thank shareholders for their continued support as we navigate this critical period, and we look forward to updating you further on our progress when we report our 1H 26 financial results in late November.

With my warm regards,

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

Administrative burdens weigh on US test volumes

Cxbladder tests processed through Pacific Edge's laboratories in the three months to the end of September 2025 (Q2 26) have weakened amid the disruption caused by transitioning US customers from Detect to Triage and the extra administrative processes faced by healthcare payers and clinicians since the loss of Medicare coverage in April 2025.

Total laboratory throughput (TLT) in Q2 26 fell 9.0% to 6,286 tests from the 6,905 tests in Q1 26. US TLT was down 13.1% to 4,971 from 5,722 in Q1 26. APAC volumes were up 11.2% to 1,315 from 1,183 tests in Q1 26, largely reflecting an increase in clinical study volumes.

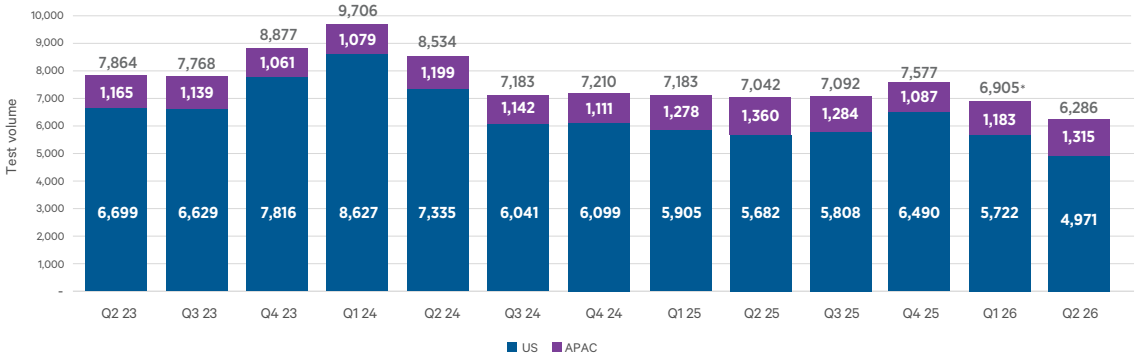
In the US Pacific Edge accelerated the decision to discontinue Detect following the inclusion of Triage in the new American Urological Association (AUA) Microhematuria Guideline in February 2025 and the Medicare non-coverage determination. We have successfully concluded that migration, with Triage and Triage Plus now accounting for 82% of tests processed at our US laboratory, up from 22% in Q4 25, the last quarter before the non-coverage determination.

Reflecting a reduction in our sales force we have seen an improvement in our sales force efficiency metric (tests per sales FTE) to 403 from 381 tests per sales FTE in Q1 26. The sales force reduction, and the loss of Medicare coverage has also impacted the number of ordering clinicians (803 ordering clinicians in Q2 26, down from the 907 in Q1 26). Tests per unique ordering clinician were steady at 6.2 in Q2 26 compared to 6.3 in Q1 26.

The fall in the number of ordering clinicians reflects the challenges associated with selling non-covered products, including the additional administrative processes imposed on clinicians and general market confusion caused by migrating customers from a well-known test to an unfamiliar one and the subtle differences in patient population for different Cxbladder tests.[1] The additional burdens include the requirement to provide patients with an advanced beneficiary notice (ABN) informing them they may be held financially responsible for the test if Medicare denies payment. ABNs insulate Pacific Edge from test non-payment.

[1] With the discontinuation of Cxbladder Detect in the US, Pacific Edge no longer provides a test to justify an intensification of a urological work up or resolve diagnostic dilemmas. The tests that remain commercially available in the US are Cxbladder Triage (a test to rule out the presence of urothelial cancer) and Cxbladder Monitor (a test used in the surveillance for urothelial cancer recurrence).

FIGURE 1: TOTAL TEST VOLUMES



*The US total of Q1 26 has been amended from the 5,717 previously reported.

