PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

JULY 23

INSIDE

LETTER FROM THE CEO

CHARTING A NEW PATH FORWARD

Dear Shareholders,

I am pleased to announce another record-breaking quarter in laboratory testing throughput for our Cxbladder products. I'm sure it is not lost on shareholders that this announcement comes on the day (US time) that we would have lost Medicare coverage, were it not for the recent announcement that Novitas[1] will not make Local Coverage Determination (LCD) L39365 effective on July 17, but will republish with the opportunity for open meetings and public comment.

This was the best possible result that we could have expected from our intense efforts since Novitas announced it had finalized what we and other commentators have noted as a substantially flawed LCD on 2 June 2023. Now, Pacific Edge will have the opportunity to address Novitas' concerns and convey our confidence that our primary clinical evidence is sufficient to support continued Medicare coverage of the tests we currently have in the US market.

Since the finalization of the adverse LCD our focus in conjunction with various partners has been on pursuing a range of actions aimed at retiring or delaying its implementation on the grounds that Novitas did not follow statutorily regulated procedure. We now appear to have prevailed on these procedural matters.

Consequently, until we are further advised, and until we have concluded the notice and comment period and a new LCD is finalized, Pacific Edge expects to continue to bill and receive reimbursement for our tests from Medicare and Medicare Advantage.

Pacific Edge will continue to argue that the new approach in the LCD to use third-party databases to preemptively non-cover diagnostic tests without evidentiary review is unprecedented, not statutorily supported and possibly unlawful. However, we will focus more heavily on the evidentiary review in the LCD of Cxbladder products, rebutting what our Medical Team and many prominent Key Urology Opinion Leaders perceive as a flawed analysis that lacks understanding of how to use our test and lacks knowledge of the standard of care in urology. We break down our analysis of the evidentiary review for investors on page 5.

> **"We now appear to have prevailed on these procedural matters."**

The events of the last few months have prompted a thorough review of our business operations in the event of a non-coverage determination, and this has already created unanticipated value, including important revisions to our strategy.

Starting today, and as flagged earlier this month, we will ask our patients to accept a greater degree of financial responsibility for the costs of performing a Cxbladder test if an insurer denies us payment. Pacific Edge will pass on a higher patient responsibility to patients with private insurance when that insurer denies the claim. Patients will be asked to sign a patient responsibility notice that will include our Patient Assist Program (see page 6).

Regarding our clinical evidence development, we announce today that we have reached the primary endpoint for the STRATA study, so will cease enrolment, and begin analysis, before deploying our clinical evidence generation resources onto other studies. Our high-level focus on clinical evidence generation remains the cornerstone of our long-term strategy (see page 8).

Despite the LCD not becoming effective on 17 July and its re-opening for notice and comment, we continue to work and develop the strategies that we set out in June.

We have finalized and announced the enhanced patient responsibility program, acknowledging it will take time to determine its efficacy.

We continue to explore establishing a second lab in a jurisdiction governed by the MolDx Program to see if it would provide greater certainty of retaining or regaining Medicare coverage.

We are also exploring the appropriate structure of the business and what other strategic options are available to the company that will enhance shareholder value.

We aim to coalesce all of our recent activities and update shareholders on these workstreams at our Annual Shareholders Meeting to be held in Auckland and online on Thursday 27 July 2023 (see page 7). The event will include presentations from our Chair Chris Gallaher, Pacific Edge Diagnostics USA President David Levison, our Chief Medical Officer, Urologist Dr Tamer Aboushwareb, and myself.

It will be an important event for shareholders, and we encourage you all to attend.

I look forward to seeing you there.

Ngā mihi nui,

Dr Peter Meintjes
Chief Executive

[1] Novitas is the Medicare Administrative Contractor (MAC) with responsibility for our US laboratory.
[2] The MolDX Program is a Medicare program that determines coverage, coding, and pricing of molecular pathology services.

TEST VOLUMES

CONTINUED TEST VOLUME GROWTH

Test volumes processed at Pacific Edge laboratories rose to a new record in the first quarter of the 2024 financial year (Q1 24) rising to 9,706, a 9% rise on the 8,877[3] tests in the prior quarter (Q4 23).

