Company Announcement
21 November 2019

PACIFIC EDGE FY20 INTERIM RESULTS AND CAPITAL RAISING

Results Snapshot for the six months to 30 September 2019 (compared to prior comparable period (pcp))

Lift in laboratory throughput, commercial test revenue and cash receipts:

- Cash receipts from customers grew to $2.4m, a 16% increase on pcp and a 37% increase on 2H19.
- Operating revenue from test sales increased 12% to $2.3m, with total revenue for the period of $2.7m.
- Total laboratory throughput (which includes commercial sales as well as tests from User Programmes) grew to 8,147 tests, a 10% increase.
- Total laboratory throughput for the PEDNZ business (New Zealand, Australia and Singapore), grew to 1,896 tests, a 50% increase, driven by continued strong demand from public healthcare providers in New Zealand and User Programmes in South East Asia.
- Total billable tests grew to 6,573 tests, an 8% increase.
- Total operating expenses were $(12.1m), a 6% increase.
- Net operating cash outflow reduced to $(7.4m), a 14% decrease.
- Overall, the Company reported a net loss of $9.4m for the half year period, an 8% increase on pcp.
- Pacific Edge had cash, cash equivalents and short term deposits of $4.7m as at 30 September 2019.
- Pacific Edge has today announced a fully underwritten capital raising of approximately $20 million via an initial placement and subsequent 1 for 4.25 pro-rata renounceable rights offer, to assist the Company to progress its commercial objectives and become cash flow positive as soon as possible. The capital raise is fully underwritten by Forsyth Barr Group Limited and Jarden Partners Limited.

Summary of Key Commercial Milestones in the Half Year Period:

- Cxbladder inclusion in USA's National Comprehensive Cancer Network (NCCN)[1] guidelines as an approved intervention for patients being monitored for recurrence of urothelial cancer (UC), further validating Cxbladder and enabling increased use by clinicians.
- Continuing adoption and increasing test use by New Zealand public healthcare providers (DHBs), with increasing commercial use expected to continue to positively impact commercial test throughput growth in 2H20.
- Publication of two further papers in peer-reviewed journals, including the world's number one urology journal, adding significant additional clinical utility evidence in support of Cxbladder.
- Updated dossier of clinical evidence accepted for formal review by the Centers for Medicare and Medicaid Services (CMS) in the USA, as part of process for inclusion in the Local Coverage Determination (LCD) for the USA market. A successful inclusion in the LCD, combined with the recently announced inclusion in the NCCN guidelines, is expected to be transformational to test adoption, revenue growth and operating cashflow.

[1] National Comprehensive Cancer Network (NCCN) guidelines provide urology guidelines for physicians treating and managing patients with cancer and are reviewed annually. Cxbladder received inclusion in the July 2019 update to the NCCN guidelines.

- Growing recognition and adoption by large healthcare institutions in the USA, with a growing number of very large and reputable healthcare providers and academic centres growing their commercial use of Cxbladder or currently evaluating Cxbladder for commercial use.
- Continuing progress in South East Asia with clinical trials with the five largest public hospitals in Singapore nearing completion. Published results from these will form the basis for a proposed Singapore-wide commercial programme.

Further details on key milestones can be viewed on pages 4 to 6 of this announcement.

Commercial Progress:

Cancer diagnostics company, Pacific Edge Limited (NZX: PEB) (**Pacific Edge** or the **Company**) is reporting increased cash receipts, revenue and laboratory throughput for the first half of the 2020 financial year (1H20) as its Cxbladder diagnostic tests are adopted into guidelines in the USA and New Zealand, with further endorsement of performance in published clinical papers.

The Company is making good progress in its target markets of the USA, New Zealand, Australia and South East Asia, with a number of important commercial achievements in the six-month period. The focus remains on gaining inclusion in the LCD for CMS patients in the USA and accelerating the commercial adoption of the suite of Cxbladder tests in all of the Company's target markets. A successful LCD inclusion decision, in combination with the recent inclusion in guidelines in New Zealand and the USA, is expected to result in strong increases in test adoption, revenue growth and operating cash flow.

The annual addressable market for the suite of Cxbladder products was estimated by EY Parthenon[2] as being US$1.2 billion. Management is focused on completing agreements for the adoption and commercial use of Cxbladder and building sales from the large institutional accounts and payers Pacific Edge is targeting in the USA, including Kaiser Permanente, Johns Hopkins Medicine, the Veterans Administration, Tricare, the CMS and other blue-chip institutions.

Demand from public healthcare providers in New Zealand is expected to continue to grow strongly and positively impact commercial test throughput volumes in the future, as remaining public healthcare providers start commercial use at scale, and those that have commenced, progress on to using more than one of the Cxbladder suite of products.

Additional peer reviewed papers are expected to be published in key urology journals over the second half of FY20, providing additional compelling evidence supporting the clinical utility of Cxbladder. The publication of these papers is also expected to support Pacific Edge's LCD application with the CMS.

