PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

INVESTOR UPDATE

APRIL 23

INSIDE

LETTER FROM THE CEO

A YEAR OF STEADY STRATEGIC PROGRESS

Dear Shareholders,

The close of the March 2023 quarter represents the completion of my first full financial year leading Pacific Edge. While we are still seeking clarity over continued Medicare coverage of our tests in the US, I am pleased to share my sense of pride with what we have achieved.

Throughout the year we have laid the foundations for success and resilience in the US by executing on the strategic pillars outlined a year ago 1) the adoption and more frequent use of Cxbladder tests; 2) generating clinical evidence to support Cxbladder coverage and their inclusion in global standards of care; and 3) continued innovation over the long term.

Steady quarter-on-quarter improvements have continued in the final three months of FY23.

The volume of tests processed in our laboratories reached a record 8,878 in the quarter (Q4 23) – a 14% increase on the prior quarter (Q3 23) and up 42% on the same quarter a year ago (Q4 22).

The result brings total testing volumes for FY 23 to 31,566 – a 37% uplift on FY 22's 23,086 tests. The number of US ordering clinicians has also continued to rise (see page 3).

At the start of the third quarter, Cxbladder Triage received a CPT[1] code and was added to the Novitas Local Coverage Article (LCA 58917) which Pacific Edge relies upon for Medicare coverage for all our tests in the US.

This development recognizes that Triage now is covered subject to medical necessity in the same manner as Detect and Monitor. Consequently, we expect it to drive a modest improvement in payment recoveries from Medicare and Medicare Advantage payors. However, we do not expect it to drive a significant uplift in usage of Triage in the US as we focus our efforts on Detect+ (see page 4).

The approach of gaining a CPT code and the inclusion in the LCA58917 also potentially offers a faster and tangible path for coverage for our new test Cxbladder Detect+, assuming of course the current or similar approach to US reimbursement of our tests is retained.

The integration of Cxbladder into the Electronic Medical Records system of our largest customer Kaiser Permanente, has progressed, but not as fast as we expected. The development teams on both sides have now completed the software development and integration testing, however, due to the substantial nature of the integration into a live system at Kaiser, additional administrative and review processes remain to be completed (see page 5).

Despite these recently added administrative requirements, the Kaiser urologists, the innovation group, the EMR implementation team and the Pacific Edge team continue to share a common goal and a common commitment to completion as soon as feasible.

Our evidence generation program continues to evolve, particularly in furtherance of achieving guidelines recommendations. Notably we have launched a new study with the VA, we have called microDRIVE, which in combination with existing studies is aimed at demonstrating the clinical validity of Cxbladder Detect+ in detecting bladder cancer in patients presenting with microhematuria. Independent studies on the utility of Cxbladder products meanwhile continue to support the evidence we gain from our own program (see page 7 and 8).

Late in the quarter, we signed a distribution agreement for Cxbladder in Israel with the Tel Aviv-based company ProGenetics as we consider global markets with an appetite for genomic oncology tests that can be sent to our US Lab (see page 6).

Finally, we continue to build capability in the leadership team. In this update we profile two new members, Glen Costin who has been appointed as our new APAC President (page 8) and Dr Daniel Shoskes, who joined a few months ago as a Medical Director in our Medical Affairs team.

Our focus now is firmly on execution. We look forward to updating shareholders on our progress when we release our 2023 financial results in late May.

Ngā mihi,

Dr Peter Meintjes
Chief Executive

[1] Current Procedural Terminology code: a set of medical codes created and maintained by the American Medical Association that are used to describe medical, surgical, and diagnostic services performed by healthcare providers in the United States.

TEST VOLUMES RISE TO A NEW RECORD

Test volumes processed at Pacific Edge laboratories rose to a new record in the fourth quarter of the 2023 financial year (Q4 23) rising to 8,878 tests, a 14% rise on the 7,768 tests in the prior quarter (Q3 23).