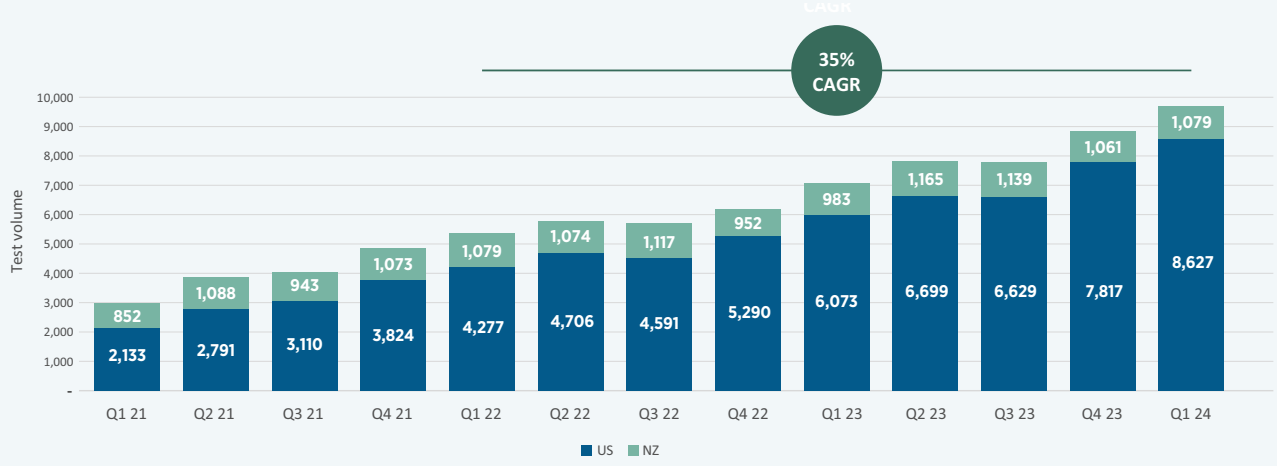
The volume processed in Q1 24 represents a 38% increase on the 7,056 tests processed in the same quarter of the prior year (Q1 23). US volumes led the growth rising to 8,627 in Q1 24, a 10% increase on the 7,816 tests in Q4 23. The figure also represents a 42% increase on the 6,073 tests processed in Q1 23.

The continued growth in test volumes comes despite Novitas' June 2023 release of the latest iteration of the 'Genetic Testing for Oncology' Local Coverage Determination and its subsequent stay earlier this month.

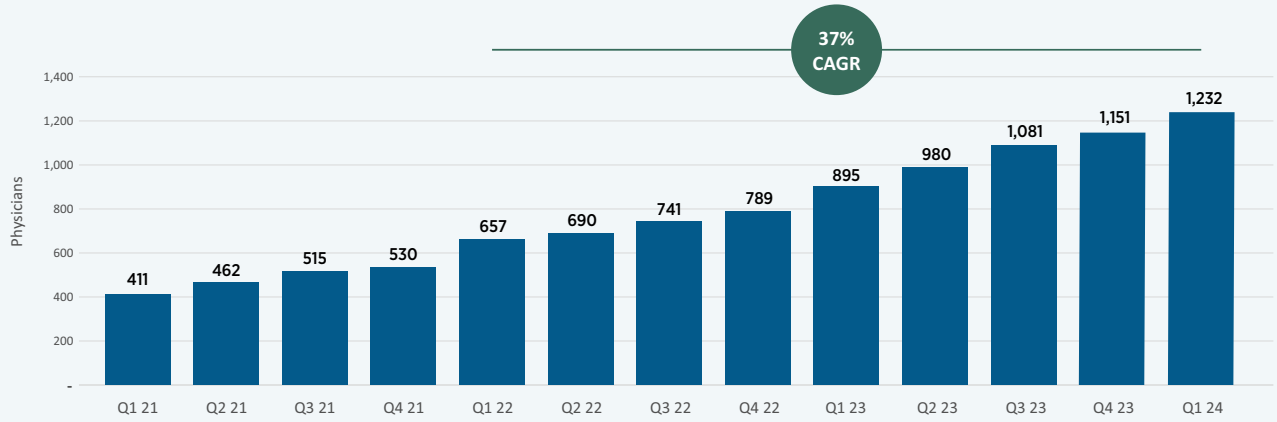
The number of unique ordering clinicians in the US has continued to grow through the quarter to 1,232 at the end of Q1 24, a figure that represents more than 10% of the 12,253[4] actively practicing urologists in the US. The figure is up 7% on the 1,150 ordering in Q4 23 and up 38% on the 895 clinicians who ordered tests in Q1 23.

