

27 February 2025

Current price 1.35p

TICKER POLX

Market Cap £16.3m

Net cash (31 Dec 2024) US\$12.1m

Free Float 61%

3mo Av. Daily Volume 2.2m

Brokers Stifel

Index FTSE AIM

Share Price Performance



Source: Bloomberg

Polarean is a medical device company whose XENOVIEW® system employing hyperpolarised Xenon-129 gas in MRI scanning enables unparalleled imaging of lung function and without the radiation risk associated with scintigraphy or CT scan.

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Polarean Imaging

FY24 update - Even better than expected

XENOVIEW® system enables unparalleled imaging of lung function

Polarean has published a trading update for the year to December which is even better than expected. Revenue for FY24 is anticipated to be US\$3.0m-US\$3.1m, above guidance of US\$2.5m-US\$3.0m, and more than treble revenue for FY23; our forecast was US\$2.8m. Moreover, net cash at YEFY24 of US\$12.1m was well above our forecast of US\$10.8m and the company reiterated that it has a cash runway through 1Q26. A YoY jump in sales of over 50% in consumables demonstrates an increase in the number of Xenon MRI scans. One third of the company's 22 Xenon MRI platform customers have either received or are pending the receipt of clinical systems, presaging a step up in average scans per system. We will update our forecasts once the results are published, but believe this update confirms that Polarean is on the cusp of hyperbolic growth with large value upside. For our initiation see here.

The purpose of AIM listed Polarean is to revolutionise pulmonary medicine through direct visualisation of lung function, thereby radically improving patient care. Current FDA approval for the use of Polarean's system in ventilation provides access to a total addressable market of US\$2bn while FDA approval for use in gas exchange would take Polarean's total addressable market to US\$5bn in the US alone.

Polarean highlighted investment into its sales effort, including the appointment of Dr Alan Huang as VP Sales, enabled by the fund raise last summer. The sales team now numbers six staff providing coverage across the US.

Core to Polarean's revenue growth is both the sale of additional Xenon MRI systems and increasing the average scans per system which is strongly associated with growth in clinical rather than academic settings. Installations for clinical purposes has been enabled both by the FDA approvals received to date and, as important, the granting of reimbursement codes which are essential to opening up the commercial opportunity in the US health system. Polarean now has seven sites which have either received or are pending the receipt of clinical hyperpolariser systems, up from three in FY23.

Post period end, Polarean entered a collaboration with SimonMed for the installation of an initial hyperpolariser system in Arizona. SimonMed is one of the largest US outpatient medical imaging providers and currently operates over 170 facilities across 11 states. SimonMed will promote the use of its initial system to its network of client doctors with plenty of scope to expand use across its network. The company also signed a distribution agreement for Taiwan with Sumtage, its first overseas distribution agreement.

Polarean has scheduled a Virtual Investor Day to take place on 12 March 2025 at 14:00 GMT for which interested investors can register <u>here</u>.

At a glance (Yr to Dec)	Revenue (US\$m)	Clinical installations	Gross profit (US\$m)	Gross margin	EPS (US\$)	Net (cash)/debt (US\$m)
FY23A	0.9	1	0.3	38%	(0.055)	(6.2)
FY24E	2.8	4	1.2	43%	(0.013)	(10.8)
FY25E	5.6	10	2.7	48%	(0.008)	(2.8)
FY26E	10.6	20	5.4	51%	(0.008)	6.2
FY27E	18.5	35	10.3	56%	(0.006)	12.1
FY28E	35.3	60	20.1	57%	0.004	5.7

Source: Polarean, CAG Research. NOT UPDATED FOR FY24 TRADING STATEMENT GUIDANCE.

Investment thesis

Polarean's Xenon MRI platform enables unique, unparalleled imaging of lung function, meeting a large unmet clinical need that cannot be satisfied by other methods. With initial FDA approval and reimbursement codes now in place, the revenue performance is transforming and could turn hyperbolic. Crossing the bridge to profitability will require additional funding but there is a cash runway through IQ26. Based on deal metrics and an NPV analysis, we demonstrate that Polarean has potential upside many times its current market capitalisation while the current valuation is so low that it could attract take-over interest.