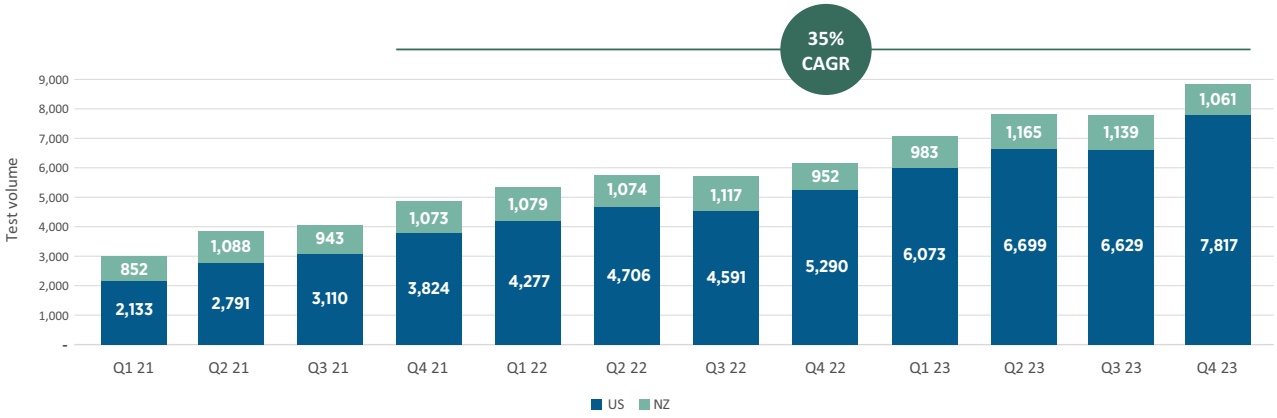
The volume processed in Q4 23 represents a 42% increase on the 6,242 tests processed in the same quarter of the prior year (Q4 22). The result brings total volumes for FY 23 to 31,566 – a 37% increase on the 23,086 tests in the prior financial year (FY 22).

US volumes led the growth rising to 7,817 in Q4 23, an 18% increase on the 6,629 tests in Q3 23. The figure also represents a 48% increase on the 5,290 tests processed in Q4 22. The result brings US test volumes for FY 23 to 27,218, an increase of 44% on the 18,864 in FY 22.

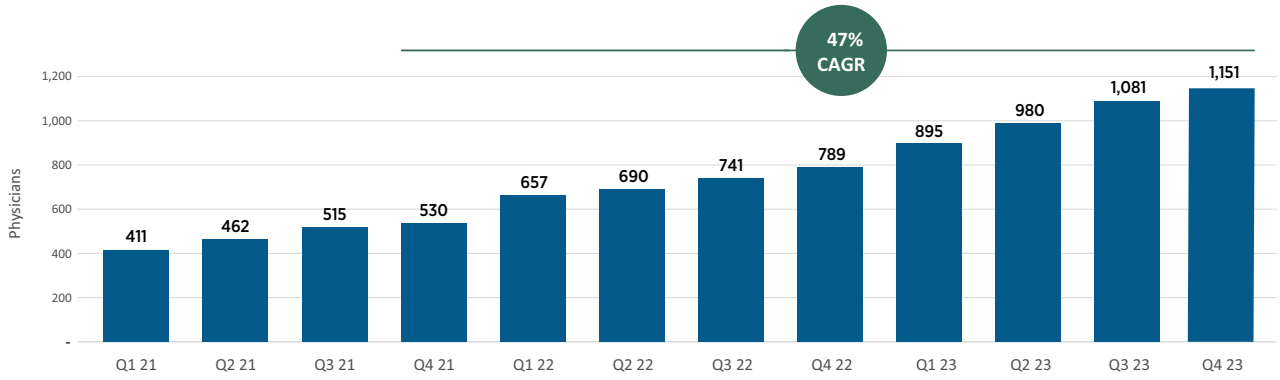
The number of unique ordering clinicians in the US has continued to grow through the quarter to 1,151 at the end of Q4 23, up 6% on the 1,081 ordering in Q3 23 and up 46% on the 789 clinicians who ordered tests in Q4 22.

Asia Pacific volumes in Q4 23 were 1,061 down 7% on the 1,139 tests processed in Q3 23, but up 11% on the 952 tests processed in Q4 22. Total APAC volumes for FY 23 were 4,348, a 3% increase on the 4,222 tests processed in FY 22. 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[2]



[2] Historic numbers of unique ordering clinicians in the US have changed slightly, correcting data recording inconsistencies determined by ongoing data provenance initiatives.