Asia Pacific volumes in Q1 24 were 1,079, up 2% on the 1,061 tests processed in Q4 23, and up 10% on the 983 tests processed in Q1 23. The volume trends in APAC reflect the maturity of the New Zealand market and the region's ongoing healthcare reforms.

TOTAL TEST VOLUMES: GROUP



UNIQUE ORDERING CLINICIANS: US



[3] Historic test throughput numbers may vary slightly from those reported in prior quarters due to data recording inconsistencies determined by ongoing data provenance initiatives.
[4] American Urological Association 2022 census.

LCD CHALLENGE

EXPLORING ALL LEGAL AND POLITICAL PATHS

With the finalization of the Novitas 'Genetic Testing for Oncology' (L39365) LCD in early June, we launched a concerted legal and political campaign aimed at retiring or delaying its implementation.

Firstly, through our industry partners we have initiated lobbying efforts to engage with our local (Pennsylvania) Congressmen and Senators to reach the White House and the Department of Health and Human Services (HHS) that oversees the Medicare Program.

Our goal here is to highlight for those political leaders the significant consequences for:

- Medicare patients who will have lost access to our tests;
- Physicians who will have lost the ability to choose our tests for their patients; and
- The Medicare Program, which will not realize the clinical and potential economic benefits of modern non-invasive biomarker tests that improve the standard of care by reducing unnecessary invasive diagnostic procedures.[5]

Secondly and coordinated in parallel, we have made procedural arguments through our US attorneys to the HHS Office of the General Counsel (OGC), which has the power to direct Medicare to retire or delay the Novitas LCD. Our focus has been on highlighting several procedural anomalies in the finalized LCD:

- We were denied 'notice and comment' on a new unpublished evidentiary review in the LCD;
- The LCD continues to rely on third-party databases[6], which have no statutory role in coverage determination, when MACs are statutorily required to determine coverage; and
- We had non-commercial products reviewed without requesting consideration;

Novitas now appears to have acknowledged 'notice and comment' argument while remaining silent on the other matters.

Thirdly, we have sent official requests to Novitas for meetings from our executives and our Medical Affairs Team to discuss the substantial misunderstandings about our peer-reviewed and published clinical evidence.

We have earnestly stressed that we would like

[5] Davidson, Peter. Presentation to Urofair Urofair 2022 Lunch Symposium: Advances in Bladder Cancer Diagnostics | Cxbladder - YouTube 2022
[6] The finalized LCD relies on three knowledge bases to determine coverage. They are Clinical Genome Resource (ClinGen); National Comprehensive Cancer Network (NCCN); Oncology Knowledge Base (OncoKB) knowledge bases.

LCD CHALLENGE CONT.

to find a mutually agreeable solution that is based on scientific and clinical evidence. We expect to have the opportunity to comment in line with their statutory obligations of 45 days, but this meeting has not yet been held, or scheduled.

Novitas now appears to have acknowledged 'notice and comment' argument while remaining silent on the other matters.

Should L39365 ultimately confirm an unfavorable result for Pacific Edge, additional options are available. Pacific Edge can initiate a Medicare appeals process on behalf of an 'aggrieved beneficiary' – a patient who has been denied coverage on the basis of this LCD – who will have standing to initiate that process.

Pacific Edge has two paths here, firstly to appeal claim-by-claim through up to five levels of appeal starting with Redetermination (level 1), Reconsideration (level 2) and a Medicare Hearing in front of an Administrative Law Judge (ALJ, level 3 – which has the authority to overturn an LCD), but secondly to directly challenge the validity of the LCD in a Medicare Hearing. Our lawyers, our Medical Affairs Team and our Market Access Team are already prepared with the arguments.

