

Polarean Imaging

FDA extends use of XENOVIEW® to 6-year-olds

2 June 2025

Current price

1.28

TICKER

[POLX](#)

Market Cap

£15.4m

Net cash (31 Dec 2024)

US\$12.1m

Free Float

57%

3mo Av. Daily Volume

2.5m

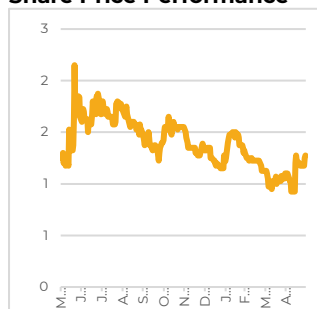
Brokers

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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XENOVIEW® system enables unparalleled imaging of lung function

The US Food and Drug Administration (FDA) has approved Polarean's proven Xenon MRI platform for use in paediatric patients as young as six years old from the previous limit of 12. This approval increases the number of eligible patients by c1 million, confirming a total addressable market (TAM) in the US of cUS\$2bn for use of the technology in evaluating ventilation. The FDA decision has come a little ahead of previous guidance. Approval for use in gas exchange, which remains subject to a clinical trial, would bring the total TAM to US\$5bn in the US alone. At its recent full-year results, Polarean revealed that the expected cost of this trial has halved to US\$4.0m-US\$4.5m. Polarean has potential upside many times its current market capitalisation, we calculate, based on observable deal metrics and our NPV analysis, while the valuation is so low, it could attract take-over interest, we believe (see [here](#)).

The purpose of AIM listed Polarean is to revolutionise pulmonary medicine through direct visualisation of lung function, thereby radically improving patient care. Polarean's proven Xenon MRI platform enables unparalleled imaging of lung function in conjunction with standard MRI scanning of the chest cavity. XENOVIEW® allows functional imaging of both ventilation (breathing) and gas exchange (oxygenation of the blood) and does so without the radiation risk to patients associated with other imaging techniques (Figure 1).

The FDA has approved Polarean's Supplemental New Drug Application to expand the indication of XENOVIEW® to paediatric patients as young as six years old from the previous limit of 12. The extension includes approval of new Dose Delivery Bags (Figure 2) sized for smaller lungs and corresponding upgrades to the HPX Polarisation Measurement Station. Polarean expects to launch a controlled US market release of the paediatric Dose Delivery Bags later this year, starting with Cincinnati Children's Hospital.

While XENOVIEW® is approved for use by all three leading manufacturers of MRI scanners, including GE and Siemens, Polarean has a strategic partnership with Philips (see [here](#)) with a particular focus on paediatric care. One of the features of the US medical system are large hospitals dedicated solely to the paediatric care of children. This extension of the use of XENOVIEW® to a much wider cohort of their patient populations will enhance the economics of investing in Polarean's technology as it improves the outcomes of their patients suffering from chronic obstructive lung disease.



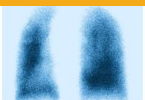

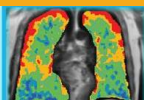
Despite the hiatus caused by the cut in funding to the US National Institutes of Health, Polarean reiterated its US\$5.0m-\$6.0m revenue guidance for 2025, confirming that it is on the cusp of hyperbolic growth.

Based on observable deal metrics we calculate an implied equity valuation for Polarean of up to US\$350m/£260m, many times the current £15m market capitalisation. Our NPV analysis indicates a valuation range of US\$114m-US\$233m, backing up the multi-market capitalisation upside suggested by deal revenue multiples and which excludes the value of any expansion of sales to the rest of the world.

At a glance (Yr to Dec)	Revenue (US\$m)	Clinical installations	Gross profit (US\$m)	Gross margin	EPS (US\$)	Net (cash)/debt (US\$m)
FY24A	3.1	4	1.4	46%	(0.011)	(12.1)
FY25E	5.4	10	2.5	47%	(0.008)	(3.9)
FY26E	10.4	20	5.3	51%	(0.006)	2.7
FY27E	18.3	35	10.1	56%	(0.004)	6.2
FY28E	35.0	60	19.9	57%	0.004	0.0

Source: Polarean, CAG Research.

Figure 1: Polarean Xenon MRI vs other methods

	 Spirometry Developed in 1846 15m US procedures/yr.	 DLCO Developed in 1954 1m Total US procedures/yr.	 Scintigraphy Developed in 1964 200k Total US procedures/yr.	 CT Scan Developed in 1971 10m Total US procedures/yr.	 Xenon MRI FDA Approval 2022
Functional Measure?	YES, Global Only	YES, Global Only	YES	NO	YES
Without using Ref. Equations?	NO	NO	YES	YES	YES
Visualisation?	NO	NO	YES	YES	YES
Radiation-free?	YES	YES	NO	NO	YES
Effort Independent?	NO (Variability)	NO (Variability)	YES	YES	YES
Other Limitations?	Insensitive to the "Silent Zone"	Insensitive to Early Membrane Changes	Low Resolution	Insensitive to the "Silent Zone"	Current Footprint

Source: Polarean, CAG Research.