MEDICARE COVERAGE

CXBLADDER TRIAGE GAINS MEDICARE COVERAGE

Cxbladder Triage, our test to assist clinicians to safely de-intensify hematuria evaluation in populations with a low incidence of bladder cancer, has now been included in the Local Coverage Article (LCA 58917) that Pacific Edge currently relies upon for Medicare coverage of all our tests in the US.[3]

Novitas, the Medicare Administrative Contractor with jurisdiction for Pacific Edge's US laboratory, listed Triage in its LCA in January as a test covered with medical necessity. It follows the issuing of a CPT[4] code (0363U) in the third quarter of the financial year.

We expect the development to lead to modest increases in rates of payment from Medicare and Medicare Advantage payors for Triage. We also see coding and listing in LCA 58917 as a faster more tangible path for our enhanced test Cxbladder Detect+ to gain coverage, should the current approach to reimbursement of our tests in the US continue.

"We expect the development to lead to modest increases in rates of payment from Medicare and Medicare Advantage payors for Triage."

That said, we do not expect the development to drive a significant increase in adoption of Triage in the US. Triage currently makes up a small fraction of commercial testing volume in the US outside of those contracted by our largest US customer Kaiser Permanente. Triage also still needs a price, established by Medicare through the national pricing process, which will make reimbursement more reliable and timely by Medicare and Medicare Advantage payors around the US.

Finally, going forward in the medium term, Pacific Edge plans to promote Cxbladder Detect+ rather than the existing Triage test as the best test for risk stratification and de-intensifying hematuria evaluation. This new approach follows the publication in December[5] of clinical evidence that demonstrated the superior performance of Detect+.

We also acknowledge the potential for Cxbladder Triage to lose its coverage in the same way as Detect and Monitor if a proposed Local Coverage Determination governing Genetic Testing for Oncology (DL39365) were to be finalized without changes and without addressing the comments and concerns from Pacific Edge.

Novitas put forward DL39365 in July 2022, and must either finalize or withdraw it within 12 months of the date of the proposal.

[3] Novitas has a policy of covering products on LCA 58917 under the 21st Century Cures Act, if clinicians deem the tests medically necessary, until the publication of an LCD either covering or denying coverage of a product.
[4] Current Procedural Terminology code is a set of medical codes created and maintained by the American Medical Association that are used to describe medical, surgical, and diagnostic services performed by healthcare providers in the United States.
[5] Lotan et al 'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification' J Urol. 2023 Apr; 209 (4): 762-772.

