Company Announcement
24 November 2022

FINANCIAL RESULTS FOR THE HALF YEAR TO 30 SEPTEMBER 2022

PACIFIC EDGE INVESTMENT FOR GROWTH DELIVERS EARLY RESULTS

HIGHLIGHTS

- Operating revenue from test sales increases 62% to $8.7 million when compared to the same period of the prior year (1H22); total revenue increases 102% to $13.6 million when compared with 1H22, with increases from commercial test volume growth boosted by foreign exchange gains
- Total laboratory throughput rises 34% to 14,917 in line with analyst expectations, lifted by a 35% increase in commercial test volumes to 12,422, with growth led by the US market
- Investments driving Cxbladder adoption and lifting US clinician engagement; staff numbers increase from 86 at the end of March 2022 to 100 full-time-equivalents (FTE) at 30 September 2022
- Kaiser Permanente using Cxbladder Triage at 11 sites, two of which are in the Top 20 sites by volume during 1H23
- Net losses after tax increased to $10.6 million, from $9.0 million in 1H22 as Pacific Edge continues to invest for growth
- Cash, cash equivalents and short-term deposits of $93.5 million as at 30 September 2022, down from $105.4 million at 31 March 2022, provides strong foundation for continued investment
- Optimistic outlook tempered by proposed LCD from Novitas and the potential to affect Medicare reimbursement.

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX PEB), today announces strong growth in revenue for the half year to the end of September 2022 as new growth investments begin to accelerate the adoption of Cxbladder, the company's suite of advanced genomic bladder cancer diagnostic tests.

Total operating revenue, the income generated from Cxbladder test sales, increased 62% to $8.7 million from $5.4 million in 1H22. Revenue growth resulted from a 35% increase in commercial tests to 12,422 from 9,192 tests in 1H22, and the sharp weakening New Zealand dollar against the US dollar. As reported in Pacific Edge's October quarterly shareholder update, total test volumes rose to 14,917, a 34% increase on the 11,136 tests processed in 1H22.

Total revenue, which includes government grants and other income, increased 102% to $13.6 million from $6.7 million in the same period of the prior year, assisted by a $3.0 million foreign exchange gain on the mark to market of USD cash balances and increased interest income accruing on cash balances.

The half year net loss after tax increased to $10.6 million, from $9.0 million in 1H22, as Pacific Edge accelerated its investment to drive the adoption of tests. Net operating expenses increased to $24.2 million from $15.7 million as the company invested for growth particularly in the US market. Expenses were also lifted by $1.7m due to the translation impact of a weaker New Zealand dollar.

Cash, cash equivalents and short-term deposits at 30 September 2022 were $93.5 million compared to $105.4 million at 31 March 2022 following a net cash outflow of $12.0 million over the six months to the end of September 2022.

Pacific Edge Chairman Chris Gallaher said, "Over the last six months Pacific Edge has carefully invested in line with the program we outlined in May to drive the adoption of our tests around the world.

"We are starting to see the benefits of this program, particularly in the US market. Awareness of the role Cxbladder can play in the diagnosis and management of bladder cancer is growing and we are seeing early signs of an acceleration in the adoption of our tests by clinicians and healthcare providers.

"These successes have been tempered by the uncertainty over the continued reimbursement of our tests by the US Centers for Medicare & Medicaid Services (CMS), from which the company receives most of its US revenues.

"We are working to resolve this uncertainty, which followed the July release of a proposed Local Coverage Determination (LCD)[1] by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory.

"Notwithstanding this possibility, given our technological leadership and the growing awareness for how Cxbladder improves clinical practice, we remain confident that our tests will, over the longer term, be integrated into global standards of bladder cancer care including those used by the key US market. Our company is well funded and remains well placed to deliver on these growth ambitions."

STRATEGIC PROGRESS

Pacific Edge Chief Executive Dr Peter Meintjes said the company had made good progress on its strategic objectives.

"We have introduced new capability and energy into the business with the establishment of our new Medical Affairs and Virtual Sales teams and the recruitment of new account executives, marketing personnel and a VP of Market Access. Our global team has risen to 100 FTEs at the end of September from 86 at the end of March.

"These investments are aligned with the strategies for value creation that we outlined in May. As expected, they have resulted in an increase in cash outflow and a larger loss for the half year period as we continue to build capability and capacity that will underpin the next phase of success for Pacific Edge.

"As we look towards the long-term, the proposed LCD from Novitas has been factored into the phasing of our investment program. At present, we continue to be reimbursed by Medicare for our tests and have not seen any reduction in demand for Cxbladder since the release of the proposed LCD. Pacific Edge

[1] LCDs are decisions made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in a MAC's jurisdiction (region) in accordance with section 1862(a)(1)(A) of the US Social Security Act.

maintains that in the absence of any adverse reporting event on the performance of Cxbladder, it would be unprecedented to lose CMS coverage.

“We therefore continue to invest prudently and do so with clear targets for the adoption of our tests and operating revenue. We remain confident that these investments set the company up to capitalize on the significant opportunities the company enjoys in both in the US and further afield,” Dr Meintjes said.

The new Medical Affairs team is at the heart of our strategy to use the expanding body of clinical evidence that supports the validity and utility of Cxbladder to influence healthcare providers’ and payers' to adopt and cover of our tests while working to have Cxbladder accepted into global standards of care.

The Medical Affairs and Marketing teams have expanded our Key Opinion Leader (KOL) engagement program and placed clinical evidence generation at the core of how we engage with KOLs,” Dr Meintjes said. At the upcoming Society for Urologic Oncology (SUO) meeting in late 2022, Pacific Edge will run its first in-person Principle Investigator Meeting for STRATA, hold its first Clinical Advisory Board Meeting and will sponsor a Symposium Session titled: Real life impact of Cxbladder tests on the diagnosis and surveillance of bladder cancer moderated by VP of Medical Affairs, Dr. Tamer Aboushwareb featuring presentations from the following KOLs:

- Dr. Sia Daneshmand: Overview, bladder biomarkers
- Dr. Sima Porten: Use of Cxbladder in-home sampling during COVID
- Dr. John Stafkianos: Cxbladder CU and real-life value in practice

REGIONAL PERFORMANCE

USA

The US business has made strong progress. For the six-month period, US test volumes were up 42% on the same period a year ago to 12,769, while commercial tests increased 42% to 10,622 from 7,476 in the same period of the prior year. The number of clinicians ordering our tests has meanwhile increased to 979 in the second quarter of FY23, a 42% increase on the 689 ordering clinicians at the same time a year ago and 10% ahead of the 894 ordering clinicians for the quarter ending June 2022.

The company is pleased with the progress it is making with Kaiser Permanente. During 1H FY23, Cxbladder tests were ordered from 11 of the 30 Kaiser Permanente Urology Centers in Southern California (SoCal), and of these clinics, two now count among our top 20 accounts.

From an operations standpoint, we have made meaningful progress implementing Cxbladder ordering and resulting from within Kaiser’s Electronic Medical Records (EMR) system, a move that is expected to accelerate Kaiser’s adoption of Cxbladder when the project is completed in the coming months. In support of this initiative, Kaiser has a dedicated project team with whom Pacific Edge meets weekly. This helps to provide good visibility into the organization.

We also continue to advance our strategy for the US Veterans Affairs (VA), the second largest integrated healthcare provider in the US. Our goal is to develop clinical evidence for medical policy within the VA

system with the DRIVE clinical study and to transition early adopting PIs from evaluation and clinical trials to broader adoption across the more than nine million veterans it covers.

ASIA PACIFIC

In the Asia Pacific, where test numbers are dominated by the relatively mature New Zealand market, total laboratory throughput volumes were flat versus the same period a year ago at 2,148 tests. Commercial test volumes increased 5% to 1,800 tests.

To increase test adoption, we continue to advocate for Cxbladder to be deployed in the New Zealand primary care setting. Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral and Te Whatu Ora Whanganui are the latest New Zealand regional public healthcare providers to adopt Cxbladder in primary care.

Pacific Edge believes Cxbladder represents a compelling case for the newly-established Te Whatu Ora – Health New Zealand and Te Aka Whai Ora, the new Māori Health Authority, as they seek to improve access to healthcare for all New Zealanders. There is clear evidence[2] from within the New Zealand healthcare system that the deployment of Cxbladder in primary care allows clinicians to reliably and safely identify patients that can be assessed in primary care with fewer referrals to secondary care and fewer invasive procedures.

Finally, the company has also taken further steps into new markets such as Australia and Singapore. We have seen a small number of tests beginning to flow out of Australia, while the company has recruited a new business development manager for Southeast Asia, based in Singapore.

OUTLOOK

Dr Meintjes said Pacific Edge is looking towards the final four months of the financial year with cautious optimism. The primary uncertainty is the range of potential outcomes from the proposed Novitas LCD.

“Our focus for the moment is continuing to cautiously execute on our strategy until we have certainty of continued CMS reimbursement. And while the loss of coverage would likely require a slowing in our intended hiring plan, we have identified a clear path to re-establish CMS coverage. In short, we remain confident, over time, of our success in the world’s largest healthcare market.

“Pacific Edge has a strong balance sheet and world leading technology for the evaluation of hematuria and the diagnosis and management of bladder cancer. Our Cxbladder tests are gaining traction in the US market and further afield while the evidence supporting their adoption continues to grow.

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

[2] Davidson P, McGeoch G, Shand B. Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. NZ Med J 2020. 133:1527

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24 November 2022

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OVERVIEW www.pacificedgex.com

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.

About Cxbladder: www.cxbladder.com

Cxbladder is a non-invasive genomic urine test optimized for the detection and management of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder is reimbursed by CMS and has been trusted by over 2,000 US urologists in the diagnosis and management of more than 80,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 70% of the population via public healthcare and all residents have the option of buying the test online.

PACIFIC EDGE

1H FY 23 Investor Presentation
24 November 2022

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

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PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

DR PETER MEINTJES
Chief Executive Officer

GRANT GIBSON
Chief Financial Officer

Cx bladder®

PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

AGENDA

1. 1H FY 23 HIGHLIGHTS
2. PACIFIC EDGE SNAPSHOT
3. DELIVERING ON STRATEGY
4. FINANCIAL RESULTS DETAIL
5. OUTLOOK

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1H FY23 HIGHLIGHTS: BUILDING MOMENTUM DESPITE CMS UNCERTAINTY

▲ 34%[1]
GLOBAL TESTING VOLUMES (TLT[2]) on 1H22

Global TLT of 14,917
US TLT increase 42% on 1H22 to 12,769 tests

▲ 35%
COMMERCIAL TEST VOLUMES on 1H22

Commercial Tests of 12,422
US Commercial Tests rise 42% on 1H22 to 10,622 tests

▲ 62%
GROWTH IN OPERATING REVENUE on 1H22

Operating revenue $8.7M
Total revenue of $13.6M up 102% on 1H22

($10.6M)
NET LOSS AFTER TAX

Increase from ($9.0M) in 1H22 amid investment for future growth

$93.5M
CASH, CASH EQUIVALENTS[3]

Strong Balance Sheet
$12.0M reduction in cash & cash equivalents[3] in 1H23

PACIFIC EDGE IS DELIVERING ON ITS STRATEGY

- RESEARCH AND INNOVATION
- EVIDENCE, COVERAGE AND GUIDELINES
- ADOPTION, RETENTION & REVENUE GENERATION

1. All comparisons are to the same period in the prior year unless otherwise stated. 2. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing 3. Cxbladder. Cash, short-term deposits and term deposits

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PACIFIC EDGE AT A GLANCE: GROWING GLOBALLY

1. Figures are cumulative across company history and represent unique patients

FROM IP DEVELOPMENT TO PATIENT

- **IP:** 4x patent families in bladder cancer, with >80 patents including RNA biomarkers and their analysis algorithms
- **Cxbladder:** Advanced genomic biomarker tests from a non-invasive urine sample for the early detection and management of bladder cancer
- **Clinical Evidence:** Peer-reviewed clinical validity and utility data that shows Cxbladder outperforms Standard of Care (SoC)
- **Reimbursement:** Cxbladder tests reimbursed by Medicare and Kaiser Health Plan in the USA
- **Patient Empowerment:** Non-invasive efficacious testing offers opportunity for increased patient compliance with surveillance and management regimes

~300K
Annual laboratory test capacity

>80,000[1]
Patients have used Cxbladder

100 FTE
60% based in US
40% APAC

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CXBLADDER IN THE PATIENT CARE PATHWAY

Typical standard of care on the patient care pathway

Primary Care Physician
Patient presents with hematuria and clinician cannot rule out cancer. Patient referred to urologist

Urologist
Current guidelines for hematuria evaluation recommend ~95% get cystoscopy[1] ahead of diagnosis & treatment

Urologist
Monitor for recurrence with cystoscopy, frequency varies according to patient presentation

Cxbladder TRIAGE

For use in the **PRIMARY CARE** and **SPECIALIST** settings to de-intensify hematuria workup or rule out urothelial cancer (UC)

Cxbladder DETECT

For use by **SPECIALISTS** to detect the presence of urothelial cancer and adjudicate diagnostic dilemmas

Cxbladder MONITOR

For use by **SPECIALISTS** to monitor for recurrence at a frequency proportional to risk

VALUE PROPOSITION

Cxbladder **TRIAGE** (CxbT) | Cxbladder **DETECT** (CxbD) | Cxbladder **MONITOR** (CxbM)

Assists clinicians to **safely de-intensify** hematuria evaluation from low incidence populations
Sensitivity 95% / NPV 99%

Assists clinicians to **adjudicate diagnostic dilemmas** (e.g., equivocal cystoscopy & atypical cytology) in any patient population
Sensitivity 82% / Specificity 85% / NPV 97%

Assists clinicians in **monitoring for UC recurrence**. Intended to reduce the frequency of surveillance cystoscopy and improve patient compliance
Sensitivity 93% / NPV 97%

Sensitivity: the likelihood of the test to be positive in a patient with the disease **Specificity:** the likelihood of the test to be negative when the patient does not have the disease; **NPV:** the likelihood of a negative test being a true negative.

