

Pacific Edge

CMS reimbursement obtained

Pacific Edge announced that it has successfully gained inclusion into a local coverage determination (LCD) enabling reimbursement at US\$760 per test from the US Centers for Medicare and Medicaid Services (CMS). This reimbursement decision covers the Cxbladder Detect and Cxbladder Monitor products that currently account for 93% of the total laboratory throughput in the US for Cxbladder products. This is a transformative milestone for Pacific Edge as it should lead to greater usage of Cxbladder (both from CMS and private payers) as well as payment on tests previously performed. As a reminder, 21,789 Cxbladder tests were performed on CMS patients as of 31 March 2020, accounting for 43% of US commercial tests.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/19	4.8	(17.8)	(3.5)	0.0	N/A	N/A
03/20	5.0	(18.8)	(3.2)	0.0	N/A	N/A
03/21e	20.2	(4.6)	(0.6)	0.0	N/A	N/A
03/22e	44.1	17.4	2.3	0.0	25.2	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Kaiser Permanente signs on

Pacific Edge recently announced that Kaiser Permanente, one of the largest non-profit health providers in the US, has reached an agreement with the company on the commercial use of Cxbladder by its urologists. Kaiser Permanente has more than 12 million members, operates 39 hospitals and employs 23,000 physicians, so this commercial agreement is a major milestone for Pacific Edge, which we expect should provide a meaningful increase in revenues.

Cxbladder sales increased 14% in FY20

The company reported an increase in Cxbladder sales of 14% in FY20 to NZ\$4.4m with a 7% increase in total laboratory throughput to 16,861 tests. Sales in the rest of the world (primarily Australia, New Zealand and Singapore) were particularly strong and were also up 14% with a 12% increase in total laboratory throughput.

COVID-19 impact in April but already recovering

Due to COVID-19 related restrictions and lockdowns, April total laboratory throughput was about half (51%) of what it was in April 2019. The impact was mitigated in part by an in-home sampling option, as the healthcare industry puts a greater emphasis on telemedicine and other alternatives to in-person care. Due to easing restrictions and the in-home sampling option a recovery has already started.

Valuation: NZ\$538m or NZ\$0.78 per share

Our DCF-based valuation has been increased from NZ\$231m (NZ\$0.33/share) to NZ\$538m (NZ\$0.78/share). This increase is mainly due to markedly increasing our revenue estimates following CMS reimbursement and rolling forward our DCF, and was partially offset by lower net cash. We continue to expect profitability for FY22 and do not forecast any additional financing needs for the company.

Financial update

Healthcare equipment & services

20 July 2020

Price **NZ\$0.58**

Market cap **NZ\$400m**

NZ\$1.56/US\$

Net cash (NZ\$m) at 31 March 2020 14.8

Shares in issue 689.7m

Free float 91.6%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 138.3 413.8 199.0

Rel (local) 133.6 379.5 183.1

52-week high/low NZ\$0.60 NZ\$0.07

Business description

Pacific Edge develops and sells a portfolio of molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Tests utilising its Cxbladder technology for detecting and monitoring bladder cancer are sold in the US, New Zealand, Australia and Singapore.

Next events

Kaiser Permanente commercial launch CY20

Additional guideline inclusions CY20

Analysts

Maxim Jacobs +1 646 653 7027

Wiktorina O'Hare +1 646 653 7028

healthcare@edisongroup.com

[Edison profile page](#)

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Reimbursement is here

Pacific Edge has now completed all three components necessary for CMS reimbursement in the US, namely the attainment of product specific CPT codes, a national price of US\$760 per test and inclusion in an LCD. An LCD is a document that includes the coverage decisions of the Medicare Administrative Contractor (MAC) and provides the conditions of the coverage as well as the price, guidance on reimbursement and coding information. This LCD inclusion covers the Cxbladder Detect and Cxbladder Monitor products, which together currently account for 93% of the company's total laboratory throughput in the US (69% for Cxbladder Detect and 24% for Cxbladder Monitor).