While we are hopeful of success, it is a lengthy process and there is no certainty that we will prevail. In the meantime, we will continue to generate clinical evidence for our products, intended to achieve coverage and guidelines inclusion.

REBUTTING NOVITAS' CRITIQUE

Pacific Edge and Novitas have conflicting views in several key areas related to our primary evidence.

NOVITAS SAYS: Populations of patients in Pacific Edge trials that were tested included a strong bias towards male patients of European ancestry and were not vetted in the context of Medicare patients.
WE SAY: Novitas appears not to understand the basic demographics of bladder cancer. Males are three times more likely than women to present with the disease, patients with European ancestry also have higher incidence when compared with other ethnicities and these demographics are therefore present in greater numbers in our clinical trials. Our evidence is relevant to Medicare patients since the average age of bladder cancer patients is over 70 and Medicare eligibility is for patients over the age of 65.

NOVITAS SAYS: Cxbladder delivers a high number of false positive results, and this leads to patient anxiety and distress.
WE SAY: Novitas appears to misunderstand how Cxbladder is used by clinicians. Cxbladder's proposition relies on its high Negative Predictive Value (NPV) i.e., a negative result allows urologists to reduce unnecessary tests and procedures confidently and safely in patients at a low risk of having bladder cancer but are required to be investigated by the current standard of care. In the event of a positive Cxbladder result, clinicians should continue the evaluation of the patient for any other cause of disease, including upper urinary tract assessment.

NOVITAS SAYS: A good test should differentiate between urothelial carcinoma vs other types of urinary tract cancers.
WE SAY: Cxbladder is not a multi cancer assay and we never claimed or attempted for it to fulfill this role. The goal of our test is only to identify the probability of presence or absence of a single cancer (urothelial carcinoma) to improve the standard of care for hematuria evaluation and/or surveillance for recurrent disease.

NOVITAS SAYS: Pacific Edge studies have a short follow up period.
WE SAY: Our tests provide a snapshot in time assessment of patients and are neither prognostic nor predictive tests. Follow up period is irrelevant for point in time diagnostics.

NOVITAS SAYS: Pacific Edge did not recruit patients with inflammatory conditions to assess the use of our products in those patients.
WE SAY: We have excluded all those patients from clinical and commercial use of Cxbladder as we already know those patients are not the right target for our tests.

NOVITAS SAYS: Pacific Edge's authoring and funding of the primary literature for Cxbladder is a concern.
WE SAY: It is the industry norm for studies demonstrating the analytical validation, clinical validation, and clinical utility of biomarkers, medical devices, and pharmaceuticals to be funded by those who develop those innovations.

MAXIMIZING REIMBURSEMENT

ENHANCING PATIENT PAYMENT RESPONSIBILITY

Pacific Edge has made changes to its billing policy that takes effect on July 17, 2023, but given the ongoing Medicare coverage, this will now look slightly different from what we announced to the market a few weeks ago.

Only tests received from patients with private insurance (except those such as Kaiser with whom we have contracted coverage) will need to submit a patient responsibility notice, and not an ABN (required for Medicare). If a patient's insurance company declines to cover the test, the patient responsibility notice provides Pacific Edge with greater means to collect payment from the patient, as they have already acknowledged this personal liability. Our Patient Assist Program will continue to offer discounts to customers based on their income benchmarked to the Federal Poverty Guidelines, but the patient responsibility will be increased in all cases.

The move is part of a broad range of actions that Pacific Edge is pursuing to ensure it conserves capital as it seeks to retain Medicare coverage of Cxbladder, while still giving patients and clinicians access to the valuable and actionable information our tests offer.

We are uncertain of the extent to which this new approach will impact demand for our test in the US, but we expect it to improve collections in the event of a denial from any non-contracted insurer and make some contribution to to revenues, thus improving the overall average selling price for commercial testing.

LCD INDUSTRY RESPONSE

US UROLOGICAL COMMUNITY PUSHES BACK ON NOVITAS LCD

Pacific Edge is incredibly grateful for the over-whelming support we have received from the US urological community and diagnostic testing industry.