[1] AUA Guidelines and Woldu SL, Ng CK, Loo RK, Slezak JM, Jacobsen SJ, Tan WS, et al. (2021a). "Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria." J Urol **205**(5): 1387-1393.

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BLADDER CANCER

IS A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

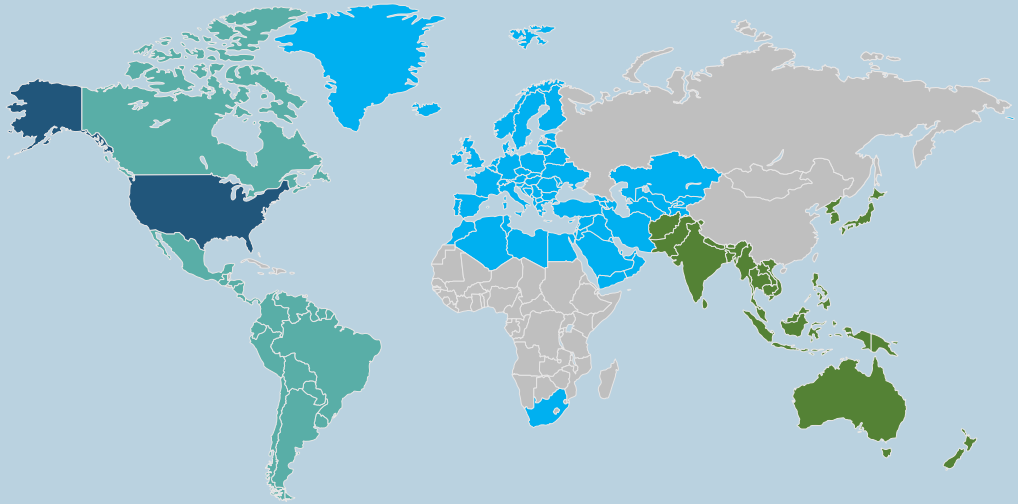
~550K
Annual cases and growing[1]

~200K
Annual deaths[1]

6TH
Most common cancer in men[1]

~70%
Recurrence

- Hematuria evaluation for suspected urothelial cancer has high detection and surveillance costs[2]
- Current American Urological Association guideline leads to recommendation for >90% cystoscopy of patients presenting with hematuria[3]
- Under guidelines in the US, 3.4 million patients should be worked up for cystoscopy, but only 1 million undergo the procedure[4]
- Only 40% of patients comply with existing standards of care due to invasive and high-cost diagnostic procedures[5]



- USA – TAM[6] US$3.5b
- Americas (non-US) – TAM US$0.5b
- EMEA (w/o most of Africa) – TAM US$1.4b
- APAC (w/o China) – TAM US$2.2b

1. Bray et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 3 cancers in 185 countries.Ca Cancer J Clin. 2018;68:394-424
2. Botterman et al. The health economics of bladder cancer: a comprehensive review of the published literature. Pharmacoeconomics 2003;21(18):1315-30.
3. AUA Guideline and **Woldu SL, Ng CK, Loo RK, Slezak JM, Jacobsen SJ, Tan WS, et al. (2021a). "Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria." J Urol 205(5): 1387-1393.**
4. Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021.
5. Schrag, D et al. Adherence to Surveillance Among Patients With Superficial Bladder Cancer JNIC, Volume 95, Issue 8, 16 April 2003.
6. TAM is the Total Addressable Market based on Pacific Edge estimates.

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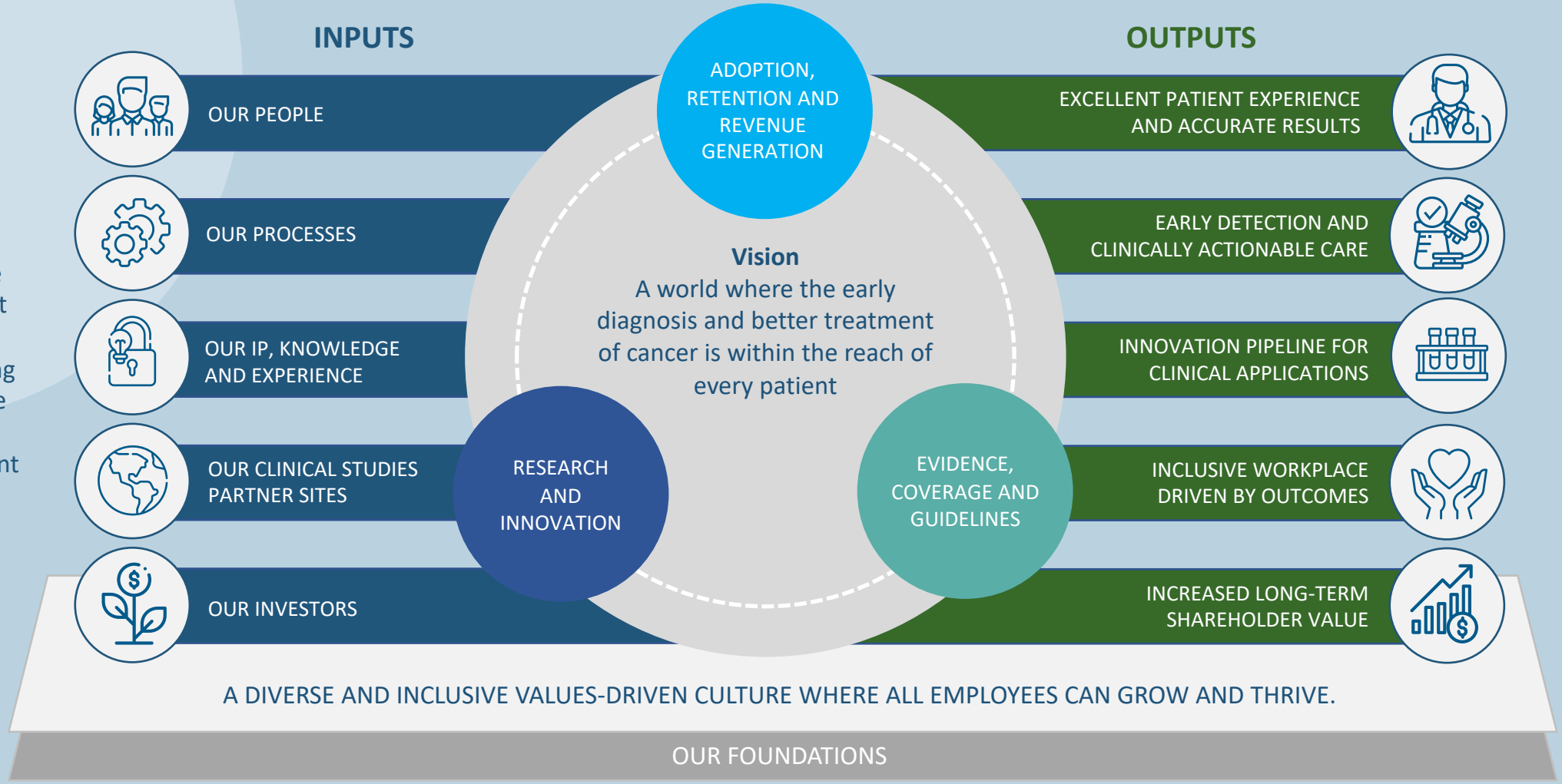
OUR INVESTMENT PROGRAM FOR GROWTH

Mission
To help improve lives and patient outcomes by providing leading solutions for the early detection and management of cancer.



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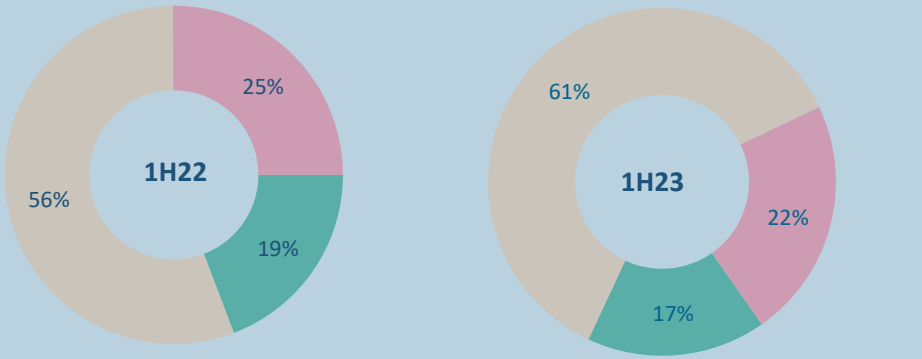
ADOPTION, RETENTION AND REVENUE GENERATION

GLOBAL: COMMERCIAL TESTS GROWING STRONGLY AS US ACCELERATES

Total Lab Throughput (TLT) has increased 34% to 14,917 tests in 1H23

- US market driving growth in commercial test volumes with new hires building momentum in test throughput
- APAC volumes steady as we drive adoption in the primary care setting
- Growth in Cxbladder Detect in test mix reflects growing US test volumes

