PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

JANUARY 2024

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LETTER FROM THE CEO

PREPARED FOR ALL OUTCOMES

Dear Shareholders,

Pacific Edge enters 2024 as we ended 2023 – looking for certainty on Medicare's coverage of Cxbladder.

I am frequently asked whether I am optimistic or pessimistic about retaining Medicare coverage for our Cxbladder products, or alternatively what a realistic outcome is. As Chief Executive, I challenge the framing that we must be optimistic, pessimistic or realistic. The question shareholders deserve an answer to is: 'does Pacific Edge have the vision, the team, the work ethic and the determination to get the job done regardless of the headwinds we face?'

To our shareholders, I say: 'we do – and we are prepared however events unfold'.

It remains a fact that at any time prior to 26 July 2024, Novitas, the Medicare Administrative Contractor with the jurisdiction for our US laboratory, could re-publish as final an unfavorable version of the draft determination 'Genetic testing for oncology' (DL39365) that would see Medicare coverage cease for Cxbladder products.

The 'best case' outcome, however, is that Novitas recognizes the merit of the evidence Pacific Edge has submitted during the 'Open Comment' period that ended on 9 September 2023, and the series of highly supportive representations from peers, industry and the professional urology community for Cxbladder products to retain the 'claim-by-claim' coverage, subject to medical necessity, we have been afforded for the last three and a half years.

> **"We are delivering on a key goal from the reorganization in August for our commercial team to operate at breakeven"**

We are meanwhile pleased to have had the opportunity to meet in November the Centers for Medicare & Medicaid Services (CMS), the body to whom Novitas is ultimately accountable on coverage decisions. This meeting precipitated a further meeting with Novitas in January, in which CMS representatives also participated. We view the involvement of CMS as a positive engagement in response to the seriousness of the issues we and others have raised, but not definitive of any particular outcome.

Even in the event that Cxbladder products retain coverage, the impact to our commercial operations from the uncertainty we have endured for 18 months have already been substantial. The test volume figures we have released today demonstrate the cumulative effects. US test volumes are now at their lowest level since I assumed leadership of Pacific Edge (see page 4) and, following the reorganization undertaken in Q2 24, our sales force is now at its smallest size.

The silver lining – and the correct reading of this quarterly result – is that the fall in test volume is due principally to the reduction in the size of our sales team[1] from 34 at its peak in February 2023 to 17. It is the inevitable consequence of the steps necessary to preserve capital given the elevated risks of a non-coverage determination and an acknowledgement that re-hiring for departing account executives prior to obtaining clarity from Novitas is simply the wrong decision.

Despite this backdrop, our commercial team has made meaningful progress in other important areas. Tests per ordering clinician after allowing for seasonal trends have held steady as we work closely with our key customers. Average tests per sales headcount[2], a new metric published for the first time today, has actually increased (see page 4). Furthermore, revenue per test has increased (data not released) predominantly as a result of introducing our 'Enhanced Patient Responsibility' and 'Patient Assist Programs' which are aimed at improving collections from patients of private payers that deny

[1,2] Includes regional Regional Sales Directors, National Accounts Executives, and Account Executives.

a Cxbladder claim. We are a better business as a consequence of these changes and will benefit when we obtain coverage certainty – a precursor for reverting to growth.

Without coverage certainty, we do not have the ability to forecast a return to growth in testing volume, but we will continue to guide investors to judge our performance by the following key metrics – throughput per sales headcount, throughput per ordering clinician and average sales price (ASP), all of which are stable or increasing in the current environment.

On the critical matter of managing capital, we want shareholders to understand that we are delivering on a key goal from the reorganization in August for our commercial team to operate at breakeven. The corollary of this is that the cash outflow is driven almost entirely by the strategic imperatives of R&D for Detect+ and Monitor+, technology transfer from R&D to lab operations, clinical evidence development for coverage and guidelines inclusion, and the digitalization and performance excellence initiatives in the existing operations.

Meanwhile, as we set out in this shareholder update, we continue to make Pacific Edge a more resilient and efficient company. We are building a presence in markets in Asia and Latin America (and Israel) that have lower barriers to entry and allow us to leverage our existing laboratory infrastructure and support staff (see page 6). Our performance excellence initiatives are focused on improving customer experience by reducing turnaround time and the number of non-resulted tests (see page 5). We are making steady progress with Kaiser Permanente, recording our highest monthly test throughput in December (see page 5), while our clinical study program continues to advance according to the timelines we've previously set for investors (see page 7).