While Pacific Edge has been a leading industry voice, the broader community has rallied together and called for the reconsideration of the 'Genetic Testing for Oncology' LCD. Without exception they share our concerns and are joining with us to advocate for change. These representations will be critical as we look to the next steps of ensuring Cxbladder remains a covered test for the Medicare population.

Key actions that support our calls include:

- Prominent members of the American Urological Association (AUA), are preparing an Op-Ed for publication in the prestigious AUA Journal of Urology that should be published in the coming weeks highlighting the value of biomarkers in the diagnosis and treatment of bladder cancer that would be eliminated by Novitas' approach.
- Industry groups including The American Clinical Laboratory Association (ACLA), The Large Urology Group Practice Association (LUGPA), the Coalition for 21st Century Medicine (C21) have written to and/or are planning to write to Novitas (and its sister MAC First Coast Service Options) during the re-opened comment period asking them to retire or delay the LCD and have joined with Pacific Edge and others to work for change.

We cannot be sure any of these efforts will deliver the outcomes we seek. However, collectively they demonstrate the sentiment and the resolve with which we must continue in the face of Novitas restarting the review process.

NATIONAL ACCOUNTS

KAISER EMR PROGRESS

Pacific Edge and Kaiser Permanente continue to work cooperatively towards the 'go live' of Cxbladder's integration with Kaiser's Electronic Medical Records (EMR) system.

Kaiser, like other private healthcare providers in the US, makes independent medical policy decisions based on their own evaluations, their own clinical evidence, and their own determination of economic value.

Kaiser's usage of Cxbladder testing continues to increase on a consistent basis, and we look forward to moving through implementation and onto logistical considerations in the near future.

2023 ASM

A PATH FOR INCREASING COVERAGE CERTAINTY

At our Annual Shareholders Meeting in Auckland on 27 July 2023, we intend to provide a consolidation of all initiatives in our strategic response to Novitas' adverse 'Genetic Testing for Oncology' LCD and the future possibility of non-coverage.

We will of course review the 2023 financial year and our significant success over that period. But in addition to this, Chairman Chris Gallaher, Chief Executive Dr Peter Meintjes, President of our US business David Levison, and Chief Medical Officer Dr Tamer Aboushwareb will discuss our approach to retaining Medicare coverage for Cxbladder and commercialize our tests in the US and around the world. We will also detail the changes we are making at the business to achieve these goals.

The team will also be available to take your questions. We strongly encourage shareholders and all other people interested in Pacific Edge to attend in person or to join the meeting virtually via the online meeting platform provided by our share registrar Link Market Services.

Details of the meeting, the agenda and how to participate virtually were included in the formal Notice of Meeting sent to shareholders in late June and are detailed below. However, should you have any questions you should contact Link Market Services.

Where: Link Market Services Board Room
Level 30, PwC Tower
15 Customs Street West, Auckland 1010

When: 10.00am 27 July 2023

Notice of Meeting:
https://www.pacificedgedx.com/news-and-events/news/2023/notice-of-annual-shareholders-meeting/

Connect virtually: www.virtualmeeting.co.nz/peb23

Virtual ASM assistance:
https://bcast.linkinvestorservices.co.nz/generic/docs/OnlinePortalGuide.pdf

https://www.linkmarketservices.co.nz/

To help us plan for catering and seating at the event Pacific Edge would appreciate you signaling your intention to attend by providing an RSVP through the following Eventbrite link: https://bit.ly/PEB-ASM2023

Please note that you do not need to RSVP to attend the Annual Shareholders Meeting.

CLINICAL EVIDENCE

STRATA SUCCESSFULLY CONCLUDING AS PRIMARY ENDPOINT ACHIEVED

With the consolidation of the Medical Affairs Team, we have reconfigured our evidence generation program to focus on the endpoints that matter most to the clinical guidelines committees of the American Urological Association and the National Comprehensive Cancer Network. With this in mind, we are bringing STRATA (Safe Testing of Risk for AsymptomaTic MicrohematuriA) to a successful conclusion.