Exhibit 1: Summary of the Cxbladder products

Product name	Function	Status	Notes
Cxbladder Detect	Detects bladder cancer in patients with haematuria.	Commercially available in NZ, Australia and the US since 2013.	Non-invasive laboratory test for the detection of bladder cancer. Adjunct to cystoscopy.
Cxbladder Triage	Segregates patients without bladder cancer.	Commercially available in NZ (2014), Australia and the US (2015).	High sensitivity and high negative predictive value.
Cxbladder Resolve	Classifies tumours as low or high grade.	Launched in New Zealand (2016) with US roll-out expected in late FY21.	Prognostic test with sensitivity and high specificity to patients with high-grade and late-stage disease.
Cxbladder Monitor	Ongoing monitoring to check for recurrence of bladder cancer.	Commercially available in NZ (2015) and the US (2016).	High sensitivity and high negative predictive value to determine patients who should receive follow-up tests.

Source: Pacific Edge

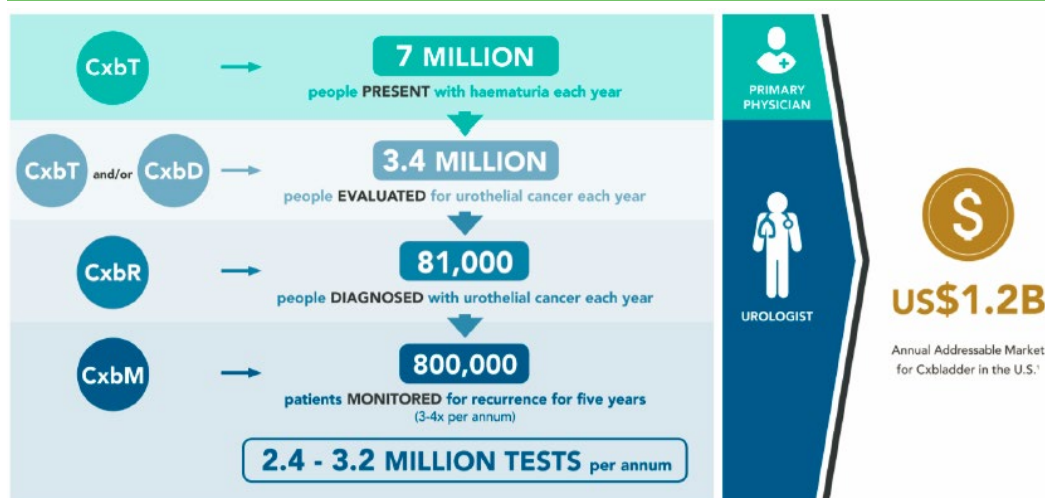
Now that LCD inclusion is attained, reimbursement from CMS (which currently represents approximately 43% of US Cxbladder commercial test volume) should become consistent and timely. Besides this immediate benefit of new tests being covered by CMS, the company will negotiate the payment terms for the 21,789 tests previously billed but not paid (as of 31 March 2020).

In addition, private payers often base their own coverage decisions and reimbursement levels on the coverage listed in an LCD, so the success here is expected to lead to faster growth for the company with other healthcare coverage providers. The company is also seeking a positive shift in guideline inclusion language in bladder cancer which may assist with obtaining additional private reimbursement.

Commercial agreement with Kaiser Permanente

Pacific Edge recently announced that Kaiser Permanente, one of the largest non-profit health providers in the US, has reached an agreement with the company on the commercial use of Cxbladder by its urologists in patients being evaluated for bladder cancer. Kaiser Permanente has more than 12 million members (approximately 3.6% of the US population), operates 39 hospitals and employs 23,000 physicians so this commercial agreement is a major milestone for the company, which we expect should provide a meaningful increase in revenues going forward. To illustrate the size of the opportunity with Kaiser Permanente, EY-Parthenon has previously estimated the size of the addressable market in the US to be US\$1.2bn (see Exhibit 2). It is unclear what percentage of tests are performed on Kaiser Permanente members, but if we assume it is 1.8% (half of its proportionate share of the population as a disproportionate number of tests are performed on people covered by CMS), this could be a US\$21.6m (NZ\$33.4m) per year opportunity for Pacific Edge.