We wish you a prosperous start to the New Year and look forward to reporting further progress to you in April.

Dr Peter Meintjes
Chief Executive

TEST VOLUMES

TEAM REDUCTIONS WEIGH ON TEST VOLUMES

Cxbladder tests processed at Pacific Edge's laboratories weakened in the three months to the end of 31 December 2023 with the fall largely reflecting the reduction of the commercial team in Q2 24.

The sales team[2] now stands at 17 from its peak of 34, ahead of the Medicare Administrative Contractor Novitas releasing its non-coverage determination in June 2023. Company-wide adaption to the Q2 24 restructure and the seasonal headwinds of holidays, reduced laboratory operating days and physician schedules also contributed to the fall in US volumes.

In the three months to the end of December 2023 (Q3 24), the team processed 7,172 tests (Figure 1), a 15.9% reduction over the 8,525 tests processed in Q2 24 and a 7.7% reduction on the 7,768 tests processed in Q3 23. The fall was led by US test volumes which were down 17.7% on Q2 24 at 6,040 and down 8.9% on Q3 23, while the number of clinicians ordering the test in Q3 24 fell to 1,016 from 1,147 in the prior quarter and 1,082 in Q3 23. Tests per clinician were down on the prior quarter, but in line with seasonal expectations over the quarter which included Christmas and Thanksgiving holidays (Figure 2).

The sales force efficiency metric described here measures the average sales by the average sales FTE[3] in each quarter, and has increased over the last two quarters despite the current headwinds (Figure 3).

Test volumes in the Asia Pacific in Q3 24 were 1,132, down 4.9% on the 1,190 tests processed in Q2 23 and down 0.6% on the 1,139 tests processed in Q3 23. The move largely reflected seasonal variations in the relatively mature New Zealand market.

[2] The sales team includes Regional Sales Directors, National Accounts Executives, and Account Executives.
[3] Average Sales FTE includes quarterly average total head count of Regional Sales Directors, National Account Managers and Account Executives.