SAVE THE DATE

CONNECT WITH US AT OUR 2023 ANNUAL MEETING

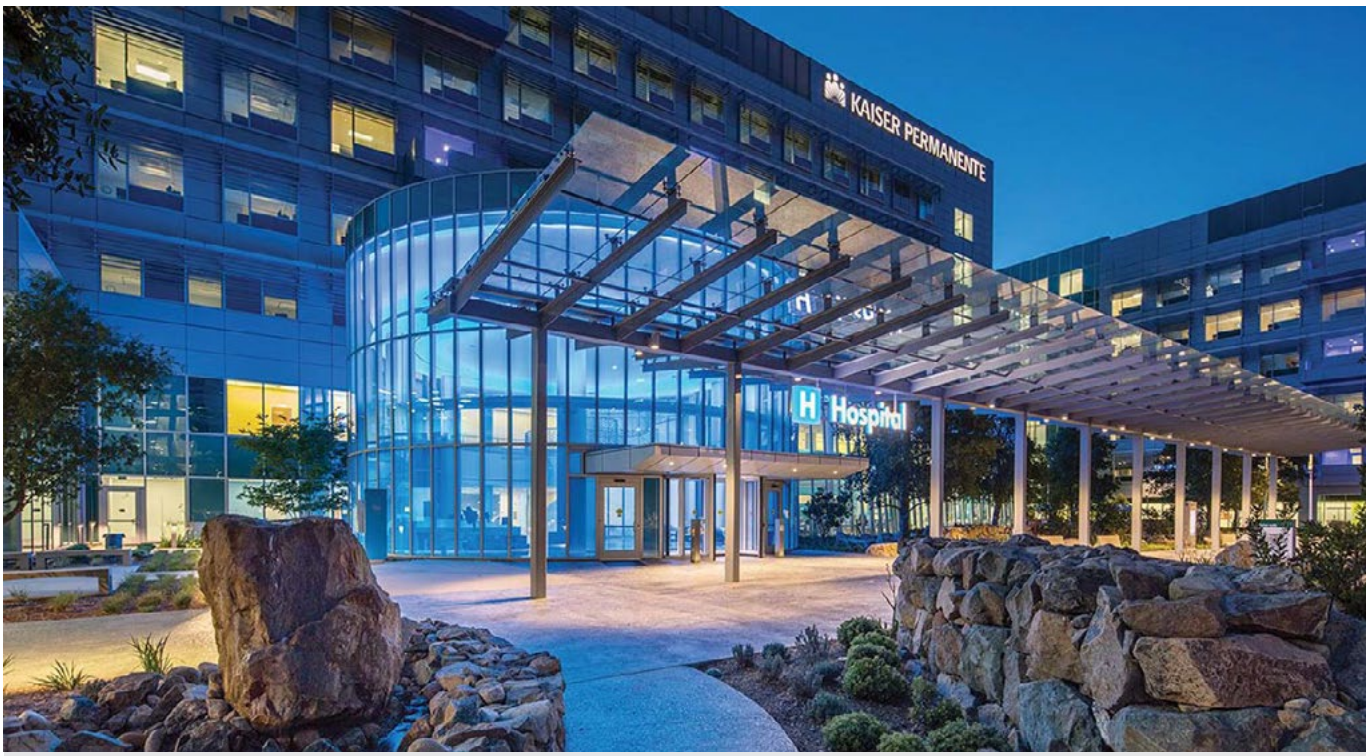
Pacific Edge's 2023 Annual Shareholders Meeting will this year be held in Auckland and we will be using it to connect shareholders with the strategies we are using to drive the success of Cxbladder in the US market.

Pacific Edge Diagnostics USA President David Levison and VP of Medical Affairs, Dr Tamer Aboushwareb, who are both on the frontline of driving the adoption of Cxbladder, will address the meeting and take shareholder questions. As usual our directors and senior management will also be present to meet shareholders. All shareholders unable to join in person in Auckland will be able to join virtually. More detail on the meeting will be released with the publication of our Annual Report.

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

When: 3:00pm 27 July 2023

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



STRATEGIC ACCOUNTS

KAISER EMR INTEGRATION TECHNOLOGICALLY COMPLETE

Pacific Edge has now completed the software development and integration testing on its project to integrate Cxbladder into the Electronic Medical Records (EMR) system of Kaiser Permanente. We continue to complete the administrative and review processes required to be a registered supplier to Kaiser Permanente to enable the project to go live.

We are excited to have achieved the important technical milestones in the project, which has spanned many teams and many person-hours across the Kaiser system, our team in the US, and our team in New Zealand.

We have significantly de-risked the project and importantly, the Kaiser urologists, innovation group, EMR implementation team and Pacific Edge team continue to share a common goal and a common commitment to completion as soon as feasible.

"Cxbladder tests have improved access to urology care as Kaiser has emerged from the pandemic."

Kaiser Permanente Southern California Permanente Medical Group urologist Dr Ronald Loo, MD, says the Cxbladder tests have improved access to urology care as Kaiser has emerged from the pandemic with unprecedented demand for services.

"The very high negative predictive value of the Cxbladder tests have allowed us to improve access by safely reducing overwhelming demand for screening and surveillance cystoscopy. It's proven to be a quadruple win: convenient and preferred by our members, high quality - reliable results, cost effective for the organization, and a sustainable way to improve the wellbeing of our healthcare teams," Dr Loo said.

Kaiser Permanente is the largest integrated healthcare provider in the US, serving 12.6 million members, which equates to approximately 3.7% of the population in the USA. It operates 39 hospitals, more than 700 medical offices, and employs 23,656 physicians and 65,000 nurses.