Testing Volumes (TLT) by Type

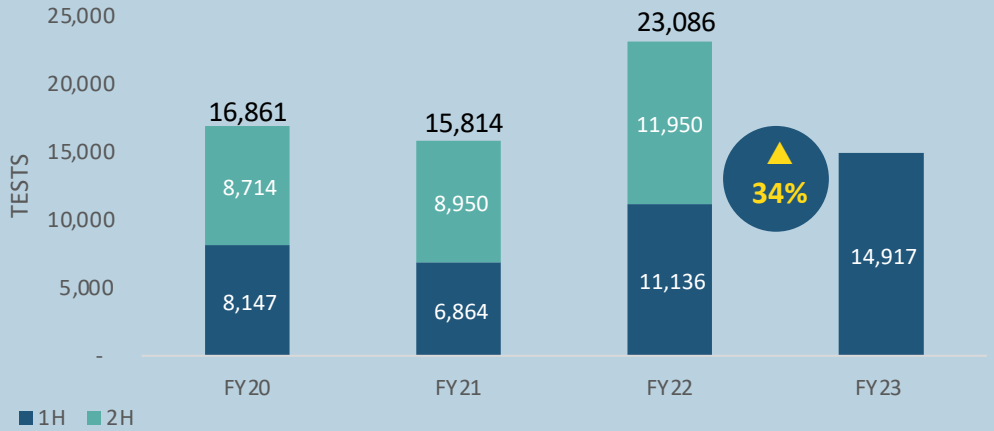


Cxbladder DETECT

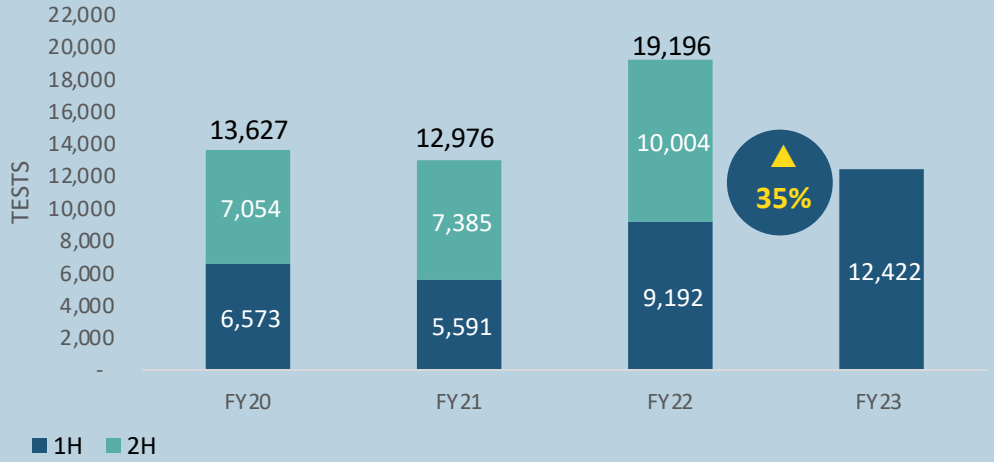
Cxbladder TRIAGE

Cxbladder MONITOR

PEL: Global Testing Volumes (TLT*)



PEL: Global Commercial Testing Volumes



*TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

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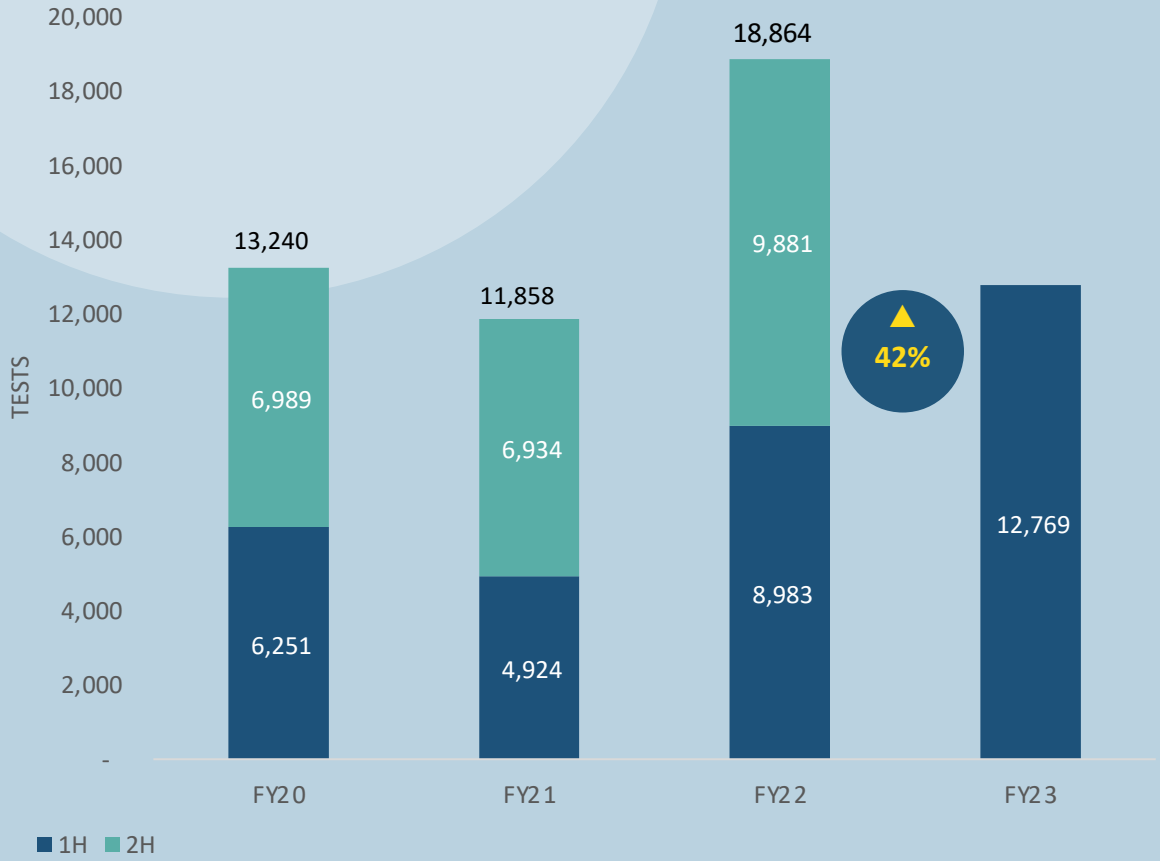
ADOPTION, RETENTION AND REVENUE GENERATION

STRONG GROWTH IN THE US: PACIFIC EDGE'S LARGEST MARKET

USA test volumes[1]

83% of TLT in 1H23 performed in the USA



KEY US PAYORS ACTIVATED

- The Kaiser Health Plan covers over 12.5m members, with >85% of those members in California
- 2 Kaiser accounts in PEB's Top 20 Accounts. 11 Kaiser sites across Southern California ordering in 1H23
- EMR integration on track with Kaiser dedicating a project team to the implementation

- The Veterans Administration (VA) is the second largest integrated healthcare system in the US serving >9m veterans each year
- DRIVE clinical study, has enrolled 80% of target patients. It is an important engagement with VA urologists to determine utility in a cohort of VA patients

- Centers for Medicare & Medicaid Services (CMS) covers more than 61.5m US citizens over 65 and people on low incomes
- CMS continues to reimburse despite proposed LCD
- Focus on selling to urologists who order based on medical necessity

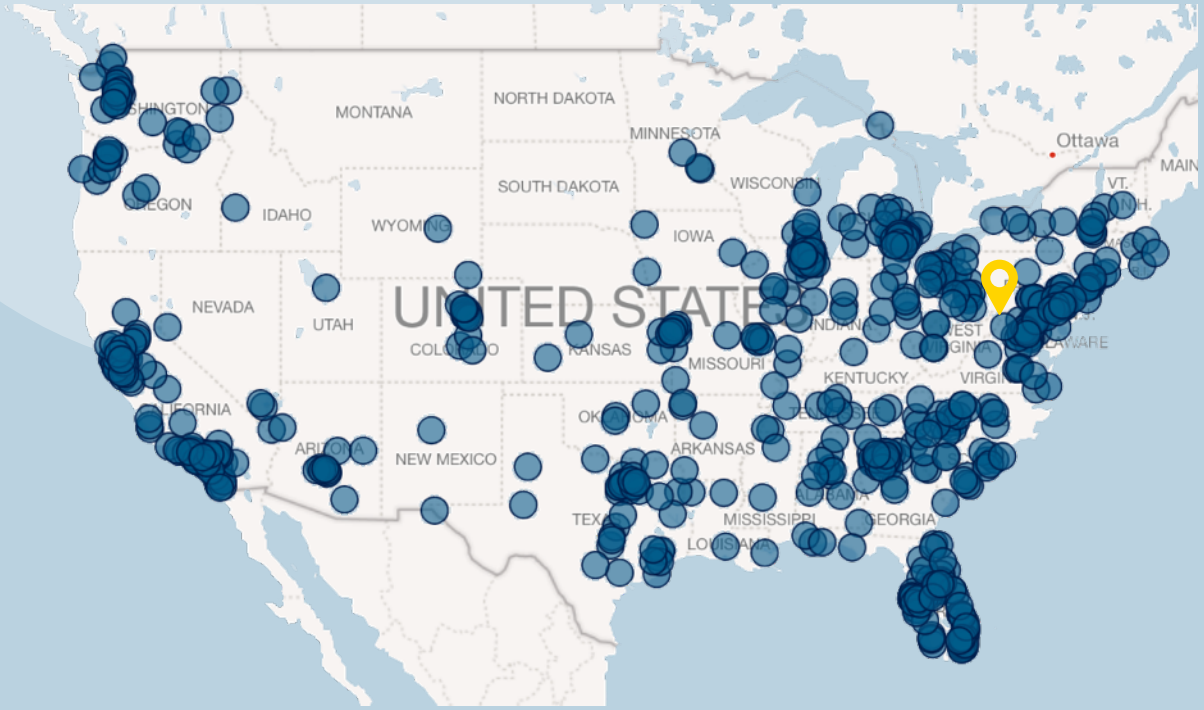
[1] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

Cxbladder

PACIFIC EDGE CANCER DIAGNOSTICS COMPANY

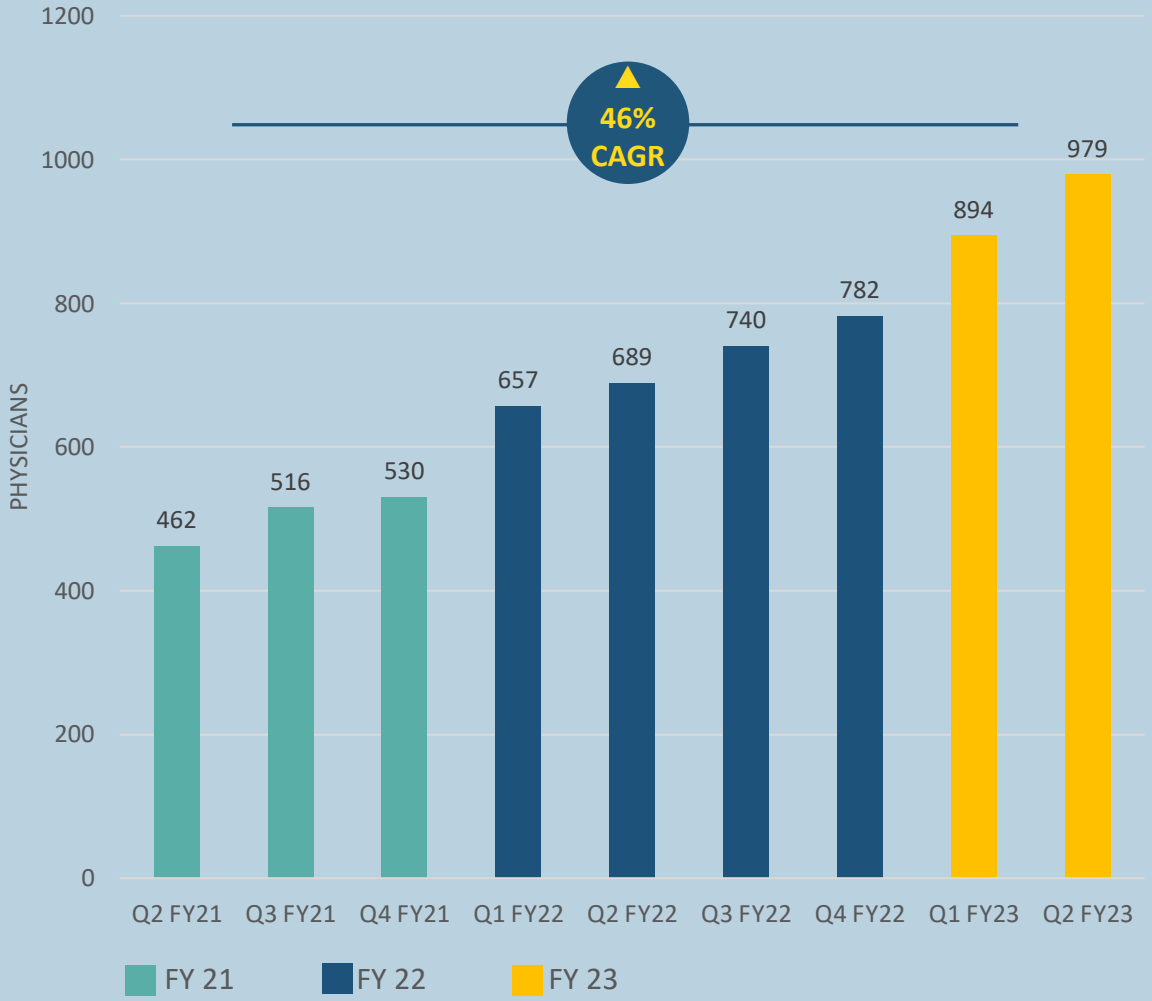
ADOPTION, RETENTION AND REVENUE GENERATION

INVESTMENTS ALREADY DRIVING US ADOPTION AND RETENTION



- Distribution of Current U.S. Customers
- Pacific Edge Diagnostics USA, *Hershey, Pennsylvania*

Unique physicians ordering Cxbladder



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ADOPTION, RETENTION AND REVENUE GENERATION

INVESTMENTS ALREADY DRIVING US ADOPTION AND RETENTION

Prudent implementation of May 2022 investment program*

COMMERCIAL DEPARTMENT	HIRING PLAN
DIRECT SALES AND MARKETING 	**Sales** - Account Executives, Regional Sales Directors, National Accounts & Virtual Sales (contractors) [+9]
	Marketing and Sales Support - Event Management, Product Marketing, Product Management, Sales Training & Sales Operations [+3]
MEDICAL AFFAIRS & MARKET ACCESS 	**Medical Affairs** - VP Medical Affairs and MSLs [+4]
	Market Access and Reimbursement - VP Market Access [+1]

**All appointments linked to the achievement of revenue milestones*

Cxbladder

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ADOPTION, RETENTION AND REVENUE GENERATION

BUILDING THE CXBLADDER BRAND WITH CLINICIANS AND HEALTHCARE PROVIDERS

TARGET US RELATIONSHIPS

50
Urology conferences across the US and APAC

13,790
Practicing urologists[1]

1,900
Large urology group practice sites[2]

Medical Affairs Team now supporting Sales at leading events as we target podium presentations and host/sponsor focused breakout sessions.