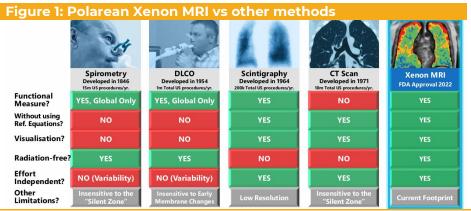
The purpose of AIM listed Polarean is to revolutionise pulmonary medicine through direct visualisation of lung function, thereby radically improving patient care.

Polarean has developed a unique technology that creates the hyperpolarised state of a specific isotope of xenon gas, Xenon-129, known as XENOVIEW® which is used as an inhaled MRI contrast agent. When paired with a specially tuned Magnetic Resonance Imaging (MRI) system, this technology provides unparalleled functional imaging of the lung, offering insights that were previously unattainable.

Hyperpolarisation results in the alignment of the atomic spin of the Xenon-129 gas atoms, dramatically enhancing the MRI signal—making it approximately 100,000 times stronger than it otherwise would be. This amplification allows the Xenon-129 gas mix to be visualised clearly in an MRI scanner.

As the lung is 85%-90% air it is extremely hard to image with other scanning techniques which also carry radiation hazard while older methods of evaluating lung performance are insensitive and provide only a broad overview of lung performance.

Figure 1 highlights the merits of XENOVIEW® MRI scanning as compared to alternative lung function evaluation methods.



Source: Polarean, CAG Research.

The complete Xenon MRI platform (Figure 2) includes the HPX (hyperpolarised xenon) Hyperpolariser System, HPX Polarisation Measurement Station (measurement equipment to confirm the level of hyperpolarization achieve), HPX Gas Handling Manifold (manages the supply of gases efficiently), the multi-dose Xenon-129 Gas Blend Cylinder, the single-use XENOVIEW® Dose Delivery Bag, XENOVIEW® 3T Chest Coil, and the XENOVIEW® imaging software (not shown). The system also includes an HPX Phantom (not shown), which ensures the required quality control of the Xenon MRI platform.

Figure 2: XENOVIEW® system









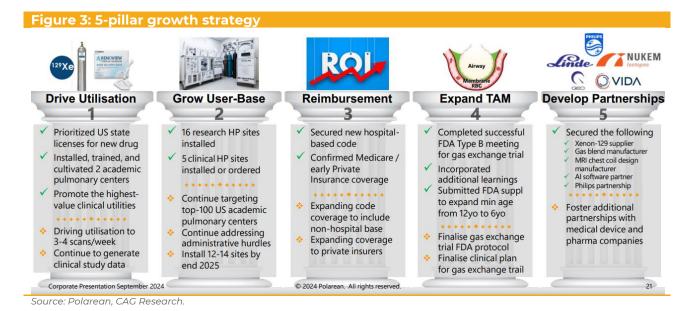


Source: Polarean, CAG Research.

Lung disease affects tens of millions of people in the US and hundreds of millions of people worldwide, making for a very large market. In the US, the TAM for ventilation, the process of breathing in and out, is estimated at US\$2bn. While the TAM for gas exchange, the actual diffusion of oxygen into the bloodstream, is estimated at US\$3bn.

The US Food and Drug Administration (FDA) approved the use of XENOVIEW® for ventilation at the end of 2022, but the reimbursement codes, which are critical to enabling clinical take-up, rather than research use, only became effective towards the end of 2023.

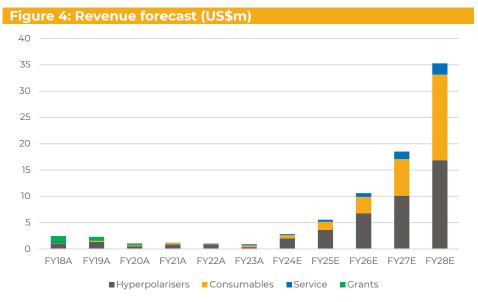
Polarean has a five-pillar growth strategy focused on the leading academic medical hospitals in the US with a view to promoting conversion of clinical from research use, expanding awareness of the benefits of Xenon MRI scanning to promote take up in new hospitals, and removing impediments for use within the US hospital system (Figure 3). The company recently announced FDA approval of its 3T Chest Coil for use with suitable GE HealthCare MRI scanners, broadening the use of its Xenon MRI scanning technology across all the major MRI vendors in the US, which now include GE, Philips, and Siemens.