NEW MARKET

ISRAELI DISTRIBUTOR FOR CXBLADDER APPOINTED

As Pacific Edge looks to develop Ex-US commercial activity from Pacific Edge Diagnostics USA (PEDUSA), ProGenetics in Israel is the first distributor with the resources and expertise to join our distributor network. The Tel Aviv-based company has been awarded exclusive sales and marketing rights in Israel and will add Cxbladder to its broad portfolio of the cancer diagnostic tools it distributes. These tests span tests for breast, prostate, ovarian, and colon cancers among several others.

David Sosa, Pacific Edge's VP Market Access & Reimbursement says: "We are delighted to be working with a company that has such a strong record of launching high-value lab developed tests and working with local healthcare plans to achieve reimbursement. ProGenetics will drive the integration of Cxbladder into local standards of care leveraging its strong relationships with clinicians, and Pacific Edge's growing body of clinical evidence."

Initially, the tests will be paid for by patients on the recommendation of their clinicians. Patient samples will be collected using Pacific Edge's Patient In-Home Sampling System and will be processed at our US laboratory in Hershey Pennsylvania. PEDUSA will support ProGenetics with its Medical Affairs team and provide training in sample collection and logistics.

CONFERENCES

STANDING ROOM ONLY AT CXBLADDER SYMPOSIUM

A Pacific Edge symposium on the use of molecular biomarkers in the detection and surveillance of bladder cancer drew strong interest at the 87th American Urological Association Southeastern Section (SESAUA) conference held in Amelia Island, Florida last month.

The conference is one of the largest AUA Section Meetings. It has a strong research focus and it offered time before the conference program to hold a Principal Investigator meeting for our STRATA clinical trial.

Additionally, Pacific Edge hosted a symposium in which more than 100 urologists and urological experts participated.

Many were left standing for the keynote address from Dr. Sia Daneshmand, Professor of Urology and Director of Clinical Research at the Keck School of Medicine, and the discussion that followed..

Pacific Edge VP of Medical Affairs, Dr Tamer Aboushwareb, who led the symposium, said he was delighted with the interest in Cxbladder at the conference.

"We were thrilled to see so many attendees at the symposium showing great interest in the utility of Cxbladder. Many more physicians identified the utility of the tests and showed interest in using them in their patient populations; they will all be followed up by Pacific Edge's sales team," he said.

At the conference, alongside the symposium, Pacific Edge led a Principal Investigator meeting (IM) for the DRIVE study – which is focused on Cxbladder Detect^{+} validation across multiple Veterans Administration sites.

The team also held multiple meetings with key opinion leaders from the SESAUA with many continuing or starting the use of Cxbladder in their respective organizations.

NEW STUDY TO VALIDATE CXBLADDER WITH MICROHEMATURIA

Pacific Edge is launching a new study to demonstrate the validity of its new test, Cxbladder Detect⁺, in detecting urothelial cancer in patients presenting with microhematuria.

The new study is microDRIVE - **D**etection and **Ri**sk Stratification in **Ve**terans Presenting with microhematuria. Microhematuria is a presentation of blood in urine that is not detectable with the naked eye. It is often found in routine testing rather than the result of examinations related to symptoms that are potentially indicative of bladder cancer.

MicroDRIVE will compare the performance of Detect⁺ against the current gold-standard for the detection of urothelial cancer, diagnostic cystoscopy and pathology. It runs alongside the existing DRIVE study with the VA. The study is seeking to recruit up to 1,000 veterans and is projected to start recruitment towards the end of 2023, with the aim of recruiting the last patient in the second quarter of 2024.