AUA Annual Meeting, New Orleans May 2022
Largest and most prestigious event in the global urological calendar
- Sponsorship of International Bladder Cancer Group Expert Forum, VA sessions
- Event and venue sponsorship, advertising

BCAN Think Tank, Denver Aug 2022
Unique in bringing together patients/ patient advocates, researchers, and urologists
- Event sponsorship

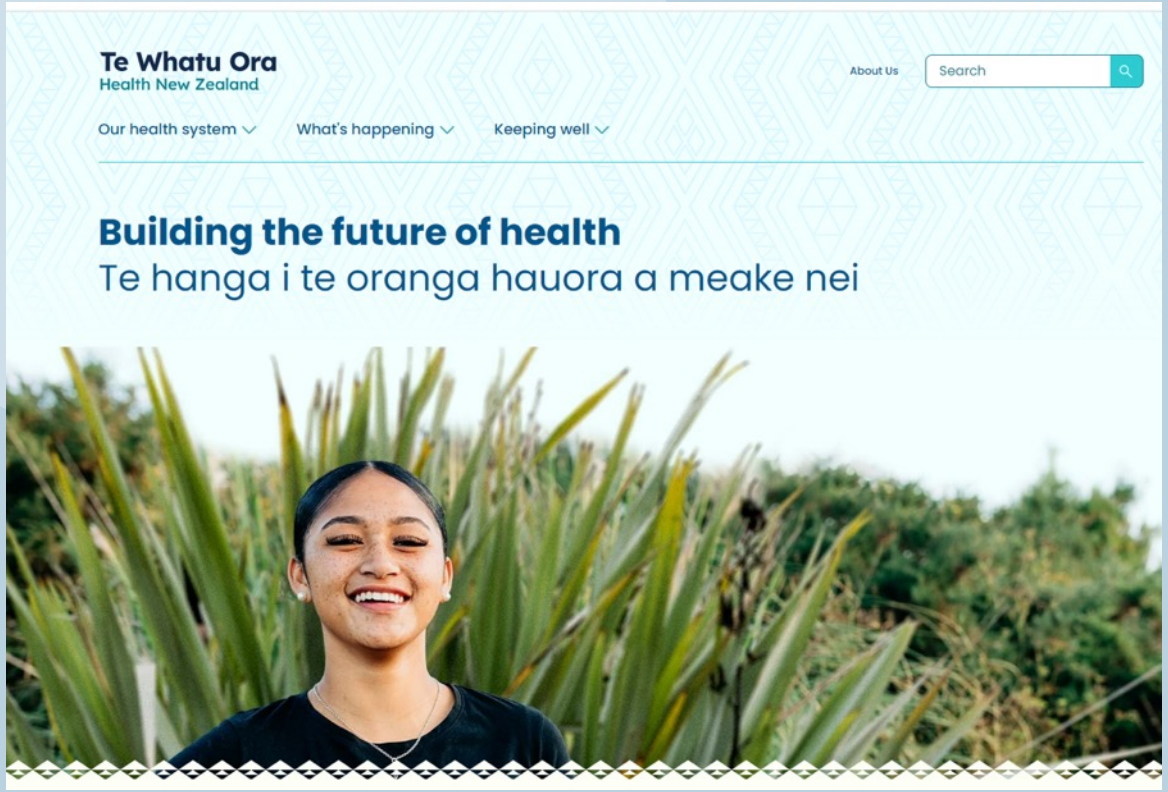
IBCN, Barcelona Sept-Oct 2022
Leading global event dedicated to bladder cancer research and care
- Breakout session focused on biomarkers in the diagnosis and surveillance of bladder cancer
- Event sponsorship

SUO, San Diego Nov-Dec 2022 (upcoming)
Leading event in the urological calendar
- Meeting of Clinical Advisory Board
- Breakfast symposium on the use of biomarkers for cancer diagnosis

[1] American Urological Assn Census 2021, [2] BHN Network

ADOPTION, RETENTION AND REVENUE GENERATION

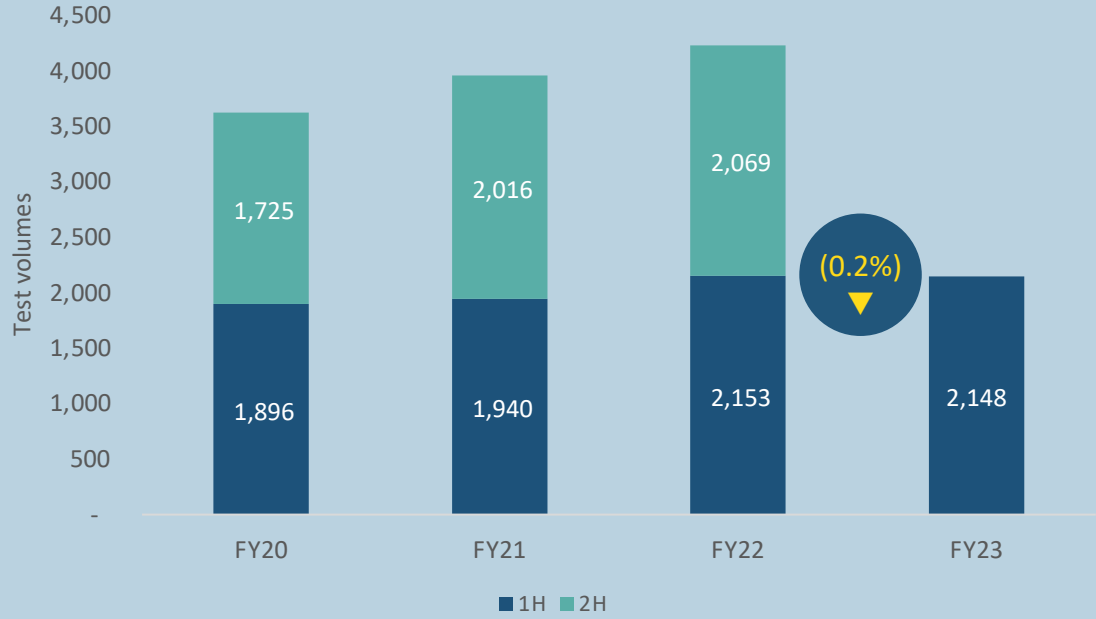
APAC: NEW ZEALAND AT THE FOREFRONT WITH ADOPTION BY PRIMARY CARE



Pacific Edge has Cxbladder coverage in 14 of the 20 new Te Whatu Ora, Health New Zealand, regions, representing >70% of the country's population

APAC QUARTERLY TEST VOLUMES[1]

Commercial tests represent 84% of TLT in 1H23 for APAC



- Volumes unchanged in APAC driven by slower growth in NZ
  - MidCentral and Whanganui district health regions adopted Cxbladder in the primary care setting (Sept, 2022)
- Australia and Southeast Asia still in business development
  - New SEA BDM (+1 FTE, hired in Sept, 2022)
  - User experience studies initiated in Australia and Singapore

[1] Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing

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MEDICARE COVERAGE UPDATE

CMS delegates administrative authority to Medicare Administrative Contractors (MACs)

NOVITAS is the MAC with jurisdiction for Pacific Edge's US Laboratory

Novitas Proposed LCD (released on July 28, 2022 in the USA)

1. Outlines a new methodology for covering molecular biomarker tests
2. Mentions codes for Cxbladder Detect and Monitor as 'not covered'
3. If adopted Pacific Edge will receive 45 days' notice of its effect
4. May be withdrawn by Novitas at any time or expire after 12 months[1]
5. Pacific Edge provided oral & written comments to Novitas prior to the close of public comment on Sept 6, 2022
6. Pacific Edge have yet to receive feedback or update from Novitas and do not have a timeline for response

Key Messages for Investors

1. Cxbladder currently **remains covered by Novitas**, and we have seen no reduction in demand for Cxbladder
2. Cxbladder has **not been singled out** in the LCD and there is **no "adverse reporting event"** associated with Cxbladder (it would be highly unusual for a test to lose coverage without an "adverse reporting event")
3. The **Proposed LCD** contains **inconsistencies**, **unintended consequences** and a methodology that **may violate Medicare's rules**
4. The **Proposed LCD** appears focused on **SNP-based PGx tests[2] for guiding therapeutic** decisions **after** a confirmed diagnosis, apparently excluding diagnostic biomarker tests from clinical tool kits
5. The LCD takes the **highly unusual step** of **'outsourcing' coverage determinations to third party databases**
6. Pacific Edge has the leadership team and the relationships with lawyers, coalitions, lobbyists, professional societies, physicians and patient advocacy groups to affect a positive outcome
7. We maintain our position that the proposed LCD is unlikely to survive in its current form and continue to responsibly plan for all eventualities

[1] Pacific Edge understands the Proposed LCD expires if it is not notified within 12 months of the date of proposal on July 28th, 2022. Pacific Edge previously understood this was 12 months after the close of comments on Sept 6th, 2022

[2] The Single Nucleotide Polymorphism-based Pharmacogenetic (PGx) tests.

EVIDENCE COVERAGE AND GUIDELINES

GLOBAL GUIDELINES PIVOTAL TO THE WIDESPREAD ADOPTION OF CXBLADDER

Recognition in national guidelines deepens and accelerates commercial use of Cxbladder tests and entrenches coverage by nationally relevant healthcare institutions.

