

Pacific Edge

A growth year

Financial update

Pharma & biotech

Pacific Edge continues to make progress in the commercialisation of its bladder cancer diagnostics tests, reporting 35% growth in the number of tests analysed and a 62% increase in operating revenue. The potential for a significant sales ramp exists as TRICARE and the Veterans Administration (VA) are now under contract and expected to come online commercially in FY18. Also, discussions with Kaiser Permanente are nearing conclusion and progress has been made with the Centers for Medicare and Medicaid Services (CMS) on the reimbursement front.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/16	6.4	(15.5)	(4.1)	0.0	N/A	N/A
03/17	9.3	(20.8)	(5.4)	0.0	N/A	N/A
03/18e	18.5	(9.2)	(2.3)	0.0	N/A	N/A
03/19e	41.8	11.2	1.9	0.0	25.8	N/A

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

TRICARE and VA are significant opportunities

Pacific Edge has agreements in place with TRICARE, which handles the healthcare for a total of 9.4 million beneficiaries (uniformed service members and their families as well as some veterans) with a total of 70.5 million outpatient visits in 2015, and with the Veterans Administration (VA), with approximately 20 million people under coverage. Sales are expected to come online for both in FY18, although the exact timing and magnitude are unknown.

Kaiser Permanente in final discussions

Kaiser Permanente, a managed care provider that serves 11.8 million members, had been evaluating the Cxbladder Triage and Detect tests in a large, blinded User Programme. According to Pacific Edge, the findings were positive, compelling and equivalent to the previously published data. The company is now in final discussions with Kaiser regarding a commercial relationship.

Monitor and Resolve launches underway

Back in December, the company launched the Cxbladder Monitor test in the US and the Cxbladder Resolve test in New Zealand. Monitor is meant for use in the ongoing monitoring of bladder cancer in order to check for recurrence and Resolve classifies tumours as low or high grade. Pacific Edge is becoming a one-stop shop to detect and manage bladder cancer through non-invasive urine tests.

Valuation: NZ\$449m or NZ\$1.12 per share

Our valuation for Pacific Edge has increased from NZ\$422m (NZ\$1.10/share) to NZ\$449m (NZ\$1.12/share). This is mainly due to rolling forward our NPV and was mitigated by adjustments to sales and expense expectations as well as a higher share count. We continue to expect profitability in FY19. Net cash of NZ\$14.6m should fund operations into forecast profitability. We believe evidence of commercial success will serve as a driver of the valuation.

1 June 2017

Price **NZ\$0.49**

Market cap **NZ\$196m**

NZ\$1.42/US\$

Net cash (NZ\$m) at 31 March 2017 14.6

Shares in issue 399.5m

Free float 92%

Code PEB

Primary exchange NZX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (17.0) (7.6) (15.5)

Rel (local) (17.2) (9.4) (16.6)

52-week high/low NZ\$0.63 NZ\$0.43

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

Updates on product launches 2017

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Pacific Edge is a research client of Edison Investment Research Limited

A broad suite of products

Pacific Edge develops and commercialises molecular tests, three of which are being commercialised in the US, for the detection and better management of urothelial cancers (UC) and is the only company worldwide to offer multiple molecular diagnostic tests for bladder cancer. The company has created a franchise of products that can be commercialised through the same channels under the Cxbladder brand to meet a series of unmet needs along the same clinical pathway. The underlying aims are to meet the clinical needs of urologists, notably a reduction in the length of current, repetitive and invasive diagnostic testing for UC, and an improvement in accuracy over those tests currently in the market. The first test in the range, Cxbladder Detect, has been shown in clinical studies to be more accurate than benchmark tests at all stages and grades. Cxbladder Monitor targets patients who are currently undergoing follow-up surveillance for UC and was recently (December 2016) launched in the US. Cxbladder Triage is designed for undiagnosed patients that present with haematuria, and launched in New Zealand in 2015 and in the US in 2016.

Pacific Edge is working towards fully commercialising its bladder cancer testing, reporting a steady increase in volumes from existing customers in recent quarters, albeit off a low base and including healthcare organisations' testing through User Programmes.

Exhibit 1: Summary of the Cxbladder pipeline

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 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.
Cxbladder Resolve (formerly Predict)	Classifies tumours as low or high grade.	Launched in New Zealand (2016) with US roll-out in 2018.	Prognostic test with high sensitivity and high specificity to patients with high-grade and late-stage disease.

Source: Pacific Edge

Continued progress in the US

Pacific Edge has successfully made inroads with large US public healthcare groups, most notably including TRICARE, which provides healthcare to members of the armed services and their families, the Veterans Administration (VA), which provides healthcare to veterans, and the Centers for Medicare and Medicaid Services (CMS), which covers 35% of Americans.