CEO of Pacific Edge, David Darling, commented: "Pacific Edge continues to move ever closer to achieving its commercial goals, particularly in the USA, and significant progress is being made. Adoption of Cxbladder is growing and commercial sales are increasing. We remain focused on further accelerating the adoption of Cxbladder by large healthcare organisations, both in New Zealand and internationally, and growing our revenue. Gaining inclusion in the LCD for CMS patients in the USA remains our priority and we are working hard on the

[2] EY Parthenon review of Cxbladder products and commercial strategy in 2018

successful execution of this next phase of our global growth plan as we continue to progress our objective of taking Cxbladder to the world."

Chairman Chris Gallaher said: "The Board remain committed to the Company's strategy and to achieving the key milestone of cash flow breakeven. The management team have achieved a number of important outcomes over 1H20, maintaining our momentum and moving us closer towards attaining our commercial goals. The Board's focus remains on cash and cash management and ensuring the resources and capital are in place for Pacific Edge to realise its potential. As such, today we have announced a capital raise consisting of a placement and renounceable rights issue to shareholders."

Capital Raising

Pacific Edge has today announced a capital raising of $20 million via an up-front placement and subsequent 1 for 4.25 pro-rata renounceable rights offer, to assist the Company to progress its commercial objectives and become cash flow positive as soon as possible. The capital raising is fully underwritten by Forsyth Barr Group Limited and Jarden Partners Limited.

Pacific Edge intends to undertake a placement of new shares at $0.15 per share to raise up to approximately $7 million. The placement will occur today while Pacific Edge is in trading halt, with participants expected to include a range of institutional and wholesale investors from New Zealand and internationally.

Following completion of the placement, a rights offer of approximately $13.1 million will allow eligible shareholders to subscribe for 1 additional share for each 4.25 existing shares held on the record date at $0.10 per share. This represents a 34.0% discount to the theoretical ex-rights price and placement adjusted price of $0.152, based off last close of NZ$0.165 as at 20 November 2019.

The full terms and conditions of the rights issue will be contained in an offer document which will be distributed to all eligible shareholders (as defined in the offer document) after the proposed record date.

<u>Rights Issue Timetable</u>

- Shares quoted "ex-rights" and rights trading commence: 28 November 2019
- Record date for rights issue: 29 November 2019
- Offer document and entitlement and acceptance forms sent to eligible shareholders: 2 December 2019
- Rights trading cease: 5 December 2019
- Rights offer closes: 11 December 2019
- Settlement and allotment of rights offer shares: 18 December 2019

All dates and times are indicative only and subject to change.

ACHIEVEMENT OF KEY MILESTONES:

Cxbladder included in the USA's NCCN guidelines as an approved intervention for patients being monitored for recurrence of urothelial cancer.

Inclusion in guidelines underpins adoption and empowers physicians to use Cxbladder in the management of patients. It provides validation of the clinical evidence for Cxbladder and enables physicians to use Cxbladder more extensively, as many healthcare providers are not able to fully use Cxbladder without coverage in guidelines. Inclusion most commonly occurs after significant adoption by physicians and, therefore, most often occurs after inclusion in the Local Coverage Determination (LCD), a driver of test adoption. The inclusion of Cxbladder in the July 2019 NCCN guidelines as an approved clinical intervention for high risk patients being monitored for recurrence of urothelial cancer, is ahead of the Company's expectations and is expected to have a positive impact on test sales growth in the USA.

Continuing adoption and increasing test use by New Zealand public healthcare providers (DHBs).

Validation from the New Zealand market continues to grow, with more than 60% of New Zealand's population now covered by contracts with national public healthcare providers. This is expected to increase as the Company works with the remaining public healthcare providers to increase coverage. The contribution from these providers is expected to continue to positively impact commercial test throughput in the second half of FY20.

The majority of the public healthcare providers in New Zealand have now adopted Cxbladder into their standard of care and in some instances, replacing the gold standard cystoscopy in both the evaluation of haematuria[3] and in the monitoring for recurrence of UC.

Many of the healthcare providers in Pacific Edge's other target markets of Australia, Singapore and the USA have similar challenges to New Zealand's public healthcare providers, with increasing demand for services, capacity limitations and constraints on servicing time, all of which may impact negatively on the patient. Accordingly, healthcare providers are continually looking for ways to deliver better care, more efficiently and cost effectively and the successful healthcare provider look-back audits are of particular interest to these parties.

Further publications of Cxbladder clinical utility performance in peer-reviewed journals adds significant additional evidence supporting reimbursement of Cxbladder.

Peer reviewed publications are the trading currency of the med-tech world and underpin adoption of any new technology. These peer reviewed publications provide the clinical evidence that drives the successful inclusion in guidelines and positive coverage decisions for reimbursement.