American Urological Association

- Most influential and largest urological association in the world
- U.S. based - 23,000 members worldwide.
- Standards of care relevant to Cxbladder:
  - Hematuria and micro-hematuria management
  - Non-muscle invasive bladder cancer (NMIBC). (Standard makes an allowance for the use of biomarkers in surveillance)
- Guidelines reviewed as new evidence emerges
- Pacific Edge can influence this process by publishing new clinical evidence

www.auanet.org

European Association of Urology

- Leading urologic authority in Europe
- Netherlands-based, 18,000 members
- Standards relevant to Cxbladder
  - Non-muscle invasive bladder cancer (NMIBC)
  - Guidelines loosely followed in New Zealand, Australia and Singapore, but localised at a national and regional level
- Guidelines recently reviewed with favourable biomarker language and are updated regularly

www.uroweb.org

National Comprehensive Cancer Network®

- US-based not-for-profit alliance of 32 leading US cancer centres
- Bladder cancer standard suggests biomarkers may be considered during surveillance of high-risk non-muscle-invasive bladder cancer
- Guidelines reviewed annually. PEB will resubmit in every year where there is new peer-reviewed evidence for Cxbladder
- Clinical Dossier updated for next review in April 2023

www.nccn.org

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EVIDENCE COVERAGE AND GUIDELINES

CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (1/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
US Primary Study	Prospective, single-arm, observational study to develop clinical evidence for Cxbladder tests, accurate risk stratification, intensifying or de-intensify hematuria evaluation and assistance in adjudicating equivocal cystoscopy or urine cytology	USA	12/12	- Enrolment complete - Analysis complete - Publication pending
Singapore Study	Prospective, single-arm, observational study to develop clinical evidence for Cxbladder tests, accurate risk stratification, intensifying or de-intensify hematuria evaluation and assistance in adjudicating equivocal cystoscopy or urine cytology	Singapore	4 / 4	- Enrolment complete - Analysis complete - Publication pending
STRATA	**S**afe **T**esting of **R**isk for **A**symptoma**TI**c Microhematuri**A** Demonstrate the clinical utility of Cxbladder using a prospective, two-arm randomized design to safely risk-stratify patients and rule out from further hematuria evaluation • Safely risk stratifying patients in order to rule out from cystoscopy • Demonstrate the clinical utility of Cxbladder against the AUA guidelines	USA Canada	11 / 11	- Enrolment total is 421, including 103 'low risk' subjects that are the focus of the study - Target enrolment: ~600 patients, 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 Prospective, single-arm, observational study to demonstrate the clinical validity & utility of Cxbladder tests in risk stratifying Veterans presenting with hematuria • Demonstrate performance with Veterans and contribute to commercial adoption of Cxbladder for use with Veterans • Critical for adoption of Cxbladder by VA. Contributes to AUA Guidelines • Recruitment re-started after COVID-related delays • Targeting inclusion of all veterans presenting for evaluation of hematuria	VA Sites (USA)	10 / 11	- Enrolment total is 507 - Target enrolment: ~600 patients - Last patient in: Q2 2023 - Follow up: until Q2 2025

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

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EVIDENCE COVERAGE AND GUIDELINES

CLINICAL EVIDENCE GENERATION TOWARDS GUIDELINE INCLUSION (2/2)

STUDY	AIM	LOCATIONS	ENROLLED SITES*	STATUS**
DEDUCT	**DE**tection of **D**isease in the **U**pper tra**CT** Prospective, single-arm, observational study to validate performance of Cxbladder for the detection of urothelial carcinoma (UC) in the upper tract (UTUC) • Evaluate Cxbladder to safely avoid ureteroscopy • Safely risk stratify patients suspected to have UTUC and avoid unnecessary ureteroscopy and radiation exposure through imaging • Targeting inclusion of Cxbladder utility for UTUC in AUA guidelines	USA	1 / 3	- One site is open for this pilot study and the first patient in is expected by Dec 2022
LOBSTER	**LO**ngitudinal **B**ladder Cancer **S**tudy for **T**umor R**E**cur**R**ence Prospective, single-arm, observational study to evaluate the performance characteristics and clinical utility of CxbM in a new surveillance protocol vs standard of care over four visits • Safely risk stratify patients under surveillance for recurrence of UC • Safely alternate CxbM with cystoscopy for intermediate and high-risk patients under surveillance for recurrence of UC • Targeting AUA guidelines inclusion for biomarkers as an alternative to cystoscopy in a surveillance setting	USA (including some VA sites) Australia	2 / 10	- Two sites are open and another 8 are at pre-activation. Enrolment is now 27 patients. - Each site will enroll 100 patients within 12 months and follow up for another 12 months

Clinical Development headcount +1 since May. Expecting further +2 headcount before EOFY

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

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EVIDENCE COVERAGE AND GUIDELINES

INVESTIGATOR INITIATED TRIALS – SUPPLEMENTING OUR EVIDENCE PROGRAM

What are Investigator Initiated Trials?

- Investigator Initiated Studies (IITs) are proposed by investigators and supported by Pacific Edge
- IITs typically provide clinical utility evidence at modest scale
- They promote familiarity and confidence with Cxbladder, the test result and how Cxbladder can be used to manage patients
- Supports local data development for market access and adoption

Left to right - **Royal Prince Alfred Hospital (Sydney)**, UT Southwestern (Dallas), Canberra Hospital (ACT)

- ***Return on investment is expected in the form of publications, abstracts and presentations from Principle Investigators of an IIT***

IIT Study Aim	Sites	Publications
Hematuria Evaluation: Local clinical validity evidence for internal hospital guidelines and budget development	6	2x Conference Abstracts
Surveillance: Local clinical validity evidence for internal hospital guidelines and budget development	7	2x Conference Abstracts
CU of Cxbladder to identify subclinical tumors in white light negative patients, confirmed by blue light	1	Pending
Risk-based hematuria evaluation of microhematuria patients by Cxbladder	1	Pending
Risk-stratification of surveillance patients for prioritization of post-TURBT care by Cxbladder	2	1x Conference Abstract

RESEARCH & INNOVATION

RESEARCH AND INNOVATION

DRIVING IP TO TECHNOLOGY

- Evaluate ‘product concepts’ to address unmet clinical needs
- +2 scientists to explore market potential of various product concepts including:
  - Prognostics or companion diagnostics in urology
  - Adjacent disease (with molecular signal in the urine)
- +2 developers and bioinformaticians to improve platforms, integrations and analysis capabilities
- MONSTER Study
- Examining new markers of **Minimum Residual Disease** (MRD)
  - Surveillance for bladder cancer immediately following surgical intervention (vs CxbM which is used six months after intervention for recurrence)

Christchurch Hospital

MONSTER	**MON**itoring **S**tudy of post-**T**reatment **E**ffectiveness for **R**esidual Disease Single-arm, observational study to validate the performance characteristics of Cxbladder against white light cystoscopy during surveillance of UC • Christchurch study to measure residual disease • To safely risk stratify patients for residual disease prior to the 6-week re-resection for high grade patients or the 3-month flexible cystoscopy check for all patients	- Finalizing protocol documentation and commenced engagement with ethics committee - Target (Q1 2023) first patient

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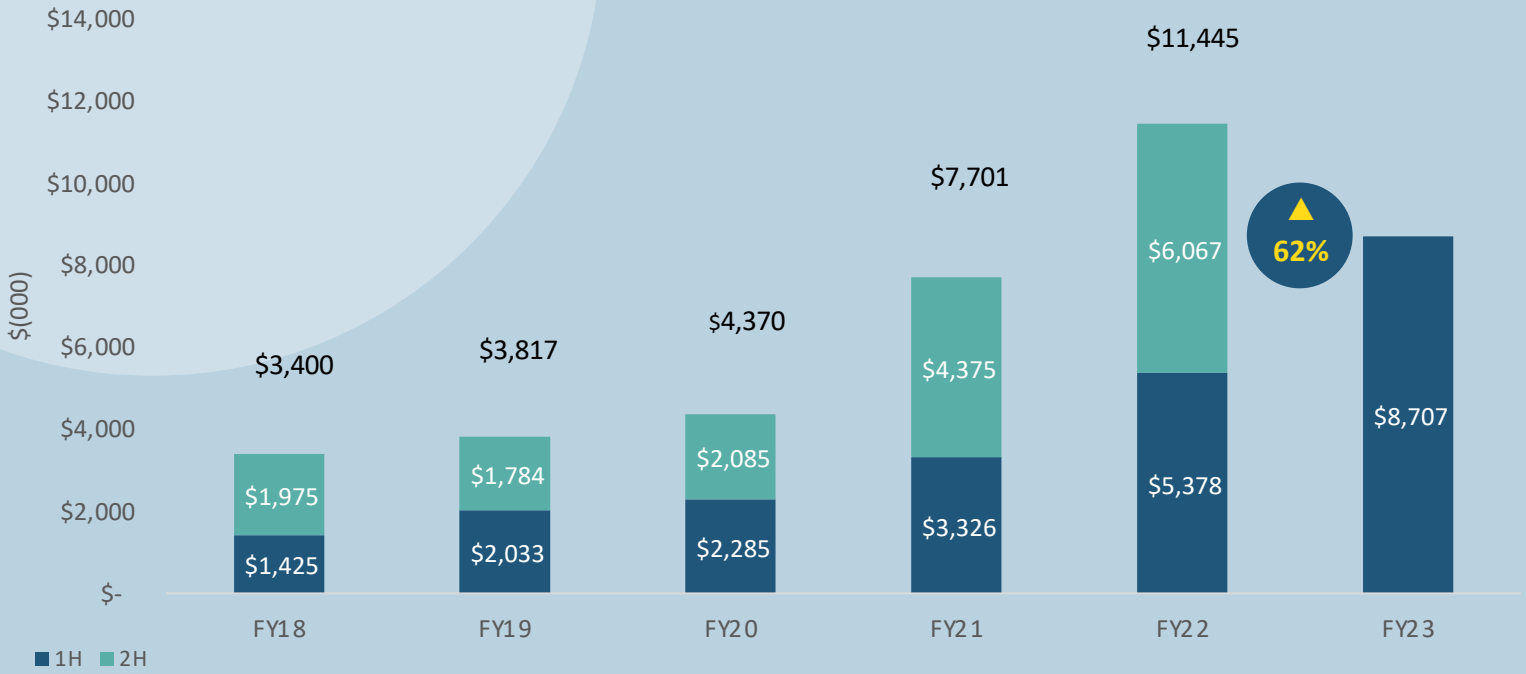
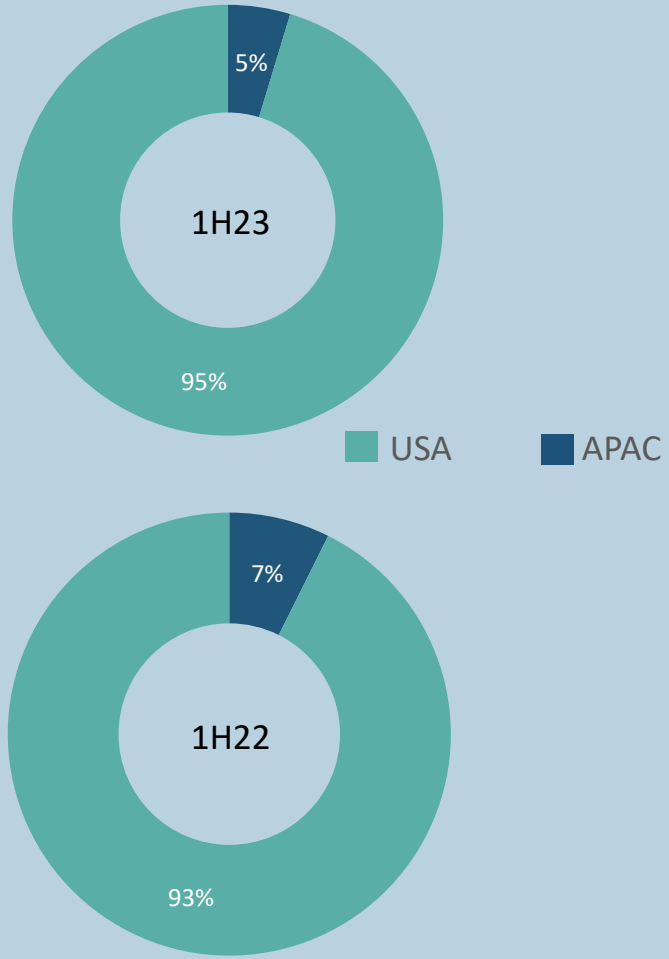
FINANCIAL RESULTS OVERVIEW

US TEST COMMERCIAL TEST VOLUME GROWTH AND FX DRIVING REVENUES

Pacific Edge Operating Revenue



Regional Revenue Split



- Operating Revenue grew $3.3m, with $2.4m driven by the 35% increase in commercial tests (42% increase in the US) and $0.9m of the growth due to the weakening of the New Zealand dollar against the United States Dollar
- US continues to grow share of total revenue

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US TEST VOLUME GROWTH AND FX GAINS LIFT REVENUE

STRONG BALANCE SHEET SUPPORTS GROWTH INVESTMENTS

Half year to 30 September	2022	2021	Variance	Change
	$000	$000	$000	%
Operating revenue	$8,707	$5,378	$3,329	62%
Total revenue	$13,593	$6,730	$6,863	102%
Operating expenses	$24,164	$15,715	$8,449	54%
Total comprehensive loss	**-$10,571**	**-$8,985**	**-$1,586**	**18%**
Cash receipts from customers	$7,316	$5,370	$1,946	36%
Net operating cash outflow	-$13,972	-$8,616	-$5,356	62%
Net cash, cash equivalents and short term deposits	**$93,455**	**$91,586**	**$1,869**	**2%**