In March 2016, its dossier for Cxbladder Detect was approved for addition to the Federal Supply Schedule (VA FSS)¹ enabling commercial access to the VA urologists and expedited payment following a lengthy review process. The government-funded VA, one of the largest healthcare programmes in the US, is an organisation that represents a considerable market providing care to approximately 20 million veterans and their families in a network of clinics, hospitals and healthcare centres across the US. The company is currently targeting five large VA clinics and expects the incorporation of the Cxbladder test into their clinical practice to begin in the near future. It also expects to set up User Programmes at larger sites so that healthcare providers can trial the tests.

In October 2016, Pacific Edge was approved as a provider and negotiated a contract price for tests with TRICARE. TRICARE covers 9.4 million beneficiaries who accounted for 70.5 million outpatient visits in 2015 in 55 military hospitals and 373 military medical centres. The company is currently leveraging existing relationships with high-volume sites in key areas. As in other areas, it anticipates User Programmes at the larger sites so that healthcare providers can trial the tests.

¹ Enables provision of goods and services to government entities and enterprises.

CMS provides healthcare services to the elderly and those on a lower income in the US. Progress has also been made in the negotiation process with the CMS and management expects the conclusion of discussion on approval and reimbursement to provide a significant lift in revenue/lab throughput for Cxbladder tests, though exact timing is uncertain as the process is long and iterative.

Pacific Edge is also targeting integrated healthcare providers such as Kaiser Permanente (KP), which serves over 11.8 million members. In the large User Programme with KP, patients presenting with haematuria for the evaluation of the Cxbladder Triage were enrolled in the large, blinded study. With the successful conclusion of the programme, the previously published Cxbladder Triage data (sensitivity of 95.1% and a negative predictive value of 98.5% according to the *BioMed Central Urology* journal) has been validated in a real-world clinical setting, based on the company's analysis. The company is now in final discussions with Kaiser regarding a commercial relationship. Commercial adoption by KP could provide a significant ramp in sales.

The markets in Australia and New Zealand

In New Zealand, Pacific Edge is seeing steadily increasing adoption of Cxbladder products by publicly and privately funded health organisations. Launched in 2011 in New Zealand, the sales effort there has focused primarily on the district health boards (DHBs). More recently the company signed an agreement with Canterbury District Health Board to provide Cxbladder testing for primary referral in the evaluation of haematuria through Canterbury DHB's HealthPathways² plan. Among private health insurance providers, nib Health Insurance and Sovereign Health have approved reimbursement for Cxbladder diagnostic tests. Also, the Waitemata District Health Board in Auckland has approved a programme in which selected low-risk patients previously diagnosed and treated for bladder cancer will receive a Cxbladder Monitor test. The company's newest test, Cxbladder Resolve, was launched in the region in December 2016.

In Australia, Pacific Edge partnered with Tolmar Australia earlier this year; Tolmar is a specialist uro-oncology company that provides healthcare to men with advanced prostate cancer. It has a specialist salesforce of nine people with strong relationships with urologists throughout Australia who will encourage the use of Cxbladder tests through User Programmes, replicating the marketing approach in the US and New Zealand.

Singapore as a beachhead to South-East Asia

Pacific Edge is evaluating the South-East Asian market opportunity and has set up Singapore as a base to do so. In early June 2015, the company announced its first entry into South-East Asia with the commencement of a User Programme agreement with Tan Tock Seng Hospital (TTSH) in Singapore. TTSH is one of Singapore's largest hospitals with 40 clinical and allied health departments and a more than 7,000 strong staff, which tends to over 2,000 patients per day. In November 2016 a User Programme agreement with Singapore General Hospital (SGH), the country's largest hospital, was signed. SGH has a team of 10,000 staff and serves over one million patients a year. We note that approximately one million medical tourists visit Singapore each year, which according to Pacific Edge is projected to exceed 1.3 million by 2018. This tourist patient population regularly pays out of pocket, thereby lowering any reimbursement hurdles.

The User Programmes with TTSH and SGH represent an initial move into a potentially significant market. In this targeted growth region, the company anticipates work with additional hospitals and clinics in South-East Asia. The company is also employing sales and marketing staff in the region to pursue commercial rollouts in Bangkok and Taipei. Financial support for the programme will be provided by a grant from New Zealand Trade and Enterprise (NZTE). The three-year NZ\$600,000

² The Canterbury HealthPathways are the main source of assessment, management and referral information about Canterbury health services for community healthcare providers, and used by 80% of general practitioners more than six times per week.

grant to aid the evaluation of the South-East Asian market opportunity will be dispersed on the basis of milestones and Pacific Edge will match NZTE funding.

While we believe that signing TTSH and SGH represents significant milestones, we do not yet include potential sales in the South-East Asian region. We await the completion of Pacific Edge's evaluation and clarity on sales potential, particularly that stemming from the potentially large medical tourist community.

Valuation

Our valuation for Pacific Edge has increased from NZ\$422m (NZ\$1.10/share) to NZ\$449m (NZ\$1.12/share). This is mainly due to rolling forward our NPV and was mitigated by adjustments to sales and expense expectations as well as a higher share count. We continue to expect profitability in FY19. Net cash of NZ\$14.6m should fund operations into forecast profitability. We believe evidence of commercial success will serve as a driver of the valuation.