FIGURE 2: CXBLADDER CLINICAL ADOPTION

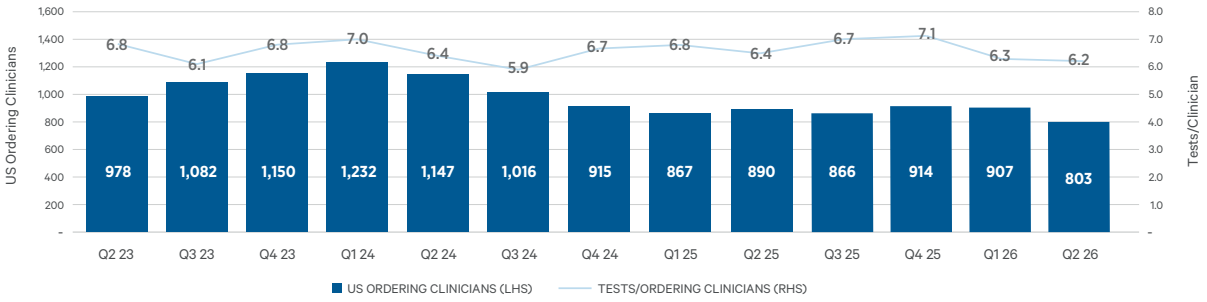
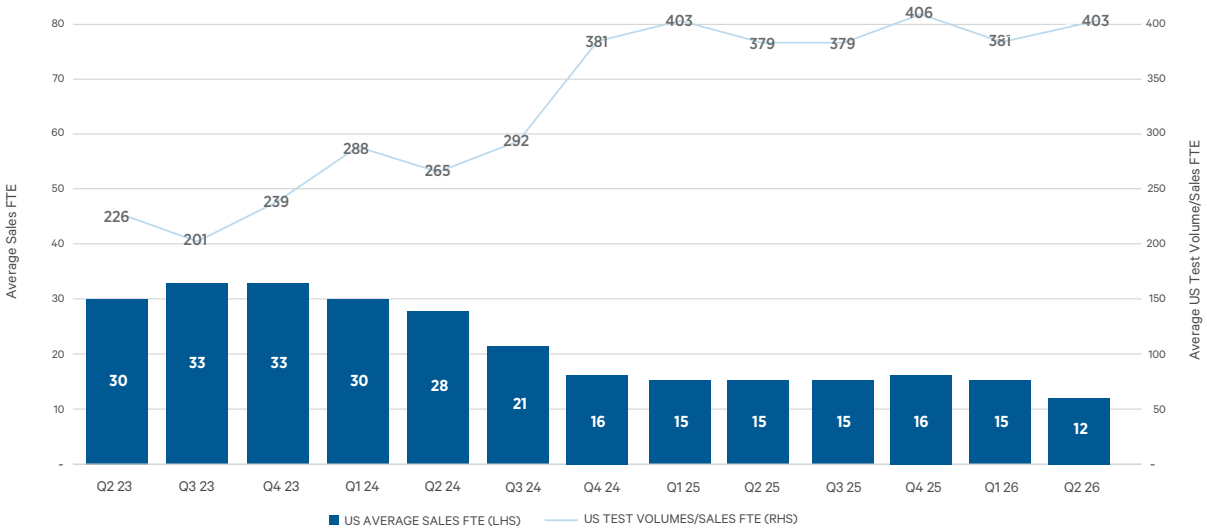


FIGURE 3: US SALES FORCE EFFICIENCY



Surveillance product name change

Pacific Edge is renaming its next generation surveillance product Cxbladder Monitor Plus to Cxbladder Surveillance Plus to better reflect the test's intended clinical use.

In clinical and regulatory contexts, the word 'surveillance' is understood as referring to patients who are expected to be disease-free but remain at risk of new or recurrent tumors. Conversely, the word 'monitor' is used in the context of patients that are suspected to have residual disease.

Our market research was conclusive that Surveillance Plus fosters a clearer understanding of the intended use of the test for physicians, patients and payers. Long term, we believe this will create greater brand equity, thereby supporting broader adoption of the test.

"the initiative... shows that Novitas has acknowledged the importance of the AUA Microhematuria Guideline."

Novitas moves closer to recognizing hematuria evaluation as a Medicare benefit

Medicare Administrative Contractor (MAC) Novitas has moved a step closer to re-opening the LCD which governs coverage for Cxbladder tests. It has announced its intention to convene an expert panel "to discuss evidence for the use of urine-based biomarkers in patients with microhematuria."

Novitas has tentatively scheduled the meeting for 19 February 2026 at 6.00pm (US Eastern Time).

In a notice sent to interested parties Novitas said: "We are in the process of gathering the most current literature, as well as developing questions relative to the available evidence, to stimulate discussion during the meeting."

We are pleased with the initiative which appears to show that Novitas has acknowledged the importance of the AUA Microhematuria Guideline and is taking a robust and credible approach to policy development. The panel, known as a Contractor Advisory Committee (CAC) is open to virtual attendance by the public and transcripts will be published to their website in audio and text format after the event. It will be comprised of urology subject matter experts and will be tasked with considering how to bring Medicare policy into alignment with the new Guideline.