FDA approval and issuance of the requisite reimbursement codes has already started to transform the revenue outlook with revenue more than trebling YoY in FY24 to US\$3.0m-US\$3.1m.

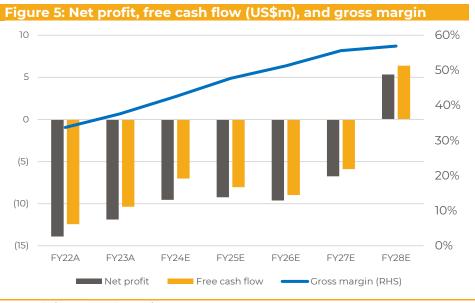
Based on company guidance and assuming that FDA approval of XENOVIEW® for gas exchange is achieved by FY28, we forecast a hyperbolic

increase in revenue and an important shift in the sales mix to the higher margin consumables associated with increased clinical utilisation (Figure 4).



Source: Polarean, CAG Research.

That would see Polarean crossing the bridge to profitability and free cash flow generation in FY28 (Figure 5).



Source: Polarean, CAG Research.

Polarean will need additional funding to reach that point both to complete a Phase III trial to win FDA approval for the use of XENOVIEW® in gas exchange and to build out the sales effort. However, the company has a cash runway through 1Q26.

The current share price indicates that investor confidence in Polarean is low. However, the fact remains that Polarean's XENOVIEW® system is a safe, unique technology that addresses unmet clinical need that cannot be satisfied by the current alternatives, and which has a combined TAM of US\$5bn in the US alone. Moreover, the existing FDA approval and reimbursement codes are already driving a transformation in revenue generation as hospitals shift from research to clinical use.

Based on observable deal metrics we calculate an implied equity valuation for Polarean of up to US\$350m/£280m on a 10x multiple of FY28 estimated revenue, many times the current £16m market capitalisation which is so low, that we believe it could attract M&A interest (Figure 6).

Figure 6: Polarean valuation based on revenue multiple (US\$m)								
Revenue multiple	FY24E	FY25E	FY26E	FY27E	FY28E			
2x	6	11	21	37	71			
4x	11	22	42	74	141			
6x	17	33	64	111	212			
8x	23	44	85	148	282			
10x	28	56	106	185	353			

Source: Polarean, CAG Research.

That observable deal multiples-based approach to valuation is supported by our NPV analysis which indicates a valuation range of US\$114m-US\$233m, based on a ten-year forecast, which excludes potential sales outside North America (Figure 7).

Figure 7: NPV valuation (US\$m), and upside to current mkt cap

			Vs mkt cap		
	5yr	10yr	5yr	10yr	
	NPV	NPV	NPV	NPV	
Systems value, 5 scans/week					
Unit value US\$500k, 30% margin	36	114	73%	452%	
Unit value US\$500k, 40% margin	38	121	84%	487%	
Unit value US\$500k, 50% margin	40	128	95%	523%	
Unit value US\$675k, 30% margin	38	121	84%	489%	
Unit value US\$675k, 40% margin	41	131	99%	537%	
Unit value US\$675k, 50% margin	44	141	114%	585%	
Systems value, 10 scans/week					
Unit value US\$500k, 30% margin	64	205	212%	896%	
Unit value US\$500k, 40% margin	67	213	223%	932%	
Unit value US\$500k, 50% margin	69	220	234%	967%	
Unit value US\$675k, 30% margin	67	213	223%	933%	
Unit value US\$675k, 40% margin	70	223	239%	982%	
Unit value US\$675k, 50% margin	73	233	254%	1030%	

Source: Polarean, CAG Research.

Xenon MRI scanning provides unparalleled and safe functional lung imaging, meeting a large unmet clinical need that cannot be satisfied by other methods. Initial FDA approval and new reimbursement codes have already transformed the revenue outlook while Phase III approval for gas exchange would more than double the existing TAM.

If Polarean delivers to guidance, the current valuation is likely to look like an extremely low entry point in the rear-view mirror and is low enough to potentially attract take-over interest.

While the company will require additional funding to cross the bridge to profitability, there is a cash runway to at least 1Q26.