- Total income lifted by increase in interest income and FX gains on mark to market of US cash balances (~$3.0m)
- Expense rise lifted by investments for growth, led by sales and marketing and the translation effect of a weaker NZD (~$1.7m)
- At constant currency, expenses would have increased 43%
- APAC expenses up 20% 1H23 over 1H22
- Operating cash outflow in 1H23 of $14.0m
- Cash and cash equivalents of $93.5m[1] down $12.0m on $105.4m in March FY2022

[1] 30 September 2022

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OPERATING COSTS RISE AS INVESTMENT FOR GROWTH CONTINUES

Operating Expenses Half year to 30 September	2022 $000	2021 $000	Variance $000	Change %
Laboratory operations	$4,467	$3,076	$1,391	45%
Research	$3,710	$2,572	$1,138	44%
Sales and marketing	$11,375	$6,179	$5,196	84%
General and administration	$4,612	$3,888	$724	19%
Total operating expenses	**$24,164**	**$15,715**	**$8,449**	**54%**

INVESTING IN FY23 TO DELIVER IN FY24

- Investment in people accounted for ~56% of the uplift in expenses (headcount, salary increases and recruitment costs) with investment weighted to the commercial teams
- Sales and Marketing investment accounted for ~61% of operating expense increase
- Laboratory operations expenses follow higher throughput and freight costs
- Research increase reflects the increased investment in the clinical evidence generation program (including a minority share of Medical Affairs)

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OUTLOOK

- Cautious optimism for the final four months of FY23 as we continue to implement our strategy recognizing the potential for disruption
- We are delivering growth in line with our expectations and investing prudently
- The proposed Novitas LCD has not impacted commercial or clinical trial throughput
- Even in the event of an adverse LCD, Pacific Edge has a path to re-establish coverage
- We have world-leading technology, a strong balance sheet and we are building momentum in the world's most important market

QUESTIONS

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APPENDIX

STRATEGY: ADOPTION, RETENTION AND REVENUE GENERATION

ADOPTION, RETENTION AND REVENUE GENERATION

FOCUS AREAS:

1. Diversify sales process to target Strategic Accounts differently, including education and Key Opinion Leader (KOL) engagement activities by our Medical Affairs team
2. Drive protocolized adoption of Cxbladder at the earliest point in the patient care pathway
3. Increase event marketing, sponsorship and marketing communications to amplify our clinical evidence generation within the urology and oncology communities
4. Establish “in-network” or contracted relationships for the reimbursement of Cxbladder with government healthcare funders and private payors
5. Empower patients through patient awareness and patient advocacy initiatives through established societies and our Cxbladder website

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ADOPTION, RETENTION AND REVENUE GENERATION

BLADDER CANCER IN THE US MARKET

90%
Five-year survival rate if detected early[1]

US$220,000
Average lifetime cost[2] per patient

US$4.9B
Forecast direct costs associated with urothelial cancer in 2020[2]

VALUE PROPOSITION

Cxbladder **TRIAGE** (CxbT) | Cxbladder **DETECT** (CxbD) | Cxbladder **MONITOR** (CxbM)

Patient care pathway

Primary Care Physician → **Urologist**

The US has >55m men and >63m women aged 50+

- **~7m** present with Hematuria[2]
- **~3.4m** require clinical workup[2]
- **>1.0m** patients receive a cystoscopy[3]
- **~81k** Annual cases of bladder cancer[4]
- **~800k** monitored for recurrence Avg1.5 CxbM/yr[5]

US$3.5B opportunity[6] (hematuria, surveillance)

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> 4.6M TEST OPPORTUNITIES

[1] Bladder Cancer Advocacy Network
[2] Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
[3] Konigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021.
[4] National Cancer Institute 2021 forecast
[5] Pacific Edge Estimate
[6] Pacific Edge estimates at US$760/Per test

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STRATEGY: EVIDENCE, COVERAGE AND GUIDELINES

CHANGE CLINICAL PRACTICE

FOCUS AREAS:

Generate high-quality clinical validation and utility evidence through clinical studies

Use Clinical Utility evidence to:

- Drive the adoption of Cxbladder by clinicians, insurers and hospitals ahead of guideline inclusion
- Pursue inclusion of Cxbladder in globally-relevant standards and guidelines of clinical care across the breadth of patient pathways
- Foster trusted relationships with key opinion leaders, relevant uro-oncology centres of excellence, professional societies and patient advocacy networks to drive a broader awareness and demand for Cxbladder
- Develop the scientific and clinical credibility of the Cxbladder brand

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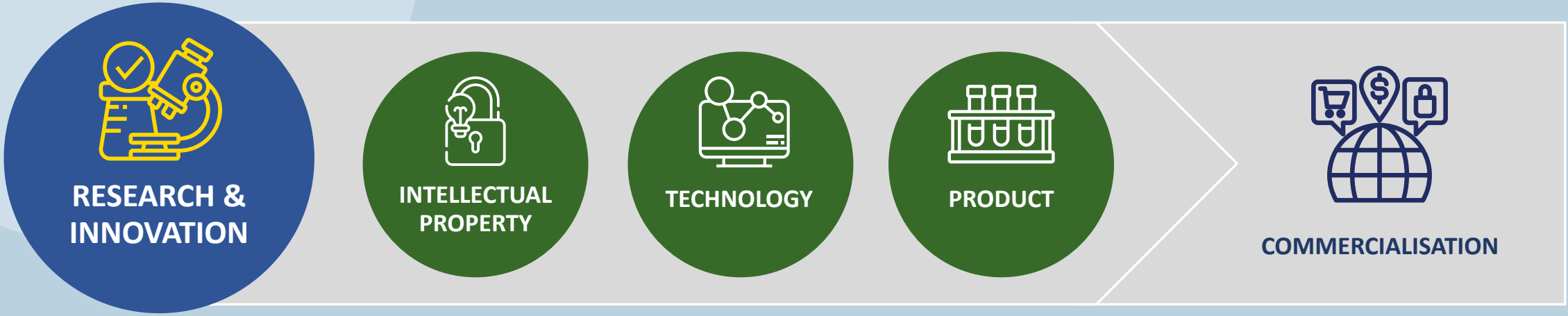
STRATEGY: RESEARCH AND INNOVATION:

UNDERSTANDING THE ENTIRE COMMERCIALISATION PATHWAY



FOCUS AREAS:

1. Evaluate ‘product concepts’ to address unmet clinical needs through market research and scientific/clinical advisory boards
2. Evaluate cutting-edge technologies to meet the market requirements of desired product concepts
3. Continue to build a patent portfolio for novel clinical applications of cutting-edge molecular technologies
4. Turn patented technology into clinically-validated molecular diagnostic tools that address an unmet clinical need

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PACIFIC EDGE: A HISTORY OF RESEARCH-LED INNOVATION AND GROWTH

2001
Pacific Edge established

2003
Listed on the NZX

2007
Commercial pivot to focus on urothelial cancer diagnostics

2008
Holyoake et al: Urine-based RNA detection of urothelial cancer Clin Cancer Res

2011
Pacific Edge Diagnostics New Zealand (PEDNZ) established

2012
O'Sullivan et al: Cxbladder Detect performance validation Journal of Urology

Dec 2012
Launch of Pacific Edge Diagnostics USA and CxbD

Mar 2013
PEDUSA receives CLIA accreditation

May 2013
First commercial sale (CxbD) for PEDNZ

Mar 2013
First commercial sale (CxbD) for PEDUSA

Dec 2014
Launch of Cxbladder Triage

Mar 2015
Kavalieris et al: CxbT performance validation BMC Urology

Dec 2015
Launch of Cxbladder Monitor

Nov 2016
Clinical trials commence in Singapore

Feb 2018
CxbT adopted into Canterbury Community Health Pathways with primary care referral

Aug 2019
Konety et al: Clinical Utility of CxbD in adjudicating atypical cytology and equivocal cystoscopy European Urology

Apr 2020
Patient in-home sampling initiated in the US

Jun 2020
Kaiser Permanente, approves commercial use of Cxbladder

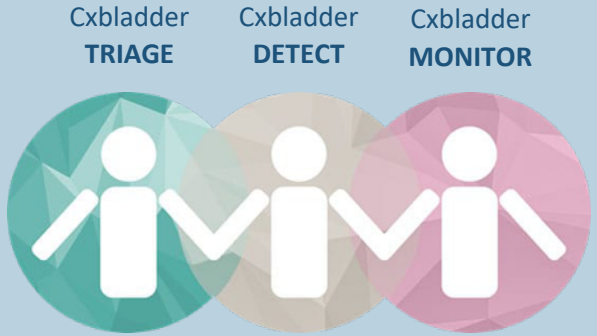
Jul 2020
CMS confirms reimbursement of Cxbladder at $760/test

Aug 2021
Cxbladder reaches 70% public healthcare coverage in NZ

Oct 2021
PEB raises $103.5m (~US$72.5m)

Dec 2021
First commercial sale of Cxbladder in Australia

2001 2007 2008 2011 2012 2013 2014 2015 2016 2018 2019 2020 2021



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PACIFIC EDGE
CANCER DIAGNOSTICS COMPANY

CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

Consolidated Interim Financial Statements

Notes to the Consolidated Interim Financial Statements

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

	NOTES	UNAUDITED SEPT 2022 6 MONTHS ($000)	UNAUDITED SEPT 2021 6 MONTHS ($000)	AUDITED 2022 12 MONTHS ($000)
REVENUE				
Operating Revenue	4	8,707	5,378	11,445
Total Operating Revenue		**8,707**	**5,378**	**11,445**
Other Income	4	761	747	1,691
Interest Income		1,099	108	549
Foreign Exchange Gain		3,026	497	193
Total Revenue and Other Income		**13,593**	**6,730**	**13,878**
OPERATING EXPENSES				
Laboratory Operations		4,467	3,076	6,498
Research		3,710	2,572	5,135
Sales and Marketing		11,375	6,179	14,277
General and Administration		4,612	3,888	7,756
Total Operating Expenses	5	**24,164**	**15,715**	**33,666**
NET LOSS BEFORE TAX		**(10,571)**	**(8,985)**	**(19,788)**
Income Tax Expense		-	-	-
LOSS FOR THE PERIOD AFTER TAX		**(10,571)**	**(8,985)**	**(19,788)**
Items that may be reclassified to profit or loss:				
Translation of Foreign Operations		380	-	114
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		**(10,191)**	**(8,985)**	**(19,674)**
Earnings per share for loss attributable to the equity holders of the Company during the period				
Basic and Diluted Earnings per share		(0.013)	(0.012)	(0.026)

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2022

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

	NOTES	SHARE CAPITAL ($000)	ACCUMULATED LOSSES ($000)	SHARE BASED PAYMENTS RESERVE ($000)	FOREIGN CURRENCY TRANSLATION RESERVE ($000)	TOTAL EQUITY ($000)
UNAUDITED 6 MONTHS TO 30 SEPT 2021						
Balance as at 31 March 2021		**190,305**	**(170,061)**	**4,038**	**827**	**25,109**
Loss After Tax		-	(8,985)	-	-	(8,985)
Other Comprehensive Income		-	-	-	-	-
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		-	(8,985)	-	-	(8,985)
Transactions with owners in their capacity as owners:						
Issue of Share Capital	7	76,045	-	-	-	76,045
Share Based Payments - Employee Remuneration	7	172	-	-	-	172
Share Based Payments - Employee Share Options	7	1,175	-	(121)	-	1,054
Balance as at 30 September 2021		**267,697**	**(179,046)**	**3,917**	**827**	**93,395**
AUDITED 12 MONTHS TO 31 MARCH 2022						
Balance as at 31 March 2021		**190,305**	**(170,061)**	**4,038**	**827**	**25,109**
Loss After Tax		-	(19,788)	-	-	(19,788)
Other Comprehensive Income		-	-	-	114	114
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		-	(19,788)	-	114	(19,674)
Transactions with owners in their capacity as owners:						
Issue of Share Capital	7	99,622	-	-	-	99,622
Share Based Payments - Employee Remuneration	7	172	-	-	-	172
Share Based Payments - Employee Share Options	7	4,040	-	(893)	-	3,147
Balance as at 31 March 2022		**294,139**	**(189,849)**	**3,145**	**941**	**108,376**
UNAUDITED 6 MONTHS TO 30 SEPT 2022						
Balance as at 31 March 2022		**294,139**	**(189,849)**	**3,145**	**941**	**108,376**
Loss After Tax		-	(10,571)	-	-	(10,571)
Other Comprehensive Income		-	-	-	380	380
TOTAL COMPREHENSIVE LOSS atttributable to equity holders of the Company		-	(10,571)	-	380	(10,191)
Transactions with owners in their capacity as owners:						
Issue of Share Capital	7	(2)	-	-	-	(2)
Share Based Payments - Employee Remuneration	7	93	-	-	-	93
Share Based Payments - Employee Share Options	7	-	-	567	-	567
Balance as at 30 September 2022		**294,230**	**(200,420)**	**3,712**	**1,321**	**98,843**