Figure 2: XENOVIEW® system



Source: Polarean, CAG Research.

Summary financial statements

December year end, US\$k	FY23A	FY24A	FY25E	FY26E	FY27E	FY28E
P&L						
Revenue	891	3,090	5,378	10,388	18,276	34,999
Cost of sales	(555)	(1,667)	(2,843)	(5,091)	(8,131)	(15,100)
Gross profit	335	1,423	2,535	5,297	10,145	19,899
Administrative expense	(3,338)	(3,102)	(3,500)	(3,500)	(3,500)	(3,500)
R&D and regulatory expense	(4,194)	(3,441)	(4,000)	(5,000)	(5,000)	(5,000)
Depreciation	(209)	(255)	(200)	(50)	(50)	(50)
Amortisation	(728)	(710)	(700)	(100)	(100)	(100)
Selling & distrib'n expense	(3,562)	(1,951)	(3,000)	(3,200)	(5,000)	(5,000)
Share-based payments	(860)	(714)	(500)	(700)	(900)	(1,100)
Total operating cost	(12,892)	(10,173)	(11,900)	(12,550)	(14,550)	(14,750)
Operating profit/(loss)	(12,556)	(8,749)	(9,365)	(7,253)	(4,405)	5,149
Finance income	299	275	0	0	0	0
Finance expense	(16)	(16)	0	0	0	0
Other gains/(losses) - net	388	(49)	0	0	0	0
Profit/(loss) before tax	(11,885)	(8,540)	(9,365)	(7,253)	(4,405)	5,149
Income tax (charge)/credit	0	0	0	0	0	0
Net profit/(loss)	(11,885)	(8,540)	(9,365)	(7,253)	(4,405)	5,149
Basic reported EPS (US\$)	(0.055)	(0.011)	(0.008)	(0.006)	(0.004)	0.004
Diluted reported EPS (US\$)	(0.055)	(0.011)	(0.008)	(0.006)	(0.004)	0.004

Source: Polarean, CAG Research.

Summary financial statements (cont)

December year end, US\$k	FY23A	FY24A	FY25E	FY26E	FY27E	FY28E
Cash flow						
Profit/(loss) before tax	(11,885)	(8,540)	(9,365)	(7,253)	(4,405)	5,149
Depreciation	209	255	200	50	50	50
Amortisation	728	710	700	100	100	100
Share-based payments	860	714	500	700	900	1,100
FX on non cash items	(72)	49	0	0	0	0
Writeback of contingent consid'n	(316)	0	0	0	0	0
Net interest	(283)	(259)	0	0	0	0
Operating cash flow before WC	(10,759)	(7,070)	(7,965)	(6,403)	(3,355)	6,399
Delta working capital	324	1,463	0	0	0	0
Cash generated from operations	(10,435)	(5,608)	(7,965)	(6,403)	(3,355)	6,399
Tax received/(paid)	0	0	0	0	0	0
Net cash generated from operations	(10,435)	(5,608)	(7,965)	(6,403)	(3,355)	6,399
Purchase of PP&E	(79)	(198)	(50)	(50)	(50)	(50)
Interest received	299	275	0	0	0	0
Net cash invested	220	77	(50)	(50)	(50)	(50)
Proceeds from share issue	18	12,578	0	0	0	0
Share issue costs	0	(908)	0	0	0	0
Interest paid	(16)	(16)	0	0	0	0
Lease liability repayments	(142)	(134)	(150)	(150)	(150)	(150)
Net cash from financing	(140)	11,520	(150)	(150)	(150)	(150)
Implied delta net debt (IAS 17)	10,355	(5,989)	8,165	6,603	3,555	(6,199)
Summary balance sheet						
Total non-current assets	1,804	1,410	1,026	993	960	926
Net assets	8,298	12,143	3,277	(3,276)	(6,781)	(532)
Total equity	8,298	12,143	3,277	(3,276)	(6,781)	(532)
Net (cash)/debt (IAS 17)	(6,172)	(12,112)	(3,947)	2,656	6,212	13
Net (cash)/debt (IFRS 16)	(6,097)	(11,737)	(3,722)	2,731	6,136	(213)

Source: Polarean, CAG Research.

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