In May 2019, a Cxbladder performance paper published in European Urology, the world's number one ranked Urology Journal, provided further compelling evidence validating the performance of Cxbladder in evaluating patients who have an inconclusive diagnosis for UC following cystoscopy and cytology. This is a significant milestone as less than 10% of the more than 2,000 annual urology papers submitted to this journal meet peer

[3] Haematuria is blood in the urine and is a symptom of bladder cancer requiring patients to be evaluated for the presence of urothelial cancer

review and are published. Key conclusions showed that Cxbladder does what existing urological technology cannot currently do, correctly adjudicating atypical cytologies and equivocal cystoscopies and also accurately ruling out 35% of patients who do not have cancer and thereby avoiding unnecessary invasive procedures.

In June 2019, public healthcare provider Canterbury District Health Board (CDHB) published a real-world clinical audit, highlighting a significant increase in clinical utility evidence and cementing the adoption of Cxbladder into the new clinical pathway for the assessment of haematuria in New Zealand. This independent, real-world evidence publication highlighted the benefits of using Cxbladder in conjunction with imaging for the initial assessment of all patients that present to the clinic with haematuria for investigation for bladder cancer, giving rise to the new clinical guidelines. The results showed that this new clinical guideline would result in approximately one third of patients avoiding the need for invasive and expensive cystoscopy procedures. Whereas previously these patients would have received a full clinical work-up, they will now be managed within primary care and will not be referred through to secondary care, delivering positive outcomes for both the patient and the healthcare provider.

The cumulative and extensive clinical evidence in the peer reviewed publications on Cxbladder, in conjunction with successful healthcare provider look-back audits, demonstrates significant increases in clinical utility from the adoption and deployment of Cxbladder for both the patient and the healthcare provider. This is expected to result in further positive reimbursement outcomes.

Presentations of this clinical evidence at international conferences and workshops by key opinion leader (KOL) urologists are an important component in building awareness of Cxbladder. A growing number of these KOL events have been held with international and New Zealand urologists sharing their positive experience of the adoption of Cxbladder with their global peers.

Updated dossier of clinical evidence accepted for formal review by the CMS, as part of process for inclusion in the Local Coverage Determination (LCD) for the USA market.

Gaining inclusion in the LCD, which would enable reimbursement from the CMS in the USA, remains a priority focus for Pacific Edge. Clinical evidence is the critical component for consideration for inclusion in the LCD, and an updated dossier of clinical evidence was submitted and accepted for review by the CMS in August 2019.

The CMS currently accounts for approximately 47% of the Company's total annual laboratory throughput in the USA. As at 30 September 2019, Pacific Edge had completed and invoiced a total of 19,361 tests for CMS patients, which are yet to be reimbursed. A successful inclusion in the CMS's LCD is expected to provide a number of commercial benefits including a significant acceleration in test adoption and revenue growth, receipt of payment for future tests performed on CMS patients, improved cash collection time for private insurance payers and the opportunity to negotiate a retrospective payment for invoiced tests previously carried out on CMS patients that currently exceed 19,000 tests.

Growing recognition and adoption by large healthcare institutions in the USA.

Pacific Edge is building on the success achieved with large healthcare providers in New Zealand as it continues to roll out its growth strategy in the USA, with increasing engagement from large institutional healthcare providers that have the potential to be scale users of Cxbladder.

The USA remains the primary commercial opportunity for Pacific Edge, with a growing number of very large and reputable healthcare providers and academic centres such as Johns Hopkins Medicine, Cleveland Clinic and Mount Sinai Hospital growing their commercial use of Cxbladder. An additional 15 healthcare institutions are also currently evaluating Cxbladder for commercial use. Many of these organisations individually, are bigger than any one of New Zealand's public healthcare providers.

Continuing progress in South East Asia.

South East Asia (SEA) has been identified as a significant potential market for Cxbladder. The population of SEA is more than double the size of the population of the USA and therefore presents a large target addressable market for Cxbladder going forward. Pacific Edge has its beachhead for SEA in Singapore and clinical trials with the five largest public hospitals in Singapore are nearing completion. The Company expects to publish the results from these clinical trials in the coming months and they will form the basis for a proposed Singapore-wide commercial programme. The focus remains on transitioning these hospitals to commercial customers and growing the adoption of Cxbladder with other large healthcare organisations in the region. In Australia, Pacific Edge has taken over the sales and distribution of Cxbladder, building on the successful practices developed in the New Zealand market.

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For more information contact:

David Darling
Chief Executive Officer
Pacific Edge Ltd
P: +64 (3) 479 5800

OVERVIEW www.pacificedge.co.nz www.pacificedgedx.com
Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. Its Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The Company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The Company's products have been tested and validated in international multi-centre clinical studies.

ABOUT Cxbladder Triage www.cxbladder.com
Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients
with haematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial carcinoma.

ABOUT Cxbladder Detect www.cxbladder.com
Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor www.cxbladder.com

Cxbladder Monitor allows urologists to monitor bladder cancer patients for recurrence of the disease. Bladder cancer has a recurrence rate of 50-80% and requires life-long surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

ABOUT Cxbladder Resolve www.cxbladder.com
Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.