ONGOING STUDY PROGRAM	ENROLLED SITES AND LOCATIONS	PROGRESS AND TARGETS*
STRATA (**S**afe **T**esting of **R**isk for **A**symptomatic Microhe**m**a**t**uria)	11/13 USA and Canada	- Enrolment total is 468, including 122 'low risk' subjects (with 400 and 105 of these subjects eligible, respectively) that are the focus of the study - Target ~600 subjects, including 120 low risk subjects randomized to test arm - Last patient in Q2 2023 - Follow up until Q2 2024
DRIVE (**D**etection and **Ri**sk Stratification in **Ve**terans Presenting with Hematuria)	8/11 (VA) USA	- Enrolment total is 551 - Target (Q2 2025) ~700 patients - Last patient in: Q3 2023 - Follow up: until Q3 2025
microDRIVE (**D**etection and **Ri**sk Stratification in **Ve**terans Presenting with **micro**hematuria)	0/0 USA	- Projected to start recruitment Sep/Oct 2023 - Target is 1000 patients - Last patient in: March/April 2024
AUSSIE (**A**ustralian **U**rologic risk **S**tratification of patient**s** **w**ith he**m**aturia)	1/1 Australia	- Contract fully executed Mar 2023 - Enrolment due to start in Q2 2023 - Last patient in: Q2 2025
DEDUCT (**De**tection of **D**isease in the **U**pper **T**ract)		- Now to be transferred to an investigator-initiated study
LOBSTER (**Lo**ngitudinal **B**ladder Cancer **S**tudy for **T**umor **Re**c**u**rrence)	3/11	- Three sites are open and another 8 are at pre-activation. Enrolment is now 63 patients - Each site will enroll 100 patients within 12 months and follow up for another 12 months
MONSTER (**Mon**itoring **S**tudy of Post-**T**reatment **E**ffectiveness for **R**esidual Disease)	0/1 New Zealand	- Finalizing protocol documentation and commenced engagement with ethics committee - Business case for this study currently in development by R&D

**Dates are calendar year not financial years*

Analytical Validity: Develop a test that is repeatable in the lab for a given indication and population.
Clinical Validity: Make sure the test works in the same way on an independent eligible population for the given indication.
Clinical Utility: Put the test in the hands of a physician to establish that it can usefully change patient management within the context of care for the defined population and indication.

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

RESEARCH AND INNOVATION

STUDY ADDS SUPPORT FOR CXBLADDER MONITOR USE IN CANCER SURVEILLANCE

New and independent[6] research supporting the clinical utility of the company's genomic biomarker test Cxbladder Monitor in the surveillance for bladder cancer recurrence is to be published in the prestigious journal Urologic Oncology.

The study undertaken at the University of California San Francisco (UCSF) and the University of Michigan examined whether a negative Cxbladder Monitor test could safely postpone a patient's next scheduled cystoscopy, the current 'gold standard' for bladder cancer surveillance.

The study covered a small sample of US-based patients under surveillance for bladder cancer recurrence during the COVID pandemic lockdown. The patients - under the virtual supervision of their clinicians - opted to use Cxbladder Monitor leveraging Pacific Edge's Patient In-Home Sampling System (PIHSS) as a first step to overcome pandemic-related limits on clinical evaluation slots and the risks of COVID infection during travel to and from appointments.

Of the sample, 66 patients tested negative for Cxbladder Monitor. Of those, 52 patients underwent a follow up cystoscopy, and all were tumor free – a result that supports the growing portfolio of evidence that Cxbladder Monitor can safely reduce surveillance cystoscopies without compromising cancer detection.[7] Meanwhile, a patient satisfaction survey of those who took the Cxbladder Monitor test at UCSF revealed strong patient acceptance for the test and the PIHSS.

Vice President of Medical Affairs Dr Tamer Aboushwareb said: "The sample size and the difficulties the researchers faced in following up all those patients that tested Cxbladder Monitor negative represent obvious limitations to the current study, but the results represent an exciting incremental addition to the evidence supporting the clinical utility of Cxbladder Monitor in safely reducing the frequency of surveillance cystoscopy."

University of California San Francisco

[6] The study, "Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer", was completed with no involvement or financial support from PEDUSA

[7] Six of the 66 CxbM negative patients did not return for a follow up cystoscopy, four elected to undergo a further CxbM test rather than a cystoscopy and the remaining four patients either stopped surveillance or died of unrelated causes. Nine of the 24 patients that tested Cxbladder Monitor positive and then had an immediate clinical evaluation and cystoscopy were found to have cancer including one patient that had cancer in the upper tract.

ASIA PACIFIC

NEW APAC LEADER

Glen Costin has been appointed into the new role of President Asia Pacific (APAC) to realize the significant potential for the company's genomic Cxbladder tests in the region.