FIGURE 1: TOTAL TEST VOLUMES

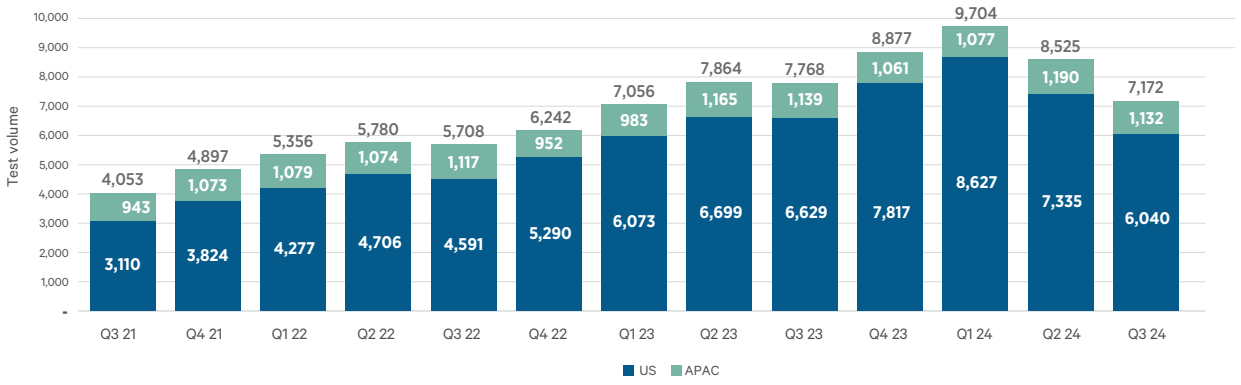


FIGURE 2: CXBLADDER CLINICAL ADOPTION

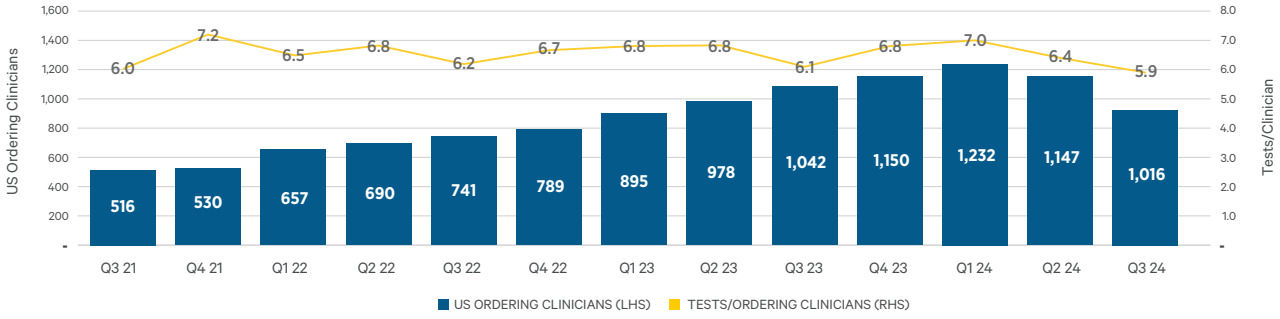
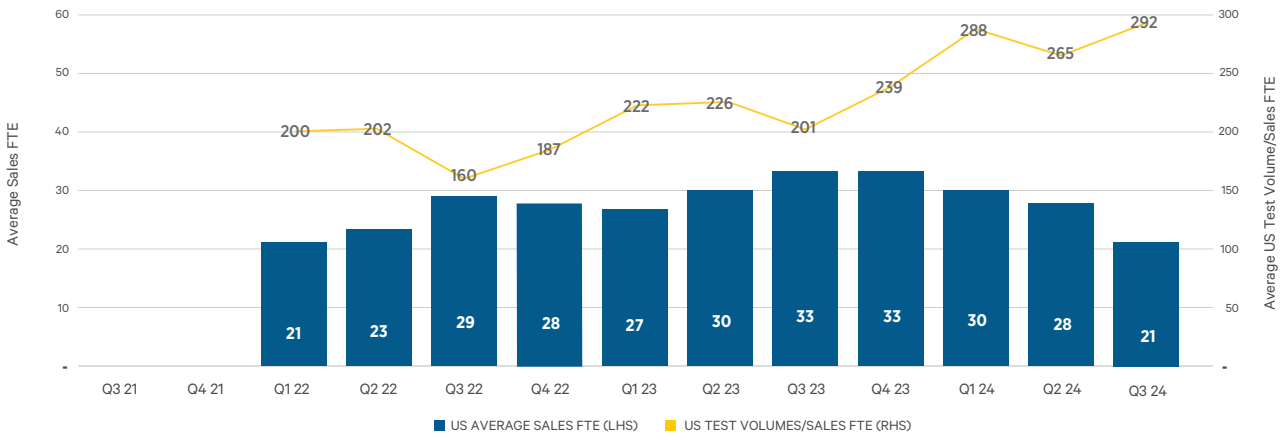


FIGURE 3: US SALES FORCE EFFICIENCY



KAISER PERMANENTE

TEST VOLUMES BUILD AS EMR GOES LIVE

Clinicians at Kaiser Permanente within Southern California are beginning to adopt Cxbladder Triage and Monitor on agreed patient types, having successfully integrated Cxbladder ordering with HealthConnect, the healthcare provider's electronic medical records (EMR) system.

The integration of Cxbladder tests into the EMR went live mid-November and the initial implementation went smoothly with the Kaiser Permanente and Pacific Edge teams quickly addressing any operational issues that arose. Clinicians across the urology medical centers of the Southern California Permanente Medical Group (Kaiser Permanente SoCal) are adopting the Cxbladder tests. The success of the integration is now visible in volumes ordered, with December recording the highest volume from the healthcare provider.

Kaiser Permanente is the largest integrated healthcare provider in the US, serving 12.6 million members, which equates to approximately 3.7% of the national population. Kaiser Permanente's Southern California region is the largest region by membership and manages the care for approximately 37% of all patients managed by the health plan. In aggregate Kaiser Permanente SoCal's urology team conducts ~25,000 cystoscopies each year across the relevant hematuria evaluation and bladder cancer surveillance clinical pathways. Kaiser Permanente and Pacific Edge are collectively working to further deliver the clinical value of Cxbladder testing broadly to Kaiser members in Southern California and across the Kaiser system.

PERFORMANCE EXCELLENCE

ENHANCING THE CLINICIAN EXPERIENCE

Faster Cxbladder turnaround times and the automation of our laboratory processes - these are among the range of performance excellence and Cxbladder simplification initiatives we are pursuing to enhance the customer experience and drive efficiencies in our operations.