Under the Medicare Program Integrity Manual, CAC meetings are initiated by the MAC and generally precede the draft issuance of a new or substantially revised Local Coverage Determination (LCD). The meetings are advisory in nature to ensure all relevant evidence is appropriately considered.

We expect the panel to consider the Guideline; the STRATA[1] Study that was ignored by Novitas' January 2025 non-coverage determination yet precipitated the Guideline revision; and all new clinical evidence published prior to the CAC meeting. This evidence includes the analytical validation study published in July[2] and the DRIVE Study recently-accepted for publication that demonstrates the clinical validity of Triage Plus (which Pacific Edge will also use to request Medicare coverage from Novitas) (see page 8).

While the timing of any decision on coverage remains uncertain, MACs generally give an indication of their intentions in relation to coverage shortly after the conclusion of the CAC. In the event of a draft LCD being proposed, the MAC is required to finalize or withdraw the LCD 365 days after issue.

[1] Lotan et al (2024) A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. J Urol 2024.
[2] Harvey et al (2025) Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.

FY26 revenue linked to appeals process success

Since the non-coverage determination for Cxbladder became effective in April, Pacific Edge has filed appeals on all Medicare claims for Cxbladder Triage that have been denied reimbursement, and it is actively advancing them through the multi-stage Medicare administrative appeals process[1].

Our success through this process — and particularly our success at the Office of Medicare Hearings and Appeals (OMHA) before an Administrative Law Judge (ALJ) — will be determinative for FY 26 US revenue. However, the process is by its nature slow, meaning any successful appeals filed since April are more likely to contribute to revenue in the second half of the financial year.

At the first and second levels of Medicare appeals, denials are largely automated and based rigidly on policy. However, at the third level of appeals, Administrative Law Judges are expected to show deference to LCDs, but are not bound by them; and can consider other evidence, including the updated AUA 2025 Guidelines, and new evidence like the May 2024 STRATA Study, the analytical validation studies, and the 2025 ECRI[2] report that gave Triage a positive 4/5 rating. Based on this stronger, most-current clinical evidence, we are significantly more confident of success at the ALJ stage. Beyond the ALJ, additional avenues remain — the Medicare Appeals Council and ultimately judicial review — but the ALJ outcome will be the most critical inflection point for revenue recovery.

MEDICARE APPEALS PROCESS

REDETERMINATION
Medicare Administrative Contractor (MAC)

Who: Novitas

Timeline: ~60 days to respond to each appeal

RECONSIDERATION
Qualified Independent Contractor (QIC)

Who: C2C Innovative Solutions

Timeline: ~60 days to respond at which point the request can be escalated to OMHA

HEARING
Office of Medicare Hearings & Appeals (OMHA)

Who: Administrative Law Judge (ALJ)

Timeline: Target 90 days, but often longer

FURTHER REVIEW
Medicare Appeals Council
Federal District Court

[1] https://www.medicare.gov/providers-services/claims-appeals-complaints/appeals/original-medicare
[2] ECRI is the Emergency Care Research Institute https://home.ecri.org/

CMS price and DRIVE Study advance Triage Plus

Pacific Edge has received two major boosts to the commercialization of Cxbladder Triage Plus, our next generation test for hematuria evaluation. First, CMS has recommended a significant uplift in the test's price, positioning the company for a step change in commercial outcomes once coverage is achieved. Second, our DRIVE Study has been published in the *Journal of Urologic Oncology*[1] confirming the test's clinical validity and supporting the case for Medicare coverage and Guideline inclusion.

CMS pricing decision positions Triage Plus for faster path to profitability

The US Centers for Medicare & Medicaid Services (CMS) recommendation of US$1,328.32 for Cxbladder Triage Plus stands to provide a significant boost to Pacific Edge's US growth prospects.

The new price compares favorably with the current US$760 CMS price for Triage and represents a material uplift from the draft price of US$1,018.44 first proposed through the 'Gapfill' process in April.

The CMS final price for Triage Plus is still subject to 60 days of notice and comment, but is typically not expected to change and is expected to become effective from 1 January 2026. Once coverage is secured, this higher reimbursement rate will substantially improve the economics of Pacific Edge's US commercial model. The new price meaningfully increases the potential revenue per test and enhances the return on investment from the sales force, facilitating more rapid scaling of the business in the US market.