Glen is charged with building on our presence in Australia and New Zealand into the broader APAC region. He will drive the strategic and operational direction in the region, which boasts an estimated total addressable market for the company's Cxbladder diagnostic tests of US$2.2 billion.[8]

For the last eight years, at the helm of his own company MDL Asia, Glen has assisted small and medium sized medical, diagnostics and life science companies to expand in the Asia Pacific. Over that period, he assisted his clients to grow annual revenues by US$20 million to US$30 million per year. Prior to that he held senior roles with biotechnology research company Abcam, laboratory equipment supplier Bio-Rad Laboratories and BD (Becton Dickinson).

He brings to Pacific Edge a strong regional network in APAC, a strong commercial background, a track record of success in business development and in bringing new technology to market. He holds a BSc from Macquarie University and an MBA from the Macquarie Graduate School of Management. He started at Pacific Edge on March 27th and will report to Dr Meintjes.

[8] Pacific Edge estimates.

JOINING THE COMPANY WITH THE MOST DATA

Dr Daniel Shoskes joined Pacific Edge Diagnostics USA at the end of October as Senior Medical Director. In his role as part of Pacific Edge's Medical Affairs team Daniel will be focused on our education mission.

He is also tasked with encouraging research into Cxbladder through the development of a program to support investigator-initiated trials as well as new registries to accumulate real world data on the use of Cxbladder.

Daniel joins Pacific Edge as a well-known member of the urological community with a wealth of experience. He has worked as an academic Urologist at UCLA and the Cleveland Clinic and has held several roles at the American Urological Association (AUA), including the presidency of two sub-specialty societies, and directorship of the AUA Board Review Course. Daniel has also served on both the AUA Research and Education Councils.

What brings you to Pacific Edge?

Pacific Edge VP Medical Affairs Dr Tamer Aboushwareb was a colleague at Exact Sciences where we worked on prostate cancer diagnostic tests, and I knew we worked together well. Additionally, it was attractive to join the company with the most data to date and a growing list of new studies poised to generate evidence that should be compelling to the committees setting clinical guidelines. .

What is the most compelling evidence in your view supporting the use of Cxbladder?

I think there are two distinct and complementary perspectives supporting the use of Cxbladder. From the patient's point of view there is convenience and reduction of anxiety. The ability to do a home test prior to scheduling an appointment or procedure can save time and cost.

With a negative Cxbladder test there is confidence in avoiding an uncomfortable procedure. From the Urologist point of view there is added confidence in getting the diagnosis right and only escalating to more invasive testing if it is warranted.

Not every hematuria patient presents with symptoms where the course of action is clearly outlined by the guidelines. For example, there are patients with benign causes of hematuria that don't warrant treatment but whose recurring hematuria technically leads to repeated cystoscopy. There are patients whose cystoscopy is very challenging with the view obscured by inflammation, bladder abnormalities, and other pathologies. In these cases, adding Cxbladder to the diagnostic armamentarium can give confidence in the diagnosis and simplify care.

What criteria will you use to judge success in your role at Pacific Edge?

In terms of new initiatives, I'm excited about our Investigator Initiated Trials program and its ability to produce high quality publications that will further the evidence for efficacy and utility of our products. On an incremental level, I hope to refine our messaging of the value proposition for using Cxbladder for Urologists and make it clearer which patient scenarios will most benefit from adding Cxbladder to the workflow.

What will make the greatest difference to driving the adoption of Cxbladder?

Being in clinical guidelines goes a long way to widespread clinical adoption as well as robust insurance coverage (in the USA). I am confident that the new clinical trials now in design and being carried out at Pacific Edge are set up to deliver the kind of compelling validity and utility data that would lead to guidelines adoption.

What is the newest addition to your Spotify playlist and why?

I deleted my Spotify account in response to their financial support of anti-vaccine podcasts, but music is an important part of my life, both listening and performing. While most of my performance has been in Renaissance and Baroque music, I have recently started playing Medieval music on the Gittern, a plucked instrument popular in the 12th to 15th centuries.

DR DANIEL SHOSKES
Senior Medical Director
MD, MSc, FRCS (C)

1994 – 2000:
Urologist. UCLA

2000 – 2005:
Urologist and Director of Kidney Transplant Program. Cleveland Clinic Florida

2005 – 2021:
Professor of Urology, Director, The Novick Centre for Clinical and Translational Research; Director The Center for Men's Health. Cleveland Clinic

2021 – 2022:
Medical Director Medical Affairs. Exact Sciences

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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