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements

CONSOLIDATED BALANCE SHEET

AS AT 30 SEPTEMBER 2022

	NOTES	UNAUDITED SEPT 2022 6 MONTHS ($000)	UNAUDITED SEPT 2021 6 MONTHS ($000)	AUDITED MARCH 2022 12 MONTHS ($000)
CURRENT ASSETS				
Cash and Cash Equivalents		37,989	80,081	35,412
Short Term Deposits		55,466	11,505	70,000
Receivables		6,017	2,978	4,012
Inventory		1,507	956	1,007
Other Assets		1,734	930	1,183
Total Current Assets		**102,713**	**96,450**	**111,614**
NON-CURRENT ASSETS				
Property, Plant and Equipment		1,753	908	1,404
Right of Use Assets		1,507	2,381	1,830
Intangible Assets		784	231	434
Total Non-Current Assets		**4,044**	**3,520**	**3,668**
TOTAL ASSETS		**106,757**	**99,970**	**115,282**
CURRENT LIABILITIES				
Payables and Accruals		5,983	4,227	4,983
Lease Liabilities		1,267	1,033	1,072
Total Current Liabilities		**7,250**	**5,260**	**6,055**
NON-CURRENT LIABILITIES				
Lease Liabilities		664	1,315	851
Total Non-Current Liabilities		**664**	**1,315**	**851**
TOTAL LIABILITIES		**7,914**	**6,575**	**6,906**
NET ASSETS		**98,843**	**93,395**	**108,376**
Represented by:				
EQUITY				
Share Capital	7	294,230	267,697	294,139
Accumulated Losses		(200,420)	(179,046)	(189,849)
Share Based Payments Reserve		3,712	3,917	3,145
Foreign Currency Translation Reserve		1,321	827	941
TOTAL EQUITY		**98,843**	**93,395**	**108,376**
FURTHER INFORMATION				
Net Tangible Assets per share ($)	14	0.121	0.118	0.133

For and on behalf of the Board of Directors

Director **Director**

Dated 23rd day of November 2022

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

	NOTES	UNAUDITED SEPT 2022 6 MONTHS ($000)	UNAUDITED SEPT 2021 6 MONTHS ($000)	AUDITED MARCH 2022 12 MONTHS ($000)
CASH FLOWS TO OPERATING ACTIVITIES				
Cash was provided from:				
Receipts from Customers		7,316	5,370	10,942
Receipts from Grant Providers		404	469	1,413
Interest Received		908	242	365
		8,628	6,081	12,720
Cash was disbursed to:				
Payments to Suppliers and Employees		22,611	14,683	30,198
Net GST cash (inflow) outflow		(11)	14	74
		22,600	14,697	30,272
Net Cash Flows To Operating Activities	8	**(13,972)**	**(8,616)**	**(17,552)**
NET CASH FLOWS FROM (TO) INVESTING ACTIVITIES:				
Cash was provided from:				
Proceeds from Short Term Deposits		71,784	17,000	51,837
		71,784	17,000	51,837
Cash was disbursed to:				
Purchase of Short Term Deposits		57,310	9,505	102,837
Capital Expenditure on Plant and Equipment		504	298	713
Capital Expenditure on Intangible Assets		487	108	413
		58,301	9,911	103,963
Net Cash Flows From (To) Investing Activities		**13,483**	**7,089**	**(52,126)**
CASH FLOWS (TO) FROM FINANCING ACTIVITIES:				
Cash was received from:				
Proceeds from Borrowings		314	-	-
Ordinary Shares Issued	7	-	80,000	103,488
Exercising of Share Options		-	657	2,306
		314	80,657	105,794
Cash was disbursed to:				
Repayment of Leases - Principal		553	506	1,147
Repayment of Leases - Interest		46	69	126
Issue Expenses	7	2	3,099	3,865
		601	3,674	5,138
Net Cash Flows (To) From Financing Activities		**(287)**	**76,983**	**100,656**
Net (Decrease) Increase in Cash and Cash Equivalents Held		**(776)**	**75,456**	**30,978**
Add Opening Cash Brought Forward		35,412	4,129	4,129
Effect of exchange rate changes on net cash		3,353	496	305
Ending Cash and Cash Equivalents Carried Forward		**37,989**	**80,081**	**35,412**

Note: These Financial Statements are to be read in conjunction with the Notes to the Financial Statements

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

3. DIVIDENDS

The Company does not propose to pay dividends to shareholders similar to previous years. This policy continues.

4. REVENUE AND OTHER INCOME

	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Cxbladder Sales			
US - Accrual Accounting	7,383	4,537	9,687
US - Cash Accounting	916	445	953
Total US Sales	**8,299**	**4,982**	**10,640**
Rest of World	408	396	805
Total Operating Revenue	**8,707**	**5,378**	**11,445**
Other Income			
Grant Revenue	300	295	321
Research Rebates and Tax Incentives	461	452	1,370
Total Other Income	**761**	**747**	**1,691**

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2022

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

5. OPERATING EXPENSES

The note below highlights total expenses shown within total operating expenses. These items are then split across functions; laboratory, research, sales and marketing and general and administration as reported in the annual report.

	Notes	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Operating Expenses				
Amortisation		123	54	156
Auditors Remuneration				
Group year end financial statements		69	80	184
Half year review of financial statements		29	27	28
Foreign statutory financial statements		13	12	12
Total Auditors Remuneration		**111**	**119**	**224**
Consultant Costs		858	400	984
Depreciation		206	127	264
Depreciation on Right of Use Assets		569	526	1,064
Directors Fees		247	186	413
Employee Benefits		10,797	6,770	16,402
Employee Share Scheme Expenses		93	172	172
Employee Share Options		567	397	839
Interest on Lease Liabilities		46	69	125
NZX / ASX / Registry Fees		225	806	901
Rental and Lease Expense		38	28	79
Site Fees - Clinical Studies		636	279	599
Other Operating Expenses		9,648	5,782	11,444
Total Operating Expenses		**24,164**	**15,715**	**33,666**

Employee Share Scheme

Employee Share Scheme Expenses are a non-cash expense. These relate to shares issued to employees in lieu of cash bonuses.

Employee Share Options

Employee Share Options are a non-cash expense. Refer to Note 8 of the latest Annual Report for details of the accounting policy for Employee Share Schemes.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

1 . SUMMARY OF ACCOUNTING POLICIES

The unaudited consolidated interim financial statements ("Interim Financial Statements") presented are those of Pacific Edge Limited ("Company") and its subsidiaries ("Group"). The Company is registered and domiciled in New Zealand for the purpose of developing and commercialising innovative diagnostic and prognostic tools for the early detection and management of cancers. Pacific Edge Diagnostics New Zealand Limited and Pacific Edge Diagnostics USA Limited manage and operate the laboratories used for the detection of bladder cancer. Pacific Edge (Australia) Pty Limited's purpose is to research and develop the Cxbladder products and other prognostic tools. Pacific Edge Diagnostics Singapore Pte Limited's purpose is sales and marketing of bladder cancer products and assisting with research and development. Pacific Edge Analytical Services Limited is a dormant entity.

The Company is a for profit entity, registered in New Zealand under the Companies Act 1993 and is a reporting entity for the purposes of the Financial Markets Conduct Act 2013. The Company is dual listed, with its primary listing of ordinary shares quoted in New Zealand on the NZX Main Board, and a secondary listing in Australia as a Foreign Exempt Entity on the ASX.

a) Basis of Preparation of Financial Statements

The Interim Financial Statements for the six months ended 30 September 2022 have been prepared in accordance with New Zealand Generally Accepted Accounting Practice (GAAP) and the Financial Markets Conduct Act 2013. They comply with the New Zealand Equivalents to International Financial Reporting Standards (NZ IFRS) and other guidance as issued by the External Reporting Board, as appropriate for entities, and with International Financial Reporting Standards.

The Interim Financial Statements have been prepared in accordance with NZ IAS 34 - Interim Financial Reporting. In complying with NZ IAS 34, these consolidated Interim Financial Statements also comply with IAS 34 - Interim Financial Reporting and should be read in conjunction with the Company's 2022 Annual Report. The Interim Financial Statements for the six months ended 30 September 2022 are unaudited. Comparative balances for 30 September 2021 are unaudited, whilst the comparative balances for 31 March 2022 are audited.

The Interim Financial Statements are prepared on the basis of historical cost, except where otherwise identified. The presentation currency used in the preparation of the financial statements is New Zealand dollars and all values are rounded to the nearest thousand dollars ($000).

b) Accounting Policies and Accounting Estimates

All significant accounting policies have been applied on a basis consistent with those used in the audited financial statements of Pacific Edge Limited for the year ended 31 March 2022.

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2022

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

The Interim Financial Statements were authorised by the Board of Directors on 23 November 2022. The Annual Financial Statements for the year ended 31 March 2022 were authorised by the Board of Directors on 25th May 2022.

c) Audit

The Interim Financial Statements have not been audited. The comparative full year financial results for the year ended 31 March 2022 have been audited.

d) Basis of Consolidation

The following entities and the basis of their inclusion for consolidation in these Interim Financial Statements are as follows:

			Ownership Interests & Voting Rights	
Name of Subsidiary	Place of Incorporation (or registration) and Operation	Principal Activity	30 Sept 2022 (%)	30 Sept 2021 (%)
Pacific Edge Diagnostics New Zealand Limited	New Zealand	Commercial Sales and Diagnostic Laboratory Operation	100	100
Pacific Edge (Australia) Pty Limited	Australia	Biotechnology Research & Development	100	100
Pacific Edge Diagnostics USA Limited	USA	Commercial Sales and Diagnostic Laboratory Operation	100	100
Pacific Edge Diagnostics Singapore Pte Limited	Singapore	Commercial Sales and Biotechnology Research & Development	100	100
Pacific Edge Analytical Services Limited	New Zealand	Dormant Company	100	100

2. INVESTMENTS IN AND ADVANCES TO SUBSIDIARIES

The consolidated Interim Financial Statements incorporate the assets and liabilities and results of Pacific Edge Diagnostics New Zealand Limited, Pacific Edge (Australia) Pty Limited, Pacific Edge Diagnostics USA Limited, Pacific Edge Diagnostics Singapore Pte Limited and Pacific Edge Analytical Services Limited, all of which are 100% owned by the Company. Subsidiaries have a 31 March balance date. The investments in and advances to subsidiaries are eliminated on consolidation in the Group financial statements.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

Other Operating Expenses

The major categories of expenditure which make up operating expenses, but are not disclosed separately on the previous page: Laboratory costs, Information Technology costs, Compliance and Regulatory costs and Investor Relations costs.

6. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer who makes strategic decisions.

There are two operating segments at balance date:

1. **Commercial**: The sales, marketing, laboratory and support operations to run the commercial businesses worldwide.
2. **Research**: The research and development of diagnostic and prognostic products for human cancer.

The reportable operating segment Commercial derives its revenue primarily from sales of Cxbladder tests and the reportable operating segment Research derives its revenue primarily from grant income. The Chief Executive Officer assesses the performance of the operating segments based on their net result for the period.