Triage Plus is central to Pacific Edge's US growth strategy: hematuria evaluation tests represent around 82% of total US laboratory throughput, and the company will prioritize migrating from Triage to Triage Plus once a local coverage determination has been made. The higher price provides the commercial headroom to expand the reach of the sales team and lift their productivity. Pacific Edge's commercial team will focus on three levers to capture this opportunity:

- Increasing the number of physicians ordering Triage Plus by expanding education and awareness.
- Growing test penetration per physician by embedding the test more deeply into clinical workflows.
- Lifting productivity per Account Executive by improving the number of tests delivered per territory.

[1] Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.

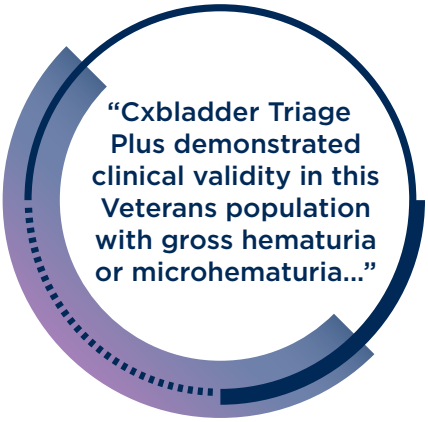
Reconsideration request to follow DRIVE publication

Our DRIVE Study — which demonstrates the clinical validity of Cxbladder Triage Plus in a veterans' population — has been published in the *Journal of Urologic Oncology*[1] clearing the way for Pacific Edge to ask Novitas to consider coverage of the test.

The DRIVE Study — The Diagnostic Performance of Cxbladder Triage Plus for the Identification and Priority Evaluation of Veterans at Risk for Urothelial Carcinoma — evaluated the performance of Cxbladder Triage Plus when compared to cystoscopy combined with histopathologic confirmation of urothelial cancer. It confirmed the performance characteristics of Triage Plus established in the Analytical Validation publication (Harvey et al. 2025)[2] in a patient population independent of the development dataset in the proof-of-concept study by Lotan et al. in 2023[3].

The authors of the study concluded: "Cxbladder Triage Plus demonstrated clinical validity in this veterans population with gross hematuria or microhematuria, with high sensitivity and specificity. These findings indicate that Triage Plus may be safely used to rule out or detect [urothelial cancer] in patients with hematuria."

Based on this evidence, we will request coverage of Triage Plus and will seek to ensure the study is considered during the Contractor Advisory Committee deliberations planned for the new year (see page 5). We also believe the study provides grounds for the AUA to consider an amendment to the Microhematuria Guideline to list Triage Plus alongside Triage. We are engaging with the AUA to determine the process for amending the Guideline to include Triage Plus.



Test	Sensitivity	Specificity	Negative Predictive Value	Positive Predictive Value	Test Negative Rate
Cxbladder Triage	93%	38%	98.5%	11%	35%
Cxbladder Triage Plus Intermediate risk patients	94%	77%	99.3%	26%	71%
Cxbladder Triage Plus High risk patients		95%		51%	90%

[1] Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.
[2] Harvey et al., submitted. Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.
[3] Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.

Evidence to drive clinical practice change

Our clinical study program is at the foundation of Pacific Edge's value. We are focused on generating the compelling clinical evidence required to drive behavior change in physicians. Specifically, we seek to produce evidence that is founded on the frameworks of Analytical Validity, Clinical Validity, and Clinical Utility, with the endpoints and sample sizes required for coverage decisions and Guideline inclusion.