Summary financial statements

December year end, US\$k	FY23A	FY24E	FY25E	FY26E	FY27E	FY28E
P&L						
Revenue	891	2,824	5,558	10,590	18,512	35,284
Cost of sales	(555)	(1,623)	(2,906)	(5,161)	(8,214)	(15,200)
Gross profit	335	1,201	2,652	5,428	10,298	20,084
Administrative expense	(3,338)	(3,350)	(3,500)	(3,500)	(3,500)	(3,500)
R&D and regulatory expense	(4,194)	(3,600)	(4,000)	(7,500)	(7,500)	(5,000)
Depreciation	(209)	(200)	(200)	(50)	(50)	(50)
Amortisation	(728)	(700)	(700)	(100)	(100)	(100)
Selling & distrib'n expense	(3,562)	(2,100)	(3,000)	(3,200)	(5,000)	(5,000)
Share-based payments	(860)	(800)	(500)	(700)	(900)	(1,100)
Total operating cost	(12,892)	(10,750)	(11,900)	(15,050)	(17,050)	(14,750)
Operating profit/(loss)	(12,556)	(9,549)	(9,248)	(9,622)	(6,752)	5,334
Finance income	299	0	0	0	0	0
Finance expense	(16)	0	0	0	0	0
Other gains/(losses) - net	388	0	0	0	0	0
Profit/(loss) before tax	(11,885)	(9,549)	(9,248)	(9,622)	(6,752)	5,334
Income tax (charge)/credit	0	0	0	0	0	0
Net profit/(loss)	(11,885)	(9,549)	(9,248)	(9,622)	(6,752)	5,334
Basic reported EPS (US\$)	(0.055)	(0.013)	(0.008)	(0.008)	(0.006)	0.004
Diluted reported EPS (US\$)	(0.055)	(0.013)	(0.008)	(0.008)	(0.006)	0.004

Source: Polarean, CAG Research. NOT UPDATED FOR FY24 TRADING STATEMENT GUIDANCE.

Summary financial statements (cont)

December year end, US\$k	FY23A	FY24E	FY25E	FY26E	FY27E	FY28E
Cash flow						
Profit/(loss) before tax	(11,885)	(9,549)	(9,248)	(9,622)	(6,752)	5,334
Depreciation	209	200	200	50	50	50
Amortisation	728	700	700	100	100	100
Share-based payments	860	800	500	700	900	1,100
FX on non cash items	(72)	0	0	0	0	0
Writeback of contingent consid'n	(316)	0	0	0	0	0
Net interest	(283)	0	0	0	0	0
Operating cash flow before WC	(10,759)	(7,849)	(7,848)	(8,772)	(5,702)	6,584
Delta working capital	324	1,000	0	0	0	0
Cash generated from operations	(10,435)	(6,849)	(7,848)	(8,772)	(5,702)	6,584
Tax received/(paid)	0	0	0	0	0	0
Net cash generated from	(10 (75)	(6.0.(0)	(E 0 (0)	(0.550)	(F 500)	6.507
operations	(10,435)	(6,849)	(7,848)	(8,772)	(5,702)	6,584
Purchase of PP&E	(79)	(25)	(50)	(50)	(50)	(50)
Interest received	299	0	0	0	0	0
Net cash invested	220	(25)	(50)	(50)	(50)	(50)
Proceeds from share issue	18	12,578	0	0	0	0
Share issue costs	0	, (915)	0	0	0	0
Interest paid	(16)	Ô	0	0	0	0
Lease liability repayments	(142)	(150)	(150)	(150)	(150)	(150)
Net cash from financing	(140)	11,514	(150)	(150)	(150)	(150)
Implied delta net debt (IAS 17)	10,355	(4,640)	8,048	8,972	5,902	(6,384)
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Summary balance sheet						
Total non-current assets	1,804	1,396	1,012	979	946	912
Net assets	8,298	11,213	2,466	(6,456)	(12,308)	(5,874)
Total equity	8,298	11,213	2,466	(6,456)	(12,308)	(5,874)
Net (cash)/debt (IAS 17)	(6,172)	(10,812)	(2,764)	6,208	12,110	5,726
Net (cash)/debt (IFRS 16)	(6,097)	(10,887)	(2,989)	5,833	11,585	5,051

Source: Polarean, CAG Research. NOT UPDATED FOR FY24 TRADING STATEMENT GUIDANCE.

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