Based on the power calculations for the primary endpoint, the study has enrolled the planned number of patients in the randomized part of the study to initiate our statistical analysis plan. When concluded, this analysis will determine if there is a statistically significant difference in the percentage of patients that receive a cystoscopy between the control arm (no Cxbladder used) and the experimental arm (Cxbladder Triage result used to inform cystoscopy). The precise performance characteristics of the study, the safety data, the follow up and the data analysis will continue, while the study has ceased enrolment effective in early July.

The clinical development program remains the most important driver of strategic value for Pacific Edge, and consequently, we will continue to invest resources to accelerate microDRIVE, DRIVE and AUSSIE for the earliest possible completion dates. Combining these remaining studies in a pooled analysis is expected to deliver clinical validation evidence on microhematuria and gross hematuria populations needed by guidelines committees to establish a recommendation for Cxbladder Detect⁺ as safe for the purposes of ruling out cystoscopy in those patient populations. Further updates to our clinical development program to accelerate our path to regaining coverage will be announced as and when appropriate.

STUDY	ENROLLED SITES* AND LOCATIONS	STATUS**
STRATA (**S**afe **T**esting of **R**isk for **A**symptoma**T**ic Microhematuri**A**)	12/13 USA/Canada	- Enrolment total is 545 - Target enrolment: 600 patients, including 120 low risk subjects (now 131) - Last patient in: Q3 2023 - Data monitoring underway and expected to be completed Q1 2024 - Follow up: until Q3 2024
DRIVE (**D**etection and **Ri**sk Stratification in **Ve**terans Presenting with Hematuria)	11/11 VA Sites (USA)	- Enrolment total is 601 - Target enrolment: ~600 patients - Last patient in: Q3 2023 - Follow up: until Q2 2025
AUSSIE (**A**ustralian **U**rologic risk **S**tratification of patient**s** **w**ith h**e**maturia)	1/2 Australia	- Target enrolment: 600 patients - Enrolment due to start July 2023
Microhematuria Pooled-analysis Pooled-analysis of Cxbladder Detect⁺ performance from multiple studies involving prospectively recruited patients from single-arm observational studies including eligible microhematuria patients	N/A USA/Australia	- DRIVE underway, AUSSIE and microDRIVE projected to start in 2023
microDRIVE (**D**etection and **Ri**sk Stratification in **Ve**terans Presenting with **micro**hematuria)	0/1 USA	- Projected to start recruitment Sep/Oct 2023 - Target is 1000 patients and 50 tumour confirmed - Last patient in: March/April 2024
LOBSTER (**Lo**ngitudinal **B**ladder Cancer **S**tudy for **T**umor **Re**cu**r**rence)	5/10 USA (including some VA sites)/Australia	- Enrolment is now 100 patients with 157 samples collected to date - Each site will enroll 100 patients within 12 months and follow up for another 12 months

Please note that dates are calendar years not financial years. For definitions of Analytical Validity (AV), Clinical Validity (CV), and Clinical Utility (CU) please refer to www.pacificedgedx.com

**Estimated number of enrolled sites **All dates are best-case estimates and subject to change*

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

INTERNATIONAL MARKETS

DISTRIBUTION AGREEMENTS IN APAC AND LATIN AMERICA

As we continue to grow our international business, Pacific Edge Diagnostics New Zealand have signed two new Cxbladder distribution agreements in the APAC Region, this time with Transviet Service and Trading Company Limited in Vietnam and Hi-Precision Diagnostics in the Philippines.

Following on from establishing Ex-US distribution with ProGenetics in Israel, Pacific Edge Diagnostics USA have added a second Distribution Partner, SouthGenetics, for distribution of Cxbladder tests in three Latin American countries, Argentina, Uruguay, and Venezuela after the education presentations to physicians and distribution partners in those regions at the recent AUA Meeting.

As we bring on these new partners, 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. Training is also key to successful distribution partnerships and is already underway or scheduled with all partners. Simultaneously, we are working to activate these distribution agreements commercially and we have seen the first signs of traction with initial tests ordered from Israel, and in the APAC markets we serve directly, like Singapore.

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.

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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