PACIFIC EDGE LIMITED ANNOUNCES IMPROVED RESULT AND CAPITAL RAISING

Pacific Edge has announced an improved half year performance and capital raising to assist the company to progress its commercial objectives.

(NZ$'000)	1H19 (unaudited)	1H18 Restated (unaudited)	1H18: 1H19 (% change)
Operating Revenue (test sales)	2,033	1,425	43%
Other Revenue	606	627	(3%)
Total Revenue	**2,639**	**2,052**	**29%**
Operating Expenses	11,358	12,091	(6%)
Net Loss	**8,719**	**10,039**	**(13%)**
Net operating cash outflow	(8,612)	(10,185)	(15%)
Cash on hand as at 30 September (cash, cash equivalents and short term deposits)	10,060	3,997	152%

- Revenue from test sales up 43% on prior comparative first half year period (pcp).
- Billable test volumes up 12%, relative to a strong pcp and currently account for 82% of total laboratory throughput.
- Net operating cash outflow has reduced to ($8.6m) for the period, a 15% decrease on the previous first half year.
- Commercial adoption of Cxbladder by national healthcare providers is at a high level in Pacific Edge's home market of New Zealand and continues to improve, with 62% coverage providing significant local and international validation (1H18: 36% coverage).
- Completion of two of the three milestones required for the USA national reimbursement being receipt of product codes and notification of a national price (US$760 per test).
- Increased focus on large healthcare organisations in all markets is providing commercial traction; resulting in the commercial evaluation of Cxbladder by Johns Hopkins Medicine, an US$8 billion integrated global health enterprise and one of the leading health care systems in the USA.
- Commercial engagement with Raffles Medical Group and User Programmes with the five largest hospitals in Singapore is driving strong engagement with other potential strategic partners across South East Asia.
- Pacific Edge intends to undertake a placement of up to $7m of new shares, followed by a share purchase plan of up to $5m, to assist the company to progress its commercial objectives and become cash flow positive as soon as possible.

Cancer diagnostics company, Pacific Edge Limited (NZX: PEB) has today announced its preliminary, unaudited results for the six months to 30 September 2018 (1H19), reporting a 43% increase in test sales, a 15% decrease in operating cash outflow and a 13% reduction in the net loss for the period.

The company, which is primarily focused on the US$1.2 billion annual addressable market[1] for its Cxbladder bladder cancer diagnostic test in the USA, continues to grow sales and build awareness amongst leading urologists and healthcare institutions.

The FY19 financial year to date has seen some notable firsts, including Cxbladder being added into local guidelines for several of the public healthcare providers in New Zealand, engagement with a number of large healthcare organisations including commencement of a commercial evaluation with Johns Hopkins Medicine, and notification of the national CMS reimbursement price in the USA of US$760 per test.

[1] EY Parthenon review of Cxbladder market size in the USA. Company strategy review document.

Validation from the New Zealand market is now at high levels, with approximately 62% of New Zealand's population now covered by contracts with the national public healthcare providers (up from 36% at the same time last year). This is expected to increase further as remaining providers come on board. The majority have now adopted Cxbladder into their standard of care and, in some cases, their clinical guidelines, replacing the gold standard cystoscopy. The company expects to see the contribution from New Zealand's public healthcare providers positively impact on commercial test throughput in the second half of FY19.

The USA market remains the priority for Pacific Edge. Management is focused on completing agreements and building sales from the large institutional accounts and payers it is targeting, including Kaiser Permanente, the recently announced Johns Hopkins Medicine, the Veterans Administration and Tricare, the CMS and other blue chip institutions.

The company has now completed two of the three cornerstones of the USA national reimbursement process, and progress continues to be made with the third of these cornerstones, which is to have Cxbladder included in the Local Coverage Determination (LCD). This will allow for reimbursement of tests used by patients covered by the CMS. The process is largely driven by peer reviewed, published clinical and utility evidence for the Cxbladder products, with a general 'rule of thumb' being that it takes around five years to generate the specific evidence and gain inclusion into the LCD. Pacific Edge commenced the LCD process in 2014 and continues to make good progress.

Following the success in New Zealand with the increased uptake by the national public healthcare providers, Pacific Edge has increased its focus on large institutional healthcare organisations in its USA, South East Asia and Australasian markets. While these customers can take longer to bring to completion, once commercial agreement is reached they can provide significant volume, require lower sales maintenance and deliver more sustainable, longer term growth opportunities.

User Programmes are now underway with all five targeted hospitals in Singapore. Several are nearing completion and the focus is on transitioning these to commercial customers. In Australia, Pacific Edge has taken over the sales and distribution of Cxbladder, building on the successful practices developed in the New Zealand market.

Adoption of Cxbladder is growing and commercial sales are increasing. Pacific Edge has experienced a year on year 12% lift in billable tests in 1H19, consolidating and growing on the strong numbers in 1H18. Total laboratory throughput, which includes commercial sales as well as tests from User Programmes, grew to 7,397 tests in 1H19.

Operating revenue[2] from test sales was up 43% to $2.0m, with total revenue for the period of $2.6m. The company accounts for its US revenue on a cash basis, and therefore operating revenue excludes tests sold in the US for which cash payment has yet to be received, as well as tests completed for patients covered by the CMS[3]. The average payment received per test by Pacific Edge is dependent on the mix of payers and insurance plans of each patient and can vary significantly from period to period.

Pacific Edge has a prudent approach to its investment into the growth of the company. Total operating expenses for the half year were down 6% to $11.4m with revenue outgrowing expenses by a net 13%. Operating expenses include research and development costs of $1.7m (a 23% year on year decrease), with the remainder being direct operating costs.

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[2] Pacific Edge adopted NZ IFRS 15 in FY18. This means revenue for US based customers is now only recognised when the cash is received. Under the previous accounting standard, which took into account all tests sold but which may not have yet been paid for, operating revenue would have been $5.6m in 1H19, compared to $4.2m in 1H18 (an increase of 33%).

[3] CMS tests account for approximately 47% of annual US laboratory throughput and cumulatively totalled in excess of 14,000 tests as at 30 September 2018. Pacific Edge will seek reimbursement for these when it is included in the CMS's Local Coverage Determination (LCD). Until then, these tests remain in the billing and reimbursement process and revenue will be accounted for when the cash is received.

Net operating cash outflows reduced to ($8.6m) for the period, a 15% decrease on 1H18. Cash receipts from customers increased 22% to $2.0m with a large portion of the cash received in 1H19 being for tests sold in prior years.

Overall, the company reported a net loss of $8.7m for the half year, an improvement of 13% on the 1H18 loss of $10.0m.

Pacific Edge had $10.1m in cash, cash equivalents and short term deposits at 30 September 2018 (1H18: $4.0m), which includes the investment of approximately $2.6m by US private investment fund, Manchester Management Company, which specialises in biotech and life sciences investments. The company is undertaking a capital raise to assist in progressing its commercial objectives and becoming cash flow positive as soon as possible.

Outlook

Pacific Edge is expecting a stronger second half of FY19, in line with annual trends as Americans with private healthcare insurance reach their annual fixed deductible level[4]. The company also expects to see demand from public healthcare providers in New Zealand positively impact commercial test throughput volumes in the second half of FY19.

Laboratory throughput is expected to increase by 23% in the second half of FY19, taking laboratory throughput for the full year to approximately 16,500 tests (FY18: 14,448 tests)[5]. Approximately 82% of these tests are expected to be billable, equating to a 14% year on year increase in commercial test volumes. The expected laboratory throughput in FY19 excludes test volumes from any new commercial agreements which have yet to be signed. The New Zealand market is expected to contribute approximately 18% of total laboratory throughput in FY19 (FY18: 14%).

Forward growth in commercial tests in the US will benefit from having a national product specific code for Cxbladder and a national CMS reimbursement price. These milestones allow the company to move into the process of negotiating contract terms with private payers, which will enable a shortening of the overall commercial transaction time and a positive reduction in the time to receipt of cash.

CEO of Pacific Edge, David Darling, said: “Many of the foundations for commercial success have now been completed. We have a proven business model, as can be seen in the uptake of Cxbladder in New Zealand, and we are using learnings from this to replicate our success in other international markets.

“We are focused on growing adoption of Cxbladder by the large healthcare organisations which will be drivers of success in our business. Gaining inclusion in the Local Coverage Determination remains a priority.”

Chairman Chris Gallaher said that the Board remained committed to the company’s strategy and to achieving the key milestone of cashflow breakeven.

“The impact Cxbladder makes for the large healthcare providers that have burgeoning patient needs, few resources and need to show value changes for their clinical services, is very clear. We are looking forward to successfully executing on the next phase of our global growth plan as we continue to progress our objective of taking Cxbladder to the world.”

[4] Annual fixed deductible is the amount a patient must pay before their insurance cover commences and they start to undertake the medically recommended actions and treatments for which they will be reimbursed by their insurance company.

[5] The company’s estimate for laboratory throughput for FY19 is expected to fall within a range of 16,000 and 17,000 tests

Capital Raising

Pacific Edge intends to undertake a placement of new shares at $0.35 to raise up to $7 m. The placement will occur today while Pacific Edge is in trading halt, with participants including a range of institutional investors. Following completion of the placement, a Share Purchase Plan (SPP) of up to $5 m will allow each New Zealand resident shareholder to subscribe for additional shares at no greater than the placement price ($0.35). The full terms and conditions of the SPP will be contained in an offer document which will be distributed to all eligible shareholders after the proposed record date.

Placement Timetable	
Pacific Edge in trading halt	29 November
Placement undertaken	29 November
Pacific Edge expected to resume trading	30 November
Allotment and Settlement of placement shares	5 December

Share Purchase Plan Timetable	
Record Date of SPP	7 December
Opening Date for SPP	10 December
Closing Date for SPP	25 January 2019
Allotment and Settlement of SPP shares	31 January 2019

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

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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 (UC) 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.