Exhibit 2: Valuation based on DCF

Discounted cash flow (NZ\$000)	434,626
Net cash (NZ\$000) 31 March 2017	14,564
Valuation (NZ\$000)	449,190
Number of shares (m)	399.53
Value per share (NZ\$)	1.12

Source: Edison Investment Research

Financials

For FY17 (ended 31 March 2017) Pacific Edge reported operating revenue of NZ\$8.1m, up 62% compared to FY16. Laboratory throughput (which includes both user programmes and commercial tests) rose 35% compared to last year. R&D expenses were NZ\$4.9m, up 10.5% compared to the prior year. SG&A expenses were NZ\$18.3m, up 71% compared to the prior year though NZ\$2.9m of the increase was due to a non-cash charge in relation to the conversion of the Employee Incentive Scheme into ordinary shares and NZ\$3.2m was due to a conservative approach to bad debt provisioning. Without these charges, SG&A expenses would have been NZ\$12.2m, up 13% compared to the prior year.

We have adjusted our FY18 revenue estimates downward by NZ\$5.6m (and by a similar amount in FY19) due to a lack of visibility into the commercial uptake of the VA and TRICARE and increased SG&A by NZ\$2.4m due to a higher than expected run rate. Pacific Edge ended the year with NZ\$14.6m in cash thanks to an NZ\$8.75m private placement in February 2017. This level of cash should be sufficient for the company to attain profitability, which we continue to estimate for FY19.

Exhibit 3: Financial summary

	NZ\$'000s	2015	2016	2017	2018e	2019e
Year end 31 March		NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP	NZ GAAP
PROFIT & LOSS						
Revenue		3,622	6,431	9,286	18,504	41,832
Cost of Sales		(588)	(1,047)	(996)	(1,850)	(3,600)
Gross Profit		3,034	5,384	8,290	16,654	38,232
EBITDA		(10,530)	(14,899)	(19,620)	(8,192)	12,323
Operating Profit (before GW and except.)		(10,838)	(15,246)	(19,973)	(8,527)	12,035
Intangible Amortisation		(151)	(159)	(189)	(82)	(131)
Exceptionals		154	223	(67)	0	0
Operating Profit		(10,835)	(15,182)	(20,229)	(8,609)	11,904
Other		(750)	(1,034)	(1,067)	(1,067)	(1,067)
Net Interest		510	762	249	437	262
Profit Before Tax (norm)		(11,078)	(15,518)	(20,792)	(9,158)	11,229
Profit Before Tax (FRS 3)		(11,075)	(15,453)	(21,048)	(9,240)	11,098
Tax		0	0	0	0	(3,107)
Profit After Tax (norm)		(11,078)	(15,518)	(20,792)	(9,158)	8,122
Profit After Tax (FRS 3)		(11,075)	(15,453)	(21,048)	(9,240)	7,990
Average Number of Shares Outstanding (m)		318.6	376.5	382.5	401.6	417.7
EPS - normalised (c)		(3.5)	(4.1)	(5.4)	(2.3)	1.9
EPS - FRS 3 (c)		(3.5)	(4.1)	(5.5)	(2.3)	1.9
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		1,362	1,237	1,166	1,246	1,343
Intangible Assets		244	248	329	525	681
Tangible Assets		1,118	990	837	721	663
Other		0	0	0	0	0
Current Assets		11,271	31,093	22,397	16,555	29,550
Stocks		623	707	824	824	824
Debtors		2,584	5,730	6,519	6,519	6,519
Cash		7,819	24,160	14,564	8,722	21,716
Other		245	496	490	490	490
Current Liabilities		(1,930)	(2,523)	(2,734)	(2,734)	(4,288)
Creditors		(1,930)	(2,523)	(2,734)	(2,734)	(4,288)
Short term borrowings		0	0	0	0	0
Short term leases		0	0	0	0	0
Other		0	0	0	0	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Long term leases		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		10,703	29,807	20,829	15,067	26,605
CASH FLOW						
Operating Cash Flow		(13,048)	(17,715)	(18,086)	(5,782)	14,804
Net Interest		510	762	249	437	262
Tax		0	0	0	0	(1,554)
Capex		(427)	(325)	(479)	(498)	(517)
Acquisitions/disposals		0	0	0	0	0
Financing		0	35,336	8,750	0	0
Dividends		0	0	0	0	0
Other		1	(1,936)	(91)	0	0
Net Cash Flow		(12,964)	16,123	(9,657)	(5,842)	12,995
Opening net debt/(cash)		(20,444)	(7,819)	(24,160)	(14,564)	(8,722)
HP finance leases initiated		0	0	0	0	0
Other		340	218	61	0	0
Closing net debt/(cash)		(7,819)	(24,160)	(14,564)	(8,722)	(21,716)

Source: Company accounts, Edison Investment Research

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