Segment income, expenses and profitability are presented on a gross basis excluding inter-segment eliminations to best represent the performance of each segment operating as independent business units. The segment information provided to the Chief Executive Officer for the reportable segment described above, for the six months ended 30 September 2022, is shown on the followng page.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

Unaudited 6 Months to 30 September 2022	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total ($000)
Income				
Operating Revenue - External	8,707	-	-	8,707
- Internal	-	-	-	-
Other Income	237	1,287	(763)	761
Interest Income	3	1,096	-	1,099
Foreign Exchange Gain	8	3,018	-	3,026
Total Income	**8,955**	**5,401**	**(763)**	**13,593**
Expenses				
Expenses	16,280	7,749	(763)	23,266
Depreciation & Amortisation	594	304	-	898
Total Operating Expenses	**16,874**	**8,053**	**(763)**	**24,164**
Loss Before Tax	**(7,919)**	**(2,652)**	**-**	**(10,571)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(7,919)**	**(2,652)**	**-**	**(10,571)**
Net Cash Flow to Operating Activities	**(8,478)**	**(5,494)**	**-**	**(13,972)**

Audited 12 Months to 31 March 2022	Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total ($000)
Income				
Operating Revenue - External	11,445	-	-	11,445
- Internal	-	-	-	-
Other Income	437	2,187	(933)	1,691
Interest Income	2	547	-	549
Foreign Exchange Gain	-	193	-	193
Total Income	**11,884**	**2,927**	**(933)**	**13,878**
Expenses				
Expenses	20,378	12,737	(933)	32,182
Depreciation & Amortisation	977	507	-	1,484
Total Operating Expenses	**21,355**	**13,244**	**(933)**	**33,666**
Loss Before Tax	**(9,471)**	**(10,317)**	**-**	**(19,788)**
Income Tax Expense	-	-	-	-
Loss After Tax	**(9,471)**	**(10,317)**	**-**	**(19,788)**
Net Cash Flow to Operating Activities	**(8,620)**	**(8,932)**	**-**	**(17,552)**

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

Unaudited 6 Months to 30 September 2021		Commercial ($000)	Research ($000)	Less: Eliminations ($000)	Total ($000)
Income					
Operating Revenue	- External	5,378	-	-	5,378
	- Internal	-	-	-	-
Other Income		239	1,034	(526)	747
Interest Income		1	107	-	108
Foreign Exchange Gain		-	497	-	497
Total Income		**5,618**	**1,638**	**(526)**	**6,730**
Expenses					
Expenses		9,137	6,396	(526)	15,007
Depreciation & Amortisation		481	227	-	708
Total Operating Expenses		**9,618**	**6,623**	**(526)**	**15,715**
Loss Before Tax		**(4,000)**	**(4,985)**	**-**	**(8,985)**
Income Tax Expense		-	-	-	-
Loss After Tax		**(4,000)**	**(4,985)**	**-**	**(8,985)**
Net Cash Flow to Operating Activities		**(3,393)**	**(5,223)**	**-**	**(8,616)**

Eliminations

These are the intercompany transactions between the subsidiaries and the Parent. These are eliminated on consolidation of Group results.

Total Laboratory Throughput

Unaudited	Commercial (#tests)	Research (#tests)	Total (#tests)
6 months ended 30 September 2022	12,422	2,495	14,917
12 months ended 31 March 2022	19,196	3,890	23,086
6 months ended 30 September 2021	9,192	1,944	11,136

Laboratory Throughput is a key metric for the Group: Laboratory Throughput provides evidence of the usage of Cxbladder products globally and the rates of adoption between different customer segments. Total Laboratory Throughput includes commercial tests, which are invoiced to customers, and research tests which are not considered to be billable as these tests relate to user programs or other non-chargeable activities.

Commercial test numbers are also a key metric for the Group: Commercial Tests are those tests for which the Company is actively seeking reimbursement and cash receipts, and tests performed at no charge in order to gain new customers.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

Segment Assets and Liabilities Information

Unaudited as at 30 September 2022	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	8,906	97,851	106,757
Total Liabilities	5,990	1,924	7,914

Audited as at 31 March 2022	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	6,031	109,251	115,282
Total Liabilities	4,571	2,335	6,906

Unaudited as at 30 September 2021	Commercial ($000)	Research ($000)	Total ($000)
Total Assets	5,529	94,441	99,970
Total Liabilities	4,073	2,502	6,575

Additions to non-current assets for the period include:

	Commercial ($000)	Research ($000)	Total ($000)
Property, Plant & Equipment	487	17	504
Right of Use Assets	-	-	-
Intangible Assets	441	30	471
Total Additions to Non Current Assets	**928**	**47**	**975**

The amounts provided to the Chief Executive Officer with respect to total assets and total liabilities are measured in a manner consistent with that of the financial statements. These assets and liabilities are allocated based on the operation of the segment and the physical location of the asset.

There are no unallocated assets or liabilities.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

Geographic Split of Revenue and Non-Current Assets

The Group generates most of the operating revenue from Commercial tests from the US and New Zealand, and also receives Grant revenue from Australia and New Zealand. Rest of World consists of Revenue from Australia and Singapore.

	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Operating and Other Revenue			
US	8,299	4,982	10,640
New Zealand	638	915	1,729
Rest of World	531	228	767
Total Operating and Grant Revenue	**9,468**	**6,125**	**13,136**

	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Non-Current Assets			
US	1,500	1,866	1,611
New Zealand	2,544	1,649	2,057
Rest of World	-	5	-
Total Non-Current Assets	**4,044**	**3,520**	**3,668**

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2022

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

7. SHARE CAPITAL

	Sept 2022 Shares 6 Months Shares (000)	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Opening Balance	**810,087**	**294,139**	**190,305**	**190,305**
Issue of Ordinary Shares - Placement			80,000	103,487
Issue of Ordinary Shares - Exercise of Share Options			1,175	4,040
Issue of Ordinary Shares - Employee Remuneration[1]	93	93	172	172
Less: Issue Expenses		(2)	(3,955)	(3,865)
Movement	**93**	**91**	**77,392**	**103,834**
Closing Balance	**810,180**	**294,230**	**267,697**	**294,139**

[1] During the period 92,985 shares were issued as part of employees remuneration in lieu of cash payments at an average price of $1.00 per share. (Six months to September 2021 and Twelve months to March 2022: 123,086 at $1.40).

There are 810,180,218 (September 2021: 788,469,244 and March 2022: 810,087,233) ordinary shares on issue.

All fully paid shares in the Company have equal voting rights and equal rights to dividends. All Ordinary Shares are fully paid and have no par value.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

8. RECONCILIATION OF CASH USED IN OPERATING ACTIVITIES WITH OPERATING NET LOSS

	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Net Loss for the Period	(10,571)	(8,985)	(19,788)
Add Non Cash Items:			
Depreciation	206	127	263
Loss on disposal of Property, Plant and Equipment	16	-	11
Amortisation	123	54	156
Employee Share Options	567	397	839
Employee bonuses paid in shares in lieu of cash	93	172	172
Depreciation on right of use assets	569	526	1,064
Interest on finance leases shown in lease repayments	46	69	126
Total Non Cash Items	**1,620**	**1,345**	**2,631**
Add Movements in Other Working Capital items:			
(Increase) in Receivables and Other Assets	(2,493)	(484)	(1,772)
(Increase) in Inventory	(500)	(166)	(217)
Increase in Payables and Accruals	998	172	1,786
Effect of exchange rates on net cash	(3,026)	(498)	(192)
Total Movement in Other Working Capital	**(5,021)**	**(976)**	**(395)**
Net Cash Flows to Operating Activities	**(13,972)**	**(8,616)**	**(17,552)**

9. CONTINGENT LIABILITIES

There were no known contingent liabilities at 30 September 2022 (September 2021: Nil and March 2022: Nil). The Company and Group have not granted any securities in respect of liabilities payable by any other party whatsoever.

10. CAPITAL COMMITMENTS

There are no capital commitments at 30 September 2022 (September 2021: Nil and March 2022: Nil).

11. SUBSEQUENT EVENTS

There are no subsequent events.

PACIFIC EDGE LIMITED CONSOLIDATED INTERIM FINANCIAL STATEMENTS 2022

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

12. RELATED PARTIES

Details of all related party relationships have been disclosed in the annual report for the year ended 31 March 2022. No new transactions with directors or key mangement personnel occurred that would be considered a related party.

13. PROPOSED LOCAL COVERAGE DETERMINATION (LCD) CHANGES - POTENTIAL IMPACT ON REVENUE

On 29 July 2022 Pacific Edge Limited became aware of proposed changes by Novitas, the Medicare Administrative Contractor (MAC) with jurisdiction for Pacific Edge's US laboratory to the LCD that governs the reimbursement of Cxbladder in the US by the US Centres for Medicare & Medicaid Services (CMS).

If the proposed LCD was approved unchanged, Cxbladder would not qualify for coverage from Novitas for tests reimbursed by the CMS. These tests represent a significant portion of current Cxbladder testing revenue. Multiple companies with dozens of diagnostic tests that have existing coverage or are seeking coverage, would similarly be impacted by this proposal.

Having consulted with US-based advisers and industry experts, Pacific Edge believes the proposed changes are unlikely to survive the ongoing review process in their current form. The consensus view Pacific Edge received was that the proposed changes to the LCD are contrary to US legal requirements and precedent. The proposed changes also fundamentally change the process for determining coverage for specific tests and could deprive US clinicians and Medicare patients access to diagnostic tools with proven, peer-reviewed clinical utility.

Novitas closed the period for public comments on the proposals on 6 September 2022. Novitas has not provided a specific date for a decision, however Pacific Edge understands the proposed LCD expires if it is not notified within 12 months from the date of proposal of July 28 2022. Regardless of a positive or negative determination, Pacific Edge understands CMS is required to give Pacific Edge at least 45 days' notice of the effective determination date. Pacific Edge continues to receive payment in line with the existing LCD.

Full details of the market update relating to the proposed LCD can be found by following the link below.

https://www.nzx.com/announcements/396175

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2022

14. NET TANGIBLE ASSETS

Accounting Policy

Net Tangible Assets per share is a non-GAAP measure that is required to be disclosed by the NZX Listing Rules. The calculation of the Group's Net Tangible Assets per share and it's reconciliation to the consolidated balance sheet is presented below.

	Unaudited Sept 2022 6 Months ($000)	Unaudited Sept 2021 6 Months ($000)	Audited March 2022 12 Months ($000)
Total Assets	106,757	99,970	115,282
Less Intangible Assets	784	231	434
Less Total Liabilities	7,914	6,575	6,906
Net Tangible Assets	**98,059**	**93,164**	**107,942**
Number of Shares Issued (000's)	810,180	788,469	810,087
Net Tangible Assets per share	**$0.121**	**$0.118**	**$0.133**

PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

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NZX
NEW ZEALAND'S EXCHANGE
TE PAEHOKO O AOTEAROA

Template
Results announcement
(for Equity Security issuer/Equity and Debt Security issuer)

Updated as at 17 October 2019

Results for announcement to the market		
Name of issuer	Pacific Edge Limited	
Reporting Period	6 months to 30 September 2022	
Previous Reporting Period	6 months to 30 September 2021	
Currency	NZD (New Zealand Dollar)	
	Amount (000s)	**Percentage change**
Revenue from continuing operations	Operating revenue $8,707 Other income $4,886	Operating revenue 62% increase Other income 261% increase
Total Revenue	$13,593	102% increase
Net profit/(loss) from continuing operations	($10,571)	18% increase in loss
Total net profit/(loss)	($10,571)	18% increase in loss
Interim/Final Dividend		
Amount per Quoted Equity Security	The Company does not propose to pay dividends to shareholders	
Imputed amount per Quoted Equity Security	Not applicable	
Record Date	Not applicable	
Dividend Payment Date	Not applicable	
	Current period	**Prior comparable period**
Net tangible assets per Quoted Equity Security	$0.121	$0.118
A brief explanation of any of the figures above necessary to enable the figures to be understood	For commentary on the results, please refer to the commentary in the released NZX release. Further information is also set out in the unaudited financial statements of the Company for the 6 months to 30 September 2022 which accompany this information.	
Authority for this announcement		
Name of person authorised to make this announcement	Grant Gibson – Chief Financial Officer	
Contact person for this announcement	Grant Gibson	
Contact phone number	+64 (3) 479 5800	
Contact email address	grant.gibson@pelnz.com	
Date of release through MAP	24/11/2022	

Unaudited financial statements accompany this announcement.