The turnaround time project is focusing on processing and documentation bottlenecks in the sample receipt, accessioning and testing processes. The project is targeting a reduction in the average amount of time between a sample arriving at our laboratory door and the result being delivered to clinicians.

In tandem with reducing turnaround time, we are automating our RNA/DNA extraction process - the rate-limiting step in our laboratory workflow. Automation not only reduces the amount of time operators spend working with samples, it also enhances the repeatability and reproducibility of our tests. We are preparing for the technology transfer of this development to our commercial labs where we will document and publish for peer review the analytical validity (AV) of the new automated workflow, further enhancing the portfolio of evidence underpinning Cxbladder.

Chief Operating Officer Darrell Morgan says: "With reduced test turnaround times clinicians are more quickly able to use our tests to determine the appropriate management of patients, while quicker results can help to alleviate patient anxiety over their prognosis. Both outcomes enhance the attractiveness of Cxbladder to all involved in the bladder cancer patient care pathway."

[4] Repeatability measures the variation in measurements taken by a single instrument or person under the same conditions, while reproducibility measures whether an entire study can be reproduced in its entirety.

ASIA PACIFIC

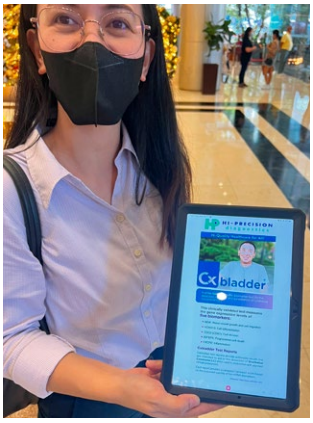
NEW ASIAN MARKETS SEEING FIRST ORDERS

Commercial test volumes are slowly developing in the new markets we're approaching in Southeast Asia, including the Philippines and Malaysia.

Volumes from these and the other markets in which we are seeking partners, i.e. Indonesia, Thailand, Hong Kong, and Vietnam, will not be significant in the short and medium term. However, over the longer term, as the clinical value of our tests become recognised in each of these local urological communities through the networks of our distributors, the cumulative volume across these territories has the potential to add meaningfully to the Pacific Edge group.

In all of these regions our focus is on populations that rely on the private healthcare systems. These populations represent a minority of the more than 600 million[5] people in these countries. But, across the regions we are considering, they represent a serviceable market equal to the size of one large US private payer or a medium-sized US state.

In such private systems the barriers to entry are much lower than those found in markets that operate universal healthcare schemes. Notably, healthcare payers in our new markets are more likely to cover tests if coverage is requested by clinicians who are already using the tests, so payer coverage may follow in certain markets after initial clinician adoption.



We select partners that have established relationships with clinical decision makers, government and private healthcare payers. In the Philippines, for example, we are partnered with Hi-Precision Diagnostics, a provider of pathology lab services that operates an extensive network of collection centres around the country. In Malaysia, where healthcare payment decisions are centralised around private hospitals and their own pathology laboratories, we have teamed up with a distributor, Wellspring Medical, which has a team that is already calling on decision makers.

In all markets the relationships the distributor/partner has with the clinicians is crucial. With the support of Pacific Edge and its Medical Affairs team, the partners in each market engage with clinicians the same way the Medical Affairs Team reach out to US clinicians - through conferences, symposia and face-to-face meetings.

[5] CIA Factbook 2023 estimates.

CLINICAL STUDIES

STRENGTHENING THE CLINICAL UTILITY CASE

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 672 across 11 US sites and in line with target - Enrolment is expected to close early 2024 with follow up continuing until Q3 2024
microDRIVE (**D**etection and **R**isk stratification **I**n **VE**terans presenting with hematuria)	• CV of Detect+ • Data for pooled analysis	• Microhematuria • Detection	- Recruitment commenced November 2023 as a network study across all VAMCs coordinated from a single US VA site - A total of 23 patients have consented for the study with 5 samples received to date - The target is 1000 patients with 35-50 tumor confirmed patients - Last patient in: May/June 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 42 subjects are enrolled to date
POOLED ANALYSIS	• CV of Detect+	• Microhematuria • Risk stratification	- Microhematuria patients from DRIVE, AUSSIE 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 205 subjects with 285 samples received to date - The enrolment phase is expected to end late 2024
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.

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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