STUDY	GOAL	POPULATION AND USE	STATUS
STRATA **S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**	• CU Triage • CV/CU Triage Plus (retrospective)	• MH • Risk stratification	• Recruitment closed with 555 patients including 223 low risk patients (test and control) • Interim analysis results published leading to AUA Guidelines inclusion in 2025 update • Database lock expected Oct 2025 and Clinical Study Report (CSR) expected Oct 2025
DRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria	• CV Triage Plus • Data MH pooled analysis	• MH and GH • Risk stratification	• Enrolment closed with 710 patients including 48 tumour confirmed patients from 10 US VA sites • Database lock completed and published October 2025
microDRIVE **D**etection and **R**isk stratification **I**n **VE**terans presenting with microhematuria	• CV Triage Plus • Data MH pooled analysis	• MH • Risk stratification	• Currently 421 samples received to date with 11 UC cases confirmed 35 targeted • Study expanded with 3 sites and all currently enrolling • Study design will be changed to include high risk patients presenting with GH • The target is 1000 patients with LPI projected Q2-4 2026
AUSSIE **A**ustralian **U**rologic risk **S**tratification of patient**S** w**I**th h**E**maturia	• CV Triage Plus • Data MH or GH for pooled analysis	• MH and GH • Risk stratification	• The target is 35 UC confirmed patients including a minimum of 10 MH UC confirmed • There are 758 subjects enrolled including 53 UC confirmed (GH+MH) including 10 MH UC patients • Enrolment is closed, database lock is projected as Q4 2025 and publication submission Q1-2 2026
POOLED ANALYSIS	• CV Triage Plus from pooled analysis	• MH and GH • Risk stratification	• MH (separately GH) patient data from DRIVE, AUSSIE & microDRIVE will be pooled and analysed • MH pooled analysis is delayed pending microDRIVE completion and is expected late 2026 • GH pooled analysis paper submission is expected in late 2026
CREDIBLE **C**ystoscopic **RED**uction **I**n **BL**adder **E**valuations for microhematuria	• CU Triage Plus	• MH • Risk stratification	• All sites have completed contracts and IRB approvals • Twelve sites actively enrolling patients (currently 82 enrolled, target is 1000)
LOBSTER **LO**ngitudinal **B**ladder cancer **S**tudy for **T**umor **R**ecurrence	• CV Monitor and Surveillance Plus	• Surveillance • Risk stratification	• Enrolment will be complete when 75 UC recurrences are observed and last patient expected Q3-2025 • Currently 428 subjects enrolled with 1142 samples including 74 confirmed UC recurrences • Protocol amendment provides for continued scheduled surveillance visits & urine collections into 2026
OCTOPUS **O**ngoing **C**xbladder **T**esting for **O**ptimized **P**atient Experience in **U**rothelial **S**urveillance	• CU Cxbladder Surveillance	• Surveillance • Risk stratification	• Currently at the planning stage with an Advisory Board scheduled for Dec-2025 to refine the study design

Microhematuria, MH / Gross hematuria, GH
Cxbladder Triage Plus (Triage Plus) / Cxbladder Monitor Plus, now called Cxbladder Surveillance
Quarterly dates are calendar year not financial years

Opening the next chapter

After nearly 10 years of service to the company Pacific Edge Diagnostics USA President David Levison is now stepping away from the business.

In addition, to the three years in the current role, David served five years as an Independent Director and was seconded to lead PEDUSA as Executive Chairman in 2020. During his management of the PEDUSA team, test volumes increased 1.6 times, and revenue grew 2.9 times.

David has maintained the primary relationship with the key opinion leaders at our key account Kaiser Permanente and helped to establish Cxbladder as a cornerstone of healthcare delivery in the Southern California Permanente Medical Group.

When you look back on your time at the company what are you most proud of?

Since I joined the Board of Directors in 2016, we have made progress in many areas. The acceleration of both the quality and quantity of our clinical data is very gratifying as it was a key objective that I discussed with the Board when I assumed responsibility of the US business.

The other areas where we have made progress - with more work still to be done - include the expansion of Cxbladder's brand recognition, the improvement of our internal data systems and analytical tools as well as a sharper sales and marketing focus on selling the clinical value of Cxbladder products.

What has been your biggest disappointment?

From an external standpoint, the inconsistent reimbursement of our products given their strong published data is a large disappointment.

What are you going to miss about the company (what have you most enjoyed in your time with the company)?

I will miss working with a dedicated group of people who have shown resilience and dedication amid the reimbursement uncertainty we have faced over the last three years.

Do you have any parting advice for the team and investors?

Success for Pacific Edge is a marathon so don't get too worried about the setbacks or too excited by the wins. If you keep the patients' interests as our top priority, success will follow.

What's next for you?

I am investigating a number of opportunities, both inside and outside of the molecular diagnostic space. The new technologies being deployed in the diagnostic industry are expanding the range of clinical value propositions that can be delivered so it is an exciting time to be in this arena.

Pacific Edge wishes David well. He will not be replaced, instead Pacific Edge has commenced a search for a Chief Commercial Officer (CCO) that will assume responsibilities for the Sales, Marketing and Market Access functions with a focus on the US.

DAVID LEVISON

- Pacific Edge Diagnostics USA – President Americas

Former roles:

- Pacific Edge Diagnostics USA - Executive Chairman
- Pacific Edge - Non-Executive Director
- Qlarity Imaging - Chief Executive Officer
- CardioDx - Director, Chief Executive Officer and Chief Strategic Officer
- CareDx - Board member
- Texas Pacific Ventures - Venture Partner
- iScribe - Founder, President, and Director

Education:

- B.A. (Williams)
- MBA (Stanford)

ABOUT US

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.

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