Exhibit 2: Addressable market in the US



Source: Pacific Edge, based on an EY-Parthenon business review of the market

Importantly, Pacific Edge will be utilising in-home sampling to service Kaiser Permanente members, as the ability to do so has become extremely pertinent during the COVID-19 pandemic. Kaiser Permanente has been especially focused on telemedicine/telehealth and has [stated](#) that 95% of its adult and family medicine visits in Northern California are now virtual. Going forward, the ability to service patients remotely will be especially important. According to [McKinsey](#), only 11% of people in 2019 conducted telehealth compared to 46% today due to the pandemic. Additionally, 76% of consumers are now interested in using telehealth going forward. Regarding Pacific Edge's business, the company moved quickly with three public healthcare providers in New Zealand, commencing in-home sampling of Cxbladder in April.

Valuation

Our DCF-based valuation has been increased from NZ\$231m (NZ\$0.33/share) to NZ\$538m (NZ\$0.78/share). This uplift is mainly due to markedly increasing our revenue estimates following CMS reimbursement (as well as the Kaiser Permanente commercial agreement). Our peak sales estimate has increased from NZ\$164m to NZ\$228.5m as we have increased our product adoption estimates across the board (although we continue to estimate limited contribution from the South-East Asia region, which the company believes is a meaningful opportunity long term). Additionally, the valuation has increased due to rolling forward our DCF and was partially offset by lower net cash.

Exhibit 3: Valuation based on DCF

Discounted cash flow (NZ\$000)	523,095
Net cash (NZ\$000) at 31 March 2020	14,784
Valuation (NZ\$000)	537,879
Number of shares (m) as of 31 March 2020	689.7
Value per share (NZ\$)	0.78

Source: Edison Investment Research

Financials

Pacific Edge recently published FY20 results with operating revenue growth of 14% from NZ\$3.8m in FY19 to NZ\$4.4m. The US segment saw operating revenue increase 15% to NZ\$3.8m while it increased 14% in the rest of world (primarily Australia, New Zealand and Singapore) to NZ\$0.6m.

Total laboratory throughput increased 7% globally to 16,861 tests, with a 6% increase in the US and a 12% increase in the rest of the world. The US remains the company's largest market, accounting for 86% of group operating revenue and 78% of total laboratory throughput in FY20. Operating expenses for FY20 were reported as NZ\$24.1m, a 5% increase compared to the prior year. This increase in spending is partially the result of an increase in the number of US sales executives from 11 to 16 over the course of the year. The FY20 operating cash flow (excluding net interest) was negative NZ\$15.4m, an improvement over the negative NZ\$17.8m level in FY19.

The company also stated that due to COVID-19 related restrictions and lockdowns, total laboratory throughput in April was about half (51%) of what it was the previous April. The impact was mitigated in part by an in-home sampling option as the healthcare industry puts a greater emphasis on telemedicine and other alternatives to in-person care. Due to easing restrictions and the in-home sampling option, a recovery has already started. Additionally, Pacific Edge has been able to reduce costs to offset income reductions, and has received financial support in the form of COVID-19 relief packages from governments in New Zealand, Australia, Singapore and the US.

We are increasing our FY21 revenue estimate from NZ\$19.1m to NZ\$20.2m, following the recent announcements on CMS reimbursement and the Kaiser Permanente commercial agreement. We consider this estimate to be conservative as we are not including the full value of the backlog payment in FY21 revenues. The size of any backlog payment will be dependent on the success of the company's negotiations with the CMS. As a reminder, Cxbladder Detect and Cxbladder Monitor accounted for 93% of the company's total laboratory throughput in the US in FY20. Assuming 93% of the 21,789 CMS tests already performed (as of 31 March 2020) can now be paid for, we calculate a potential backlog payment of US\$15.4m (NZ\$23.8m), based on a US\$760 per test national price.

We are also conservative in our estimates for the contribution from the Kaiser Permanente commercial agreement. We calculate a NZ\$33.4m annual opportunity for Pacific Edge with Kaiser Permanente but the pace of the ramp-up is unknown and the benefit to FY21 revenues will only be for a partial year.

We are also introducing our FY22 estimates, which include NZ\$44.1m in revenues as well as full year profitability (see Exhibit 4).

Exhibit 4: Financial forecast changes

	FY21e		FY22e
	Old	New	New
Revenue (NZ\$m)	19.1	20.2	44.1
PBT (normalised) (NZ\$m)	(5.8)	(4.6)	17.4
EPS (NZ\$)	(0.01)	(0.01)	0.02

Source: Edison Investment Research

During FY20, the company raised a total of NZ\$20.1m, and had net cash of NZ\$14.8m at 31 March 2020. Based on our current estimates, we believe the company will not need to raise additional capital.

Exhibit 5: Financial summary

	NZ\$'000s	2019	2020	2021e	2022e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS					
Revenue		4,807	4,954	20,177	44,052
Cost of Sales		(4,594)	(5,181)	(5,699)	(6,269)
Gross Profit		213	(227)	14,478	37,783
EBITDA		(17,840)	(17,703)	(3,522)	19,243
Operating Profit (before amort. and except.)		(18,077)	(19,007)	(5,087)	17,365
Intangible Amortisation		(154)	(123)	(148)	(177)
Exceptionals		(4)	(101)	0	0
Operating Profit		(18,235)	(19,231)	(5,235)	17,188
Other		0	0	0	0
Net Interest		323	249	444	0
Profit Before Tax (norm)		(17,754)	(18,758)	(4,643)	17,365
Profit Before Tax (FRS 3)		(17,912)	(18,982)	(4,791)	17,188
Tax		(9)	0	0	0
Profit After Tax (norm)		(17,763)	(18,758)	(4,643)	17,365
Profit After Tax (FRS 3)		(17,921)	(18,982)	(4,791)	17,188
Average Number of Shares Outstanding (m)		504.4	581.3	717.1	745.8
EPS - normalised (c)		(3.5)	(3.2)	(0.6)	2.3
EPS - FRS 3 (c)		(3.6)	(3.3)	(0.7)	2.3
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		1,002	2,412	2,254	2,067
Intangible Assets		233	179	100	(8)
Tangible Assets		769	652	573	494
Other		0	1,581	1,581	1,581
Current Assets		15,564	16,916	14,315	34,116
Stocks		842	796	796	796
Debtors		1,265	642	642	642
Cash		12,847	14,784	12,183	31,984
Other		610	694	694	694
Current Liabilities		(2,624)	(4,253)	(4,253)	(4,253)
Creditors		(2,572)	(3,270)	(3,270)	(3,270)
Short term borrowings		0	0	0	0
Short term leases		(52)	(983)	(983)	(983)
Other		0	0	0	0
Long Term Liabilities		(32)	(571)	(571)	(571)
Long term borrowings		0	0	0	0
Long term leases		(32)	(571)	(571)	(571)
Other long term liabilities		0	0	0	0
Net Assets		13,910	14,504	11,746	31,359
CASH FLOW					
Operating Cash Flow		(17,830)	(15,385)	(2,789)	19,991
Net Interest		323	(65)	444	0
Tax		0	0	0	0
Capex		(156)	(183)	(191)	(191)
Acquisitions/disposals		0	0	0	0
Financing		14,569	20,136	0	0
Dividends		0	0	0	0
Other		(275)	(2,342)	(65)	0
Net Cash Flow		(3,369)	2,161	(2,601)	19,800
Opening net debt/(cash)		(16,143)	(12,763)	(14,784)	(12,183)
HP finance leases initiated		15	0	0	0
Other		(26)	(140)	0	0
Closing net debt/(cash)		(12,763)	(14,784)	(12,183)	(31,984)

Source: Company reports, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia