Polarean Imaging

Initiation – On the cusp of hyperbolic growth

25 November 2024

Current price
1.55

TICKER
POLX

Market Cap
£18.7m

Net cash (30 June 2024)
US$15.2m

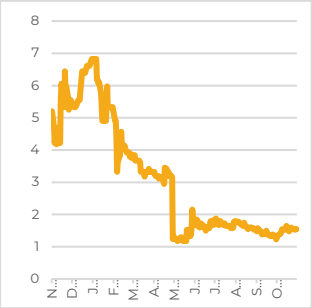
Free Float
61%

3mo Av. Daily Volume
4.7m

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.

Colin Smith
+44 20 7082 5522
Email the Analyst

XENOVIEW® system enables unparalleled imaging of lung function

Despite initial FDA approval and grant of the requisite reimbursement codes, investor confidence in Polarean is low, as reflected in the current share price. However, revenue growth is already accelerating and is set to go hyperbolic as Polarean's Xenon MRI platform meets a large unmet clinical need that cannot be satisfied by other methods. Crossing the bridge to profitability will require additional funding but there is a cash runway through 1Q26. 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.

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 creates a hyperpolarised isotope of xenon gas, Xenon-129, called XENOVIEW®. This, first of its kind, FDA-approved, inhaled MRI contrast agent 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, such as scintigraphy or CT scans.

Lung disease affects tens of millions of people in the US and hundreds of millions of people worldwide with a total addressable market (TAM) in the US alone of US$5bn. The current FDA approval for ventilation provides Polarean access to US$2bn of that TAM with access to the gas exchange market requiring FDA approval, following a Phase III trial, expected to be concluded by late 2027/early 2028.

Revenue is already set to more than treble in FY24 as clinical roll-out gets underway and, assuming access to the gas exchange TAM 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. We forecast Polarean to achieve profitability and turn free cash flow positive from FY28, consistent with company guidance.

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 £19m market capitalisation. Our NPV analysis indicates a valuation range of US$114m-US$233m, based on a ten-year forecast, 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)
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.

Contents

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 'until at least 1Q26'. 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.

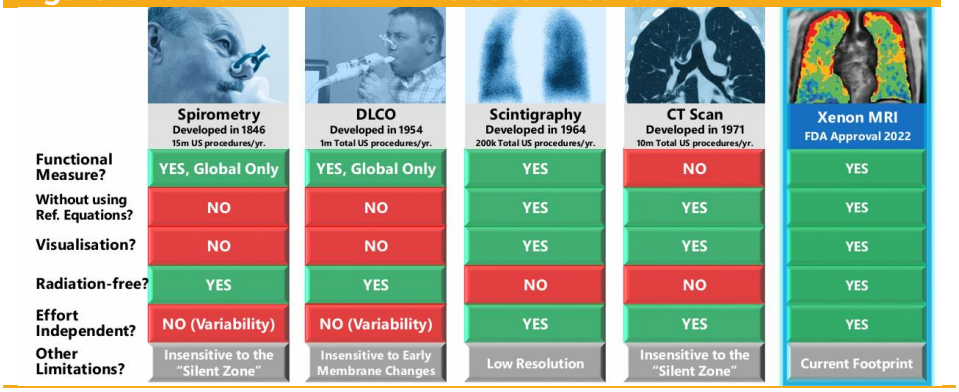
Hyperpolarisation results in the alignment of the atomic spin of the Xenon-129 gas atoms, dramatically enhancing the MRI signal—making it approximately 100,000 times stronger than it otherwise would be. This amplification allows the Xenon-129 gas mix to be visualised clearly in an MRI scanner.

Dr Christopher von Jako, CEO of Polarean, has a particular personal interest in Polarean's technology as his father, an eminent surgeon, succumbed to Idiopathic Pulmonary Fibrosis which could not be accurately diagnosed with the technology available at the time, but which could have been properly identified, diagnosed, and its treatment monitored utilising the XENOVIEW® system.

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.

Figure 1: Polarean Xenon MRI vs other 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

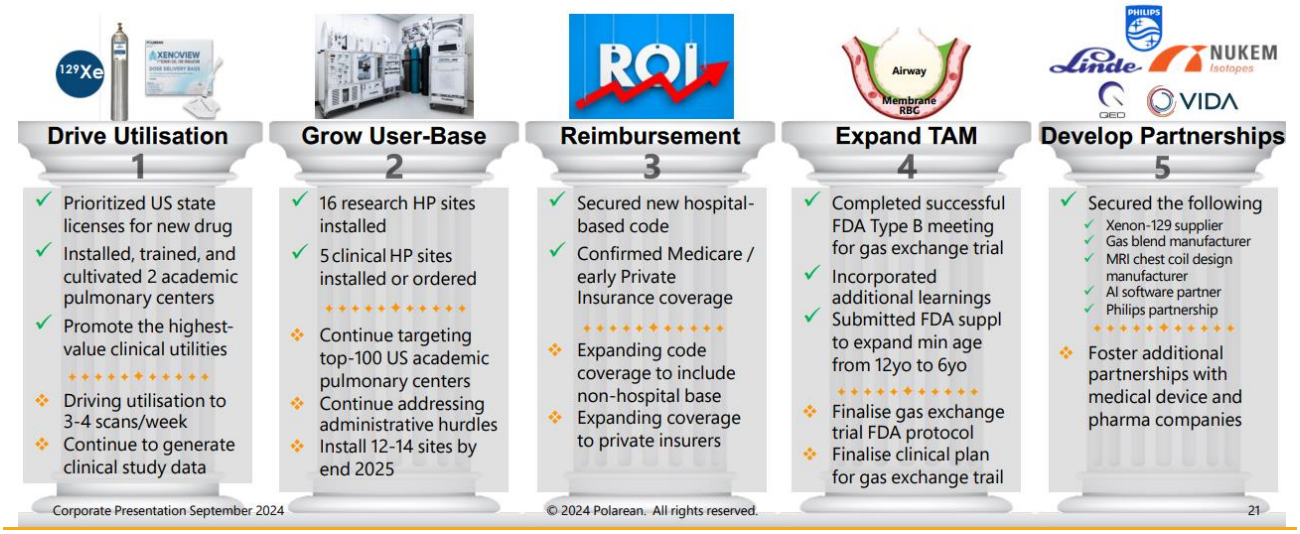
Source: Polarean, CAG Research.

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.

Considerably later than initially expected, 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 has just 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.

Figure 3: 5-pillar growth strategy

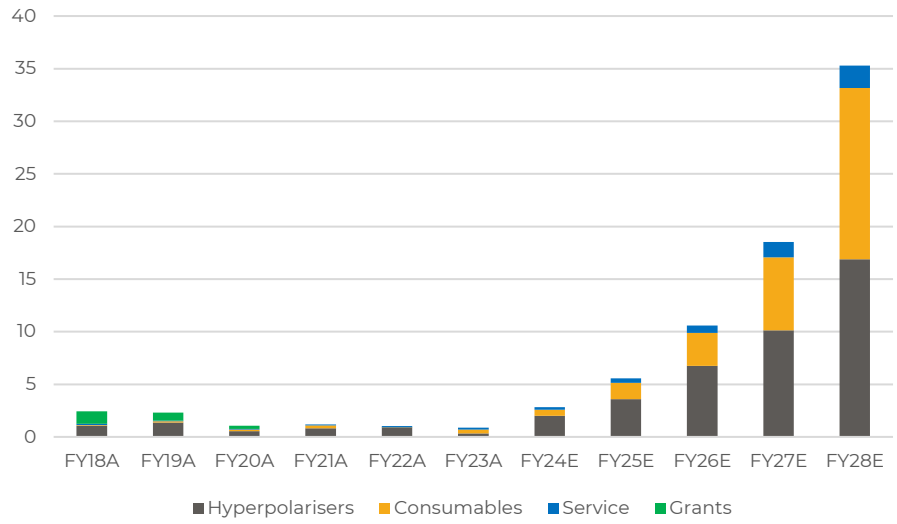


Source: Polarean, CAG Research.

FDA approval and issuance of the requisite reimbursement codes has already started to transform the revenue outlook with revenue set to more than treble this year.

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).

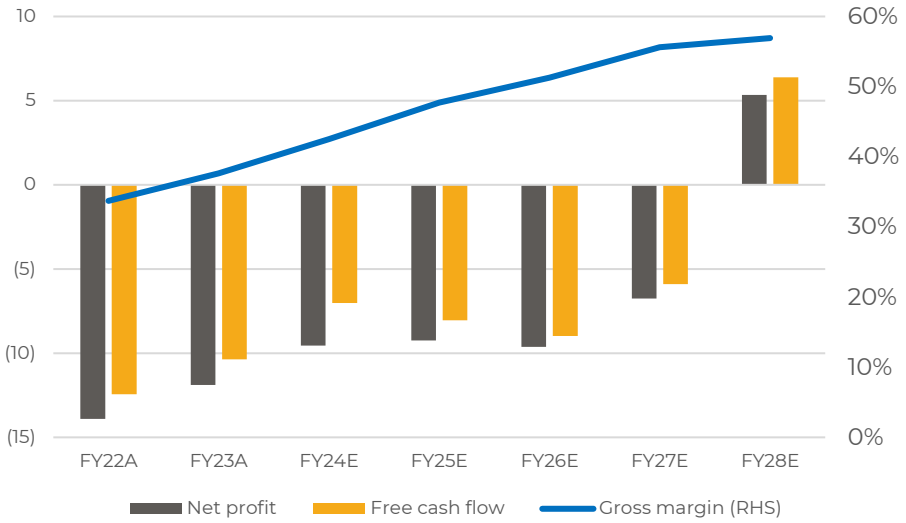
Figure 4: Revenue forecast (US$m)



Source: Polarean, CAG Research.

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

Figure 5: Net profit, free cash flow (US$m), and gross margin



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 'until at least 1Q26'.

The current share price indicates that investor confidence in Polarean is low (see Valuation). 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 £19m 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 NPV	10yr NPV	5yr NPV	10yr NPV
Systems value, 5 scans/week				
Unit value US$500k, 30% margin	36	114	52%	386%
Unit value US$500k, 40% margin	38	121	62%	418%
Unit value US$500k, 50% margin	40	128	72%	449%
Unit value US$675k, 30% margin	38	121	63%	420%
Unit value US$675k, 40% margin	41	131	76%	462%
Unit value US$675k, 50% margin	44	141	89%	504%
Systems value, 10 scans/week				
Unit value US$500k, 30% margin	64	205	175%	779%
Unit value US$500k, 40% margin	67	213	185%	810%
Unit value US$500k, 50% margin	69	220	195%	842%
Unit value US$675k, 30% margin	67	213	185%	812%
Unit value US$675k, 40% margin	70	223	199%	854%
Unit value US$675k, 50% margin	73	233	212%	897%

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.

Purpose, opportunity, and strategy

Polarean's purpose is to revolutionise pulmonary medicine through direct visualisation of lung function, thereby radically improving patient care with its Xenon MRI platform. FDA approval of the XENOVIEW® system for ventilation and issuance of the associated reimbursement codes were received last year opening clinical access to an initial US$2bn TAM market in the US with worldwide application. Uniquely, XENOVIEW® can also be used to image gas exchange (diffusion) performance offering potential for use expansion in the US to an additional TAM worth US$3bn which is being actively pursued by Polarean as part of its label expansion strategy.

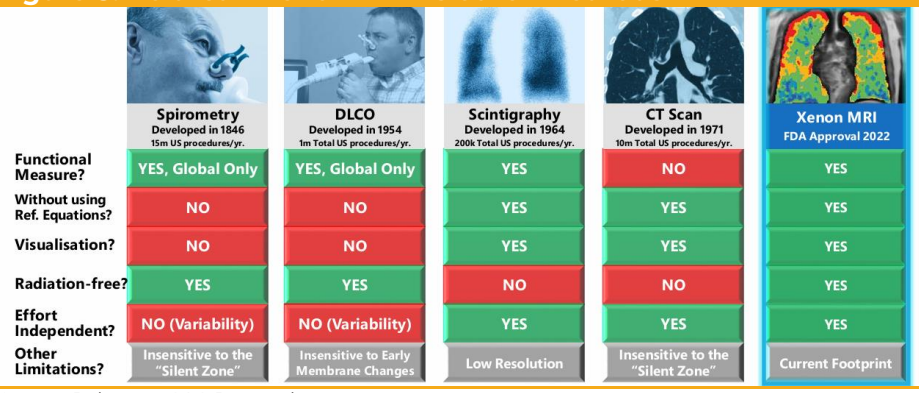
Polarean's purpose is to revolutionise pulmonary medicine through direct visualisation of lung function, thereby radically improving patient care across the full range of more complex lung disease and associated conditions.

As the lung mainly consists of void space full of air, existing imaging tools such as scintigraphy and CT scans struggle to provide a good image and expose the patient to radiation. More common procedures such as spirometry and Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) which directly measure a patient's ability to breathe, provide high level values only with no imaging and their inaccuracy renders them even more insensitive when measuring the progression of disease or response to any particular drug regime (see The lung and Imaging the lung).

Polarean's unique solution, initially developed by GE HealthCare with around US$40m of investment, is to use a particular non-radioactive isotope of the noble gas Xenon, known as Xenon-129 in which the atoms are hyperpolarised so that their atomic spin is aligned. This specially prepared Xenon-129 gas blend, XENOVIEW®, is then inhaled and held for one breath by a patient undergoing an MRI scan. This results in an MRI signal which is approximately 100,000 times stronger than it otherwise would be, enabling the generation of a clear image of lung functionality together with extremely important information on the gas exchange process with the bloodstream, which is the purpose of the lung (see Business, The lung). Moreover, the process is comparably comfortable for the patient, relative to the effort required in direct testing and without the radiation risk involved in scintigraphy or CT scanning, which limits their use, particularly where multiple measurements may be required over time.

Thus, Polarean's Xenon MRI platform ticks all the boxes and has none of the drawbacks of the other tools available to the pulmonologists, surgeons and other respiratory specialists (Figure 8).

Figure 8: Polarean Xenon MRI vs other methods



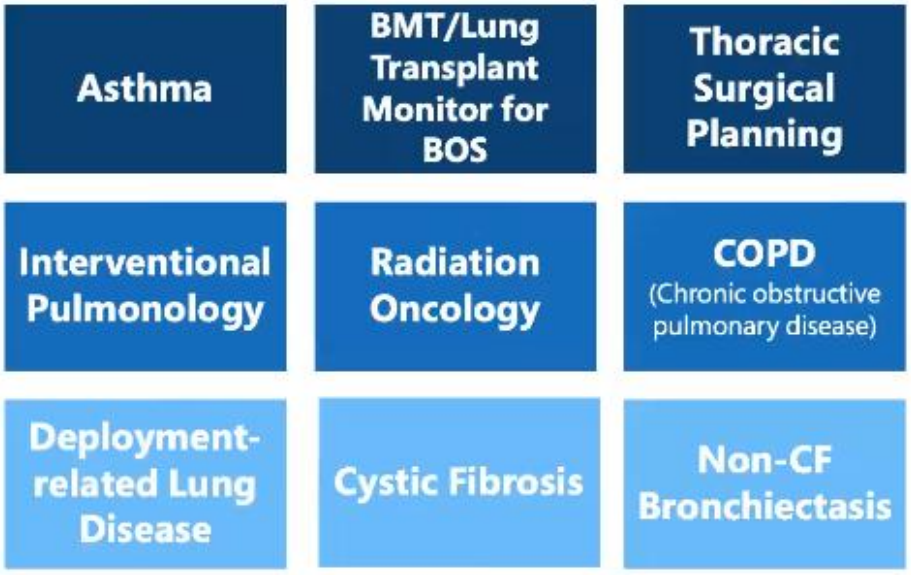
Source: Polarean, CAG Research.

The US regulatory approval process was complicated by the fact that the FDA treated the XENOVIEW® gas mix as a drug requiring completion of two Phase

III trials while the equipment needed to prepare and deliver the gas was treated as a device, subject to a different approval procedure. Covid also got in the way. However, at the end of 2022, the FDA granted approval for Polarean's XENOVIEW® drug device product, clearing the way for its use in the evaluation of lung ventilation in adults and paediatric patients aged 12 year and older. The overall approval covers the HPX Hyperpolariser System, HPX Polarization Measurement Station, HPX Gas Handling Manifold, the multi-dose Xenon-129 Gas Blend Cylinder, the single-use XENOVIEW® Dose Delivery Bag, XENOVIEW® 3T Chest Coil, HPX Phantom, and the XENOVIEW® imaging software (Figure 2 and see Business).

That approval means the XENOVIEW® system has approval for clinical use in a market with a total TAM of US$2bn for the 40m Americans suffering from pulmonary diseases including chronic lung disease and lung cancer. The priority areas for ventilation clinical use are shown in Figure 9.

Figure 9: Priority areas for ventilation clinical use



Source: Polarean, CAG Research. BMT: bone marrow transplant; BOS: bronchiolitis obliterans syndrome.

Polarean currently has an application under evaluation by the FDA to extend the use of XENOVIEW® for ventilation use in paediatric care to children aged six and above from the current 12 and above which would add about 1 million patients to complete the lung ventilation TAM of US$2bn. This does not require any additional clinical testing and a response from the FDA is expected by next summer.

Because XENOVIEW® can also be used to differentially image gas exchange across the membrane which separates the lung and the bloodstream and within the bloodstream (see Imaging the lung), it has a large potential market in evaluating lung performance in gas exchange to help identify and monitor tissue damage, such as in Idiopathic Pulmonary Fibrosis, and in pulmonary vascular disease with a combined potential additional US$3bn TAM.

Approval for clinical use in gas exchange will require another Phase III clinical trial to test XENOVIEW® in this setting for safety and efficacy. Polarean has held advanced discussions with the FDA over the design of the trial which is tentatively estimated to take two years and cost up to US$10m.

The historic strategy of the company has been to build out research use of its hyperpolarised Xenon-129 technology in leading academic medical hospitals, typically grant funded, while progressing regulatory approval, aiming for

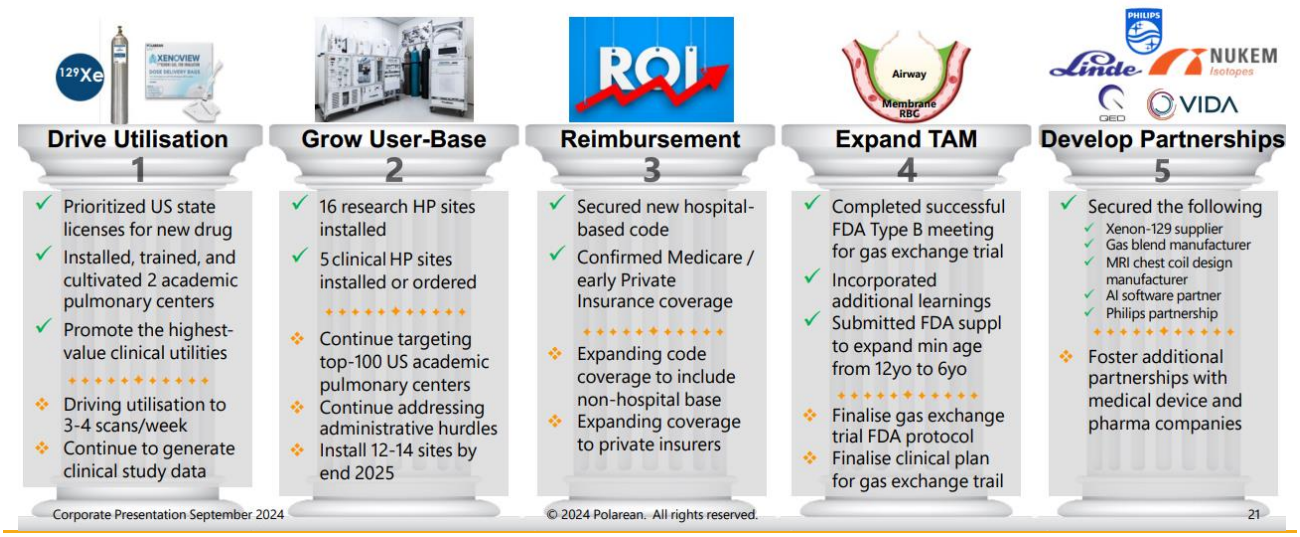
rapid expansion into clinical use once FDA approval was received (see Business).

The nature of the US medical system also requires that private insurers together with Medicare, which provides universal coverage for persons aged 65 and older, and Medicaid, which provides coverage for certain low-income families, enable hospitals to recover the cost of the treatment provided. This is done through the use of reimbursement codes without which hospitals will not put the diagnostic or treatment into general clinical use.

The US Centers for Medicare and Medicaid only granted a code for the production and administration of XENOVIEW® to patients for a Xenon MRI scan toward the end of 2023. This C9791 code along with additional existing applicable codes for the whole process, including a standard chest MRI scan, is estimated by Polarean to enable hospitals to claim a total reimbursement of approximately US$2,500 per scan under Medicare and typically 1.5x-2.0x higher for private insurers. That creates a strong economic incentive for the Xenon MRI scan, provided it is deemed 'medically necessary'. The decision on medical necessity is at the discretion of the pulmonologist or other lead medical practitioner in charge of the patient's care.

In February 2024, Polarean announced an evolution of this strategy consisting of five pillars (Figure 10).

Figure 10: 5-pillar growth strategy



Source: Polarean, CAG Research.

The main thrusts of the strategy remain the same with a focus on the top 100 academic medical hospitals in the US with a view to promoting conversion into 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. As before, there is also a drive to expand the potential market through widening the approved use for XENOVIEW® (label expansion), most notably into gas exchange. There is also an increased emphasis on partnerships particularly with the major MRI scanner manufactures but also to improve the imaging software.

Polarean has a non-exclusive relationship with Philips, one of the three large MRI suppliers in the US with the intention to co-market the technology, leveraging Philips' larger sales force, skill in improving customer experience, and especially strong links in paediatric MRI scanning. Polarean also works closely with Siemens and GE, the other large MRI vendors in North America, for the same reasons and to ensure that the MRI scanners are compatible with XENOVIEW® meaning that they are able to read the specific radio

frequencies generated by the MRI scanning process when used in conjunction with XENOVIEW®. The company has just received FDA approval for the use of its 3T Chest Coil with GE 3T MRI scanners.

Besides the scanner manufacturers, Polarean also has a partnership with VIDA, a clinical imaging technology company, to improve the imaging software, partly with a view to promoting Xenon MRI scanning to pharma and biotech companies whose trials would benefit from Polarean's Xenon MRI technology. The vastly superior lung function imaging enabled by XENOVIEW® can reduce the cost of testing relevant drugs significantly and is thus an attractive option for the pharma and biotech industry.

Business

Polarean's XENOVIEW® system delivers unique, unparalleled lung imaging through MRI scanning using hyperpolarised Xenon-129 gas produced by Polarean's XENOVIEW® system. Following key approvals in 2023, Polarean is now rolling out clinical installations with four set for installation this year. Reimbursement codes enable total recovery of US$2,500 per scan of which US$1,250 relates to the direct use of XENOVIEW®. Polarean estimate that hospitals can break even on the cost of XENOVIEW® running at c2.5 scans per week for Medicare only.

Polarean generates revenue through the sale of its Xenon MRI platform, the service agreements for the platform after expiry of the one-year warranty, and follow on consumables to hospitals, with a primary focus on the US and Canada. The FDA approval for the clinical use of XENOVIEW® in imaging lung ventilation, together with the establishment of reimbursement codes has cleared the way for Polarean to step up its marketing with a view to transitioning sales for research purposes to a full clinical setting.

The complete Xenon MRI platform (Figure 11) includes the HPX Hyperpolariser System, HPX Polarization 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 11: XENOVIEW® system

Source: Polarean, CAG Research.

Hyperpolarisation of Xenon-129 gas is achieved by placing the gas into a beam of circularly polarised laser light in the presence of a very small concentration of the alkali metal Rubidium, which acts as a physical catalyst in the hyperpolarisation process. The result is Xenon-129 gas atoms whose nuclear magnetic spin is highly aligned but not chemically or biologically different to unpolarised Xenon-129. The hyperpolarised state persists for around two hours.

The hyperpolarised Xenon-129 mix is blended down with nitrogen and the prepared dose of XENOVIEW® is checked for quality and put into a single dose delivery inhalation bag. The XENOVIEW® is inhaled by the patient from the dose delivery bag and held for one breath while undergoing MRI scanning.

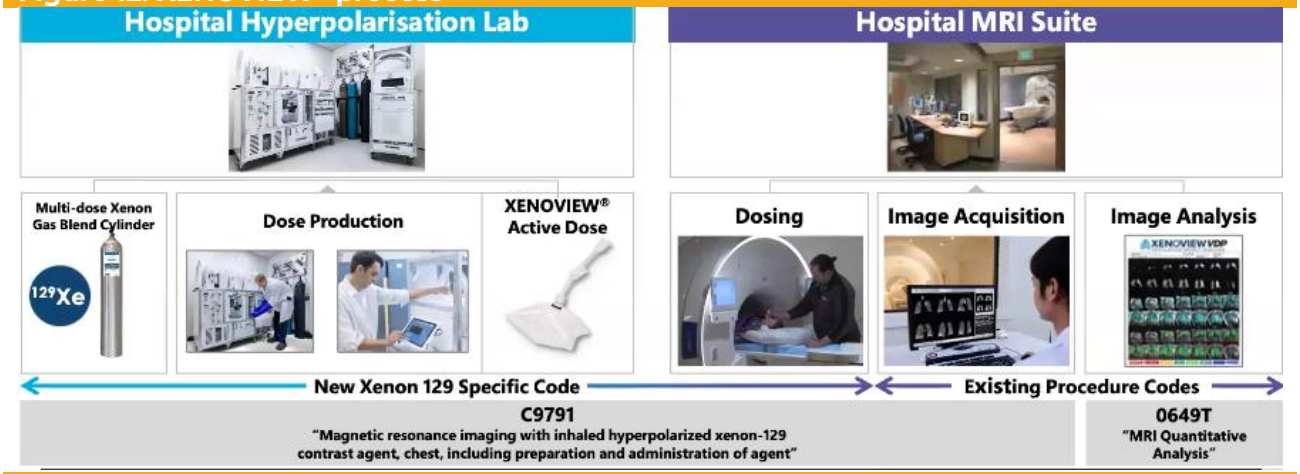
The radio frequencies produced by Xenon under MRI scanning are unique to the gas and imaging is enhanced through the use of a specialised Polarean chest coil, which sits over the patient's chest, and which is specifically tuned to the frequencies produced. The output is processed through Polarean's proprietary imaging software.

The physical equipment is manufactured by a contract manufacturer under Good Manufacturing Practices (GMP). The raw Xenon-129 gas is supplied by NUKEM Isotopes and blended to the appropriate blend of Xenon-129, Nitrogen, and Helium for hyperpolarisation by Linde for supply in multi-dose gas cylinders under GMP.

Ideally, dosing should take place within 60 minutes of production, so the hyperpolarisation installation is typically in close proximity to the MRI scanner suite itself.

The C9791 reimbursement code covers the production and administration of XENOVIEW® to patients for a Xenon MRI scan, while standard chest MRI image acquisition, and analysis are covered by other existing codes. That generates a total recovery to the hospital of around US$2,500 per scan of which US$1,250 relates to the direct use of XENOVIEW® as an inhaled MRI contrast agent (Figure 12). Usage covered by private insurers typically achieves 1.5-2.0x the reimbursement rate available under Medicare/Medicaid. Polarean estimates that hospitals can break even on the cost of XENOVIEW® running at c2.5 scans per week for Medicare only.

Figure 12: XENOVIEW® process



Source: Polarean, CAG Research.

Polarean's technology has widespread patent coverage enhanced by the FDA grant of a New Chemical Entity designation for the prepared XENOVIEW® Xenon-129 gas blend which gives Polarean a five-year exclusivity period through February 2028.

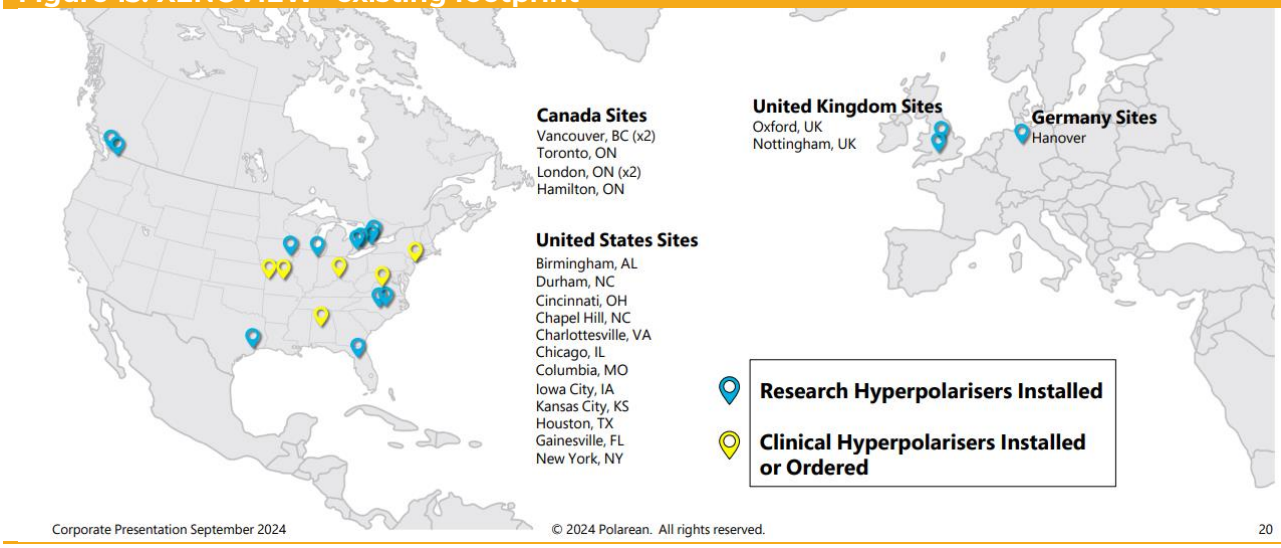
The hyperpolariser suite carries a significant up-front capital cost which has averaged around US$500k per unit for research installations. Polarean expects that the unit capital cost will increase as research installations are upgraded for full clinical use and as demand increases in existing and new hospital clients. In practice, that has meant that historically, most of Polarean's revenue has been generated through capital sales. However, as the rate of scanning increases, Polarean expects a rapid growth in revenue from the sale of the gas cylinders and other consumables (see Financials) converting the revenue profile into one that looks more like a razor/razor blade model in which the revenue from the follow-on sale of consumables becomes much more significant than for the initial capital investment.

Now that the opportunity for clinical use has been established, Polarean has recently beefed up its sales team with the appointments of a new VP Sales, Dr Alan Huang and it has also appointed Dr Chase Hall as Chief Medical Advisor.

Polarean currently has XENOVIEW® systems installed in 21 hospitals (Figure 13) of which two, Cincinnati Children's hospital, which is the top ranked

paediatric hospital in the US, and University of Missouri Health Care have been upgraded to clinical installations. In addition, the University of Kansas and University of Virginia Health System are upgrading their current research installations to clinical grade while the University of Alabama is a completely new customer for XENOVIEW® which will be the first such system in the Southeast US.

Figure 13: XENOVIEW® existing footprint



Source: Polarean, CAG Research.

Given the economics, Polarean is focused on the North American market, but its XENOVIEW® technology has worldwide application.

Financials

FDA approval for the use of XENOVIEW® in ventilation MRI scanning and the issuance of reimbursement codes have cleared the way for an initial ramp up in sales of the system for clinical, rather than research use only. That is already set to see revenue more than treble this year. FDA approval for gas exchange could see revenue hit at least US$30m in FY28, which should be sufficient to see Polarean cross the bridge to profitability and turn free cash flow positive. Increased system installations and higher utilisation should transform revenue generation from consumables, particularly the Xenon-129 gas blend used in XENOVIEW® MRI scanning. While Polarean will need additional funding to achieve profitability, it is financed 'until at least 1Q26' by which time Polarean should have been able to demonstrate what should be hyperbolic growth in revenue, now that XENOVIEW® is moving from research to full-blown clinical use.

Polarean's sales revenue has historically been driven by sales of one to three HPX Hyperpolariser systems per annum for research purposes and to help broaden the clinical knowledge base of what Xenon MRI scanning can offer, pending FDA approval for use. Until FY20, Polarean also benefitted from grant revenue, but this has since fallen to zero and is not expected to return.

Because the HPX Hyperpolariser systems were used for research purposes, their utilisation intensity was relatively low, and they were sold on relatively low margins, as Polarean worked to build a future base of demand and build-out a Polarean consumable product revenue pipeline with development of the multi-dose Xenon-129 gas blend cylinders and the single-use dose delivery bags.

Phase III trials for ventilation use were successfully completed in early 2020 and a New Drug Application was submitted to the FDA in October 2020, later than intended and well behind initial hopes in mid-2019 that commercial sales might be achieved in 2H20. Covid impacted the FDA approval process, and the company suffered a shock initial negative response from the FDA in October 2021, connected with technical and manufacturing related issues in respect of the HPX Hyperpolariser system itself, rather than the efficacy of the science. The NDA application was resubmitted in March 2022 and FDA approval for use in ventilation was received for the drug device combination in December 2022 with the Xenon-129 gas granted a New Chemical Entity designation in February of 2023, which brings a five-year exclusivity period.

As discussed, (see Business), to enable widespread take-up and clinical-intensity utilisation, FDA approval is a necessary but not sufficient enabler for clinical adoption. That also requires the appropriate reimbursement codes to be set which was not achieved until towards the end of 2023.

FDA approval and removal of the reimbursement bureaucratic hurdle has now cleared the way for an expansion into full clinical use for the US$2bn TAM ventilation market. The impact has been potent with sales expected to more than treble YoY in FY24.

The bigger prize still, is to win FDA approval for use of XENOVIEW® in gas exchange which has a TAM of US$3bn and which would be served by the same XENOVIEW®-enabled MRI scanners, markedly increasing the commercial attractiveness of investing into the technology from the commercial perspective of current and prospective hospital clients.

Polarean is targeting completion of the necessary Phase III clinical trial and achieving FDA approval to expand use into gas exchange in late2027/early 2028. This is the basis of the company's guidance as shown in Figure 14.

Figure 14: Polarean guidance

Year	Revenue range (US$m)	Clinical installations	Average scans per week
FY24	2.5-3.0	5-7	3-4
FY25	5.0-6.0	12-14	5-6
FY28	35-40	60-70	>10

Source: Polarean, CAG Research.

Polarean expects to be profitable once it is generating minimum revenue of US$25m-US$35m and calculates that hospitals will make a profit on their investment in Polarean's Xenon MRI platform at 3-4 scans per week per installation.

We estimate the consumables cost per scan at cUS$600, so with Medicare/Medicaid direct reimbursables at cUS$1.3k (Figure 12), the margin is over 50% just from the Xenon-129 specification code with an annual net revenue potential of US$110k-US$150k per installation. That would roughly equate to a 5-6 year payback on a new, full priced clinical XENOVIEW® installation. In addition, there would be the potential to increase utilisation, while the reimbursable rate in private use is 1.5x-2.0x that for government funded healthcare, promising significantly enhanced economics.

We calculate revenue for Polarean on a disaggregated basis split between capital sales of the complete Polarean Xenon MRI platform, sales of consumables, and service. Our estimates broadly map into company guidance with important parameters shown in Figure 15. Polarean expects the sales value of new installations to be higher than the historic research installations with scope for margin expansion, as it is now selling complete systems including upgraded technology for higher utilisation clinical use.

Figure 15: Key forecast assumptions

	FY24E	FY25E	FY26E	FY27E	FY28E
Total hyperpolariser installed base[1]	23	27	35	48	71
Clinical hyperpolariser installed base	4	10	20	35	60
Hyperpolariser system unit value (US$k)	500	600	675	675	675
Hyperpolariser margin	35%	40%	45%	50%	50%
Average scans per week[2]	2	4	5	7	10
Cylinder demand[2]	4	21	52	127	312
Unit value per cylinder (US$k)	50	50	50	50	50
Cylinder gross margin	65%	65%	65%	65%	65%

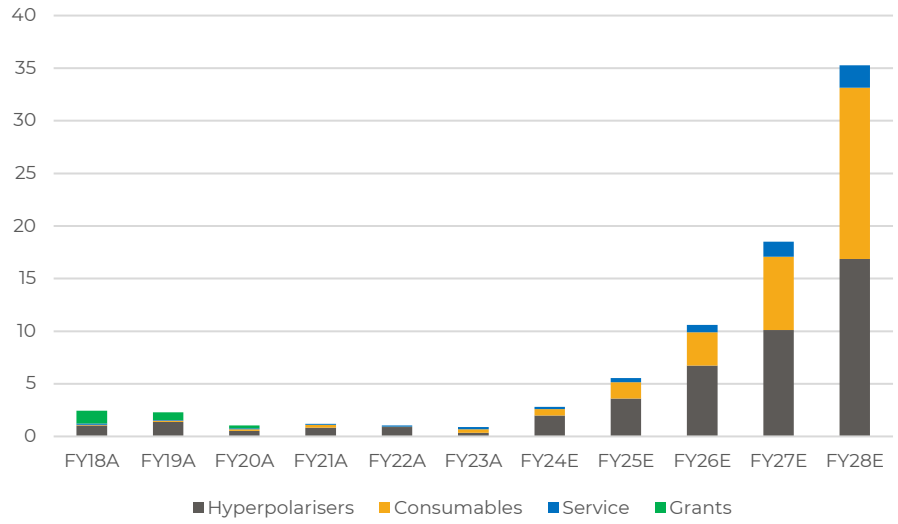
Source: Polarean, CAG Research. 1) Includes research installations; 2) Clinical installations only.

While revenue over the next two-to-three years will continue to be weighted heavily to new system installations, the transition to clinical use with much higher utilisation rates is expected to drive an exponential increase in demand for Xenon-129 gas blend and associated XENOVIEW® Dose Delivery Bags, which should account for around 20% of total consumables revenue. In addition, higher utilisation is likely to drive higher demand for servicing and maintenance.

While this can be likened to a razor/razor blade business model in the sense that expanded use drives higher margin sales of consumables, we do expect Polarean to make a substantial, and indeed increasing margin on capital sales (Figure 15).

Graphically, Figure 16 demonstrates the potential exponential growth in sales we forecast, and the shift in sales mix as XENOVIEW® builds market position. It is also important to note that the pace of growth has already jumped ahead of FDA approval for use in gas exchange.

Figure 16: Revenue forecast (US$m)

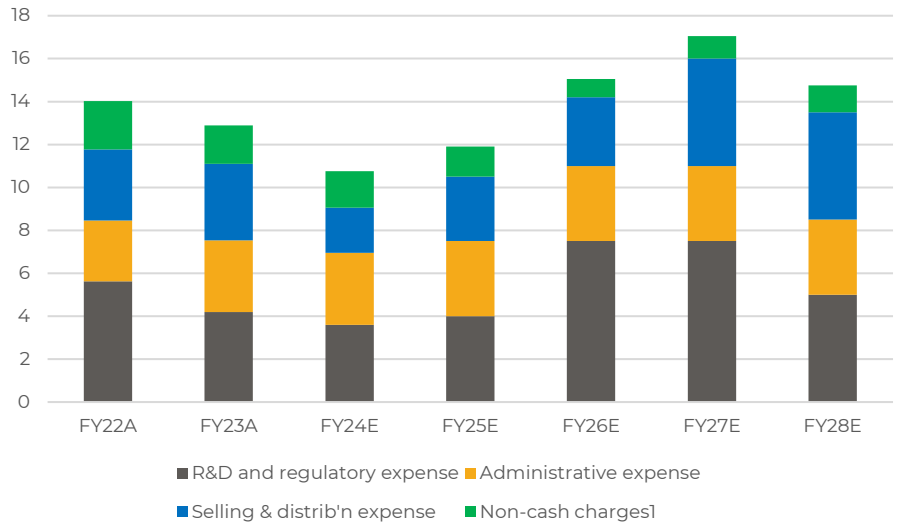


Source: Polarean, CAG Research.

Even sales of US$35m in 2028 would represent less than 1% of a then US$5bn TAM for Polarean.

Increased sales are the primary route to profitability for Polarean but the process is accelerated by a reduction in costs once the Phase III gas exchange trial costs begin to fall away, which we model peaking in FY26-FY27, partly offset by an increased sales effort as Polarean fully engages with the opportunity approval for both ventilation and gas exchange affords (Figure 17).

Figure 17: Cost structure (US$m)



Source: Polarean, CAG Research. 1) Depreciation, amortisation & share based payments.

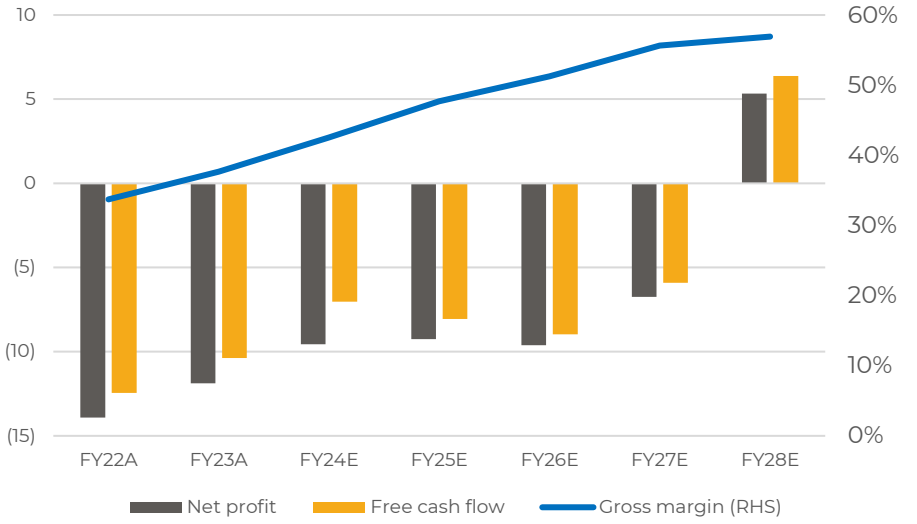
In our modelling, we assume funding will be from equity, or possibly partner funding (see Structure, management and shareholders), rather than debt as we do not believe debt markets are currently accessible for Polarean.

Consequently, we do not apply dynamic debt modelling as this would generate an improbable interest burden on profit and in cash flow.

On that basis, we forecast Polarean to move into profitability in FY28 and turn free cash flow positive (Figure 18) with gross margin increasing from 34% in FY22 to 57% in FY28.

Figure 18 also conveys important features of Polarean's financial structure. Non-cash charges are relatively minor (Figure 17) and there is very little direct capital investment as almost all costs are expensed. Consequently, net profit and free cash flow are very similar with free cash flow running marginally stronger than net profit. Not so obvious is the zero tax rate and cash tax position which reflects the loss making position Polarean is in and which will shield profits for some years, once the company becomes profitable (see Summary financial statements).

Figure 18: Net profit, free cash flow (US$m), and gross margin



Source: Polarean, CAG Research.

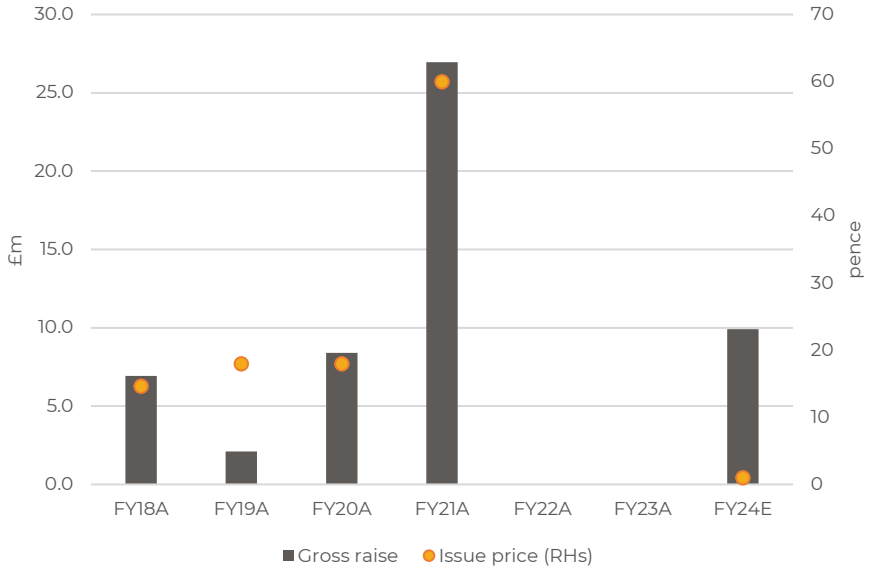
In order to cross the bridge to profitability, Polarean has made no secret that it will require additional funding. Prior to the FY24 raise, Polarean had indicated a requirement for US$30m-US$35m of funding to achieve profitability. We forecast cumulative negative free cash flow of US$30m for FY24-FY27 inclusive before Polarean achieves profitability in FY28.

Our forecast embeds US$10m as a nominal cost of the gas exchange Phase III trial in R&D and regulatory expense, which explains the forecasted jump in such expenditure in FY26 and FY27. Polarean has had extensive discussion of the design of the test with the FDA and expects to request a Type C meeting later this year, which should finalise the design.

As Polarean is effectively a clinical development company, notwithstanding a long record of revenue generation, historic funding has all been sourced from equity.

Prior to the hiatus in clearing the initial FDA and reimbursement hurdles, investor interest was strong, based on what is highly differentiated science that addresses a large unmet clinical need. However, previous delays in meeting initial guidance and with profitability still some years away, confidence has evidently drained away and the last US$13m raise was done at a heavily discounted 1p per share (Figure 19).

Figure 19: Equity raises[1]



Source: Polarean, CAG Research. 1) Excludes equity raised from the exercise of options and warrants.

At the time of the last raise, Polarean guided to a cash runway to 1Q26 and strengthened that guidance to 'until at least 1Q26' with the interim results. Our forecast is consistent with that guidance (Figure 20).

Figure 20: Financial position (US$m)

	FY23A	FY24E	FY25E	FY26E	FY27E	FY28E
Net (cash)/ debt	(6.2)	(10.8)	(2.8)	6.2	12.1	5.7

Source: Polarean, CAG Research.

Valuation

Investor confidence in Polarean is low despite initial FDA approvals for use and associated reimbursement codes which are already transforming the revenue performance and which could herald a hyperbolic lift off in sales. Based on observable deal metrics, Polarean could have equity value potential ranging up to US$350m/£280m on FY28 estimated revenue, we calculate. Our NPV calculations also support a valuation multiples above the current market capitalisation. If Polarean delivers to guidance the current valuation is likely to look like an extremely low entry point in the rear-view mirror, while the shares are at a level that could attract take-over interest, we believe.

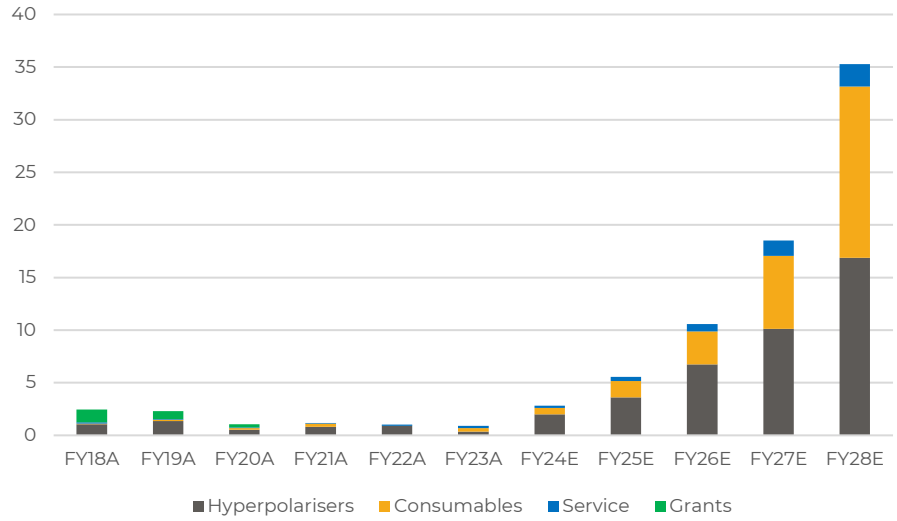
Since the euphoria that momentarily drove Polarean's market capitalisation above £220m, the come down bottomed out by the fund raise earlier this year has been hard (Figure 21). In our view, that is a reflection of the delays to FDA approval, slower than initially guided ramp-up in sales, and the further investment required to reach profitability (see Financials).

Figure 21: Polarean market capitalisation (£m)

Source: Polarean, CAG Research.

While that performance has severely dented investor confidence, 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 with a combined TAM of US$5bn in the US alone. It also overlooks the US$40m GE HealthCare initially spend on developing the technology together with almost US$70m in net equity raised by Polarean to get to the point where clinical sales of its Xenon MRI platform have now commenced. Moreover, The existing FDA approved use for ventilation and associated reimbursement codes have already resulted in a rapid acceleration in revenue that could herald a hyperbolic lift off in sales (Figure 22).

Figure 22: Revenue forecast (US$m)



Source: Polarean, CAG Research.

Although that sales profile is likely to require FDA approval for the use of XENOVIEW® in gas exchange, investors will be able to judge whether it is developing in the way we forecast before additional funding is required in FY26.

In our view, if Polarean delivers as we describe, the current valuation is likely to look like an extremely low entry point in the rear-view mirror. We also believe there is reasonable potential that Polarean could be a take-over target, given the current market capitalisation of under £20m when set against the potential value of the opportunity.

Medical device company M&A transactions are quite common, but their terms often have limited visibility as they are frequently private transactions with the targets part of larger groups.

Figure 23 shows the multiples of revenue paid, often the only available metric, for recent UK medical device transactions and selected international deals. As the table shows, the typical multiple range is a wide 1.6x-9.7x. However, we note that Vectura was initially acquired for US$1bn while ROTECH's business is in home care which we believe is likely to mean that revenue multiples of c2x are unrealistically low when considering a valuation for Polarean.

Figure 23: Medical device M&A transactions

Target	Acquirer	Date	Business	Value (US$m)[1]	Revenue (US$m)	Revenue multiple (x)
UK						
Vectura Group	Molex Asia	Sep-24	Inhaled therapeutics	387	238	1.6
Endomagnetics	Hologic	Apr-24	Breast surgical guidance	310	35	8.9
Point of Care Technology	Roche	Dec-23	PoC technology	350	126	2.8
FingerPrint Medical	Halcyon	Mar-23	Track & trace software for medical equipment during medical procedures	161	n/a	n/a
Astrea Bioseparations	Biotage	Feb-23	Chromatography solutions	280	29	9.6
International						
IRRIMAX	Archimed	Aug-24	Wound irrigation	n/a	n/a	n/a
Donatelle	Dupont	Jul-24	CDMO	313	47.4	6.6
ROTECH	OM	Jul-24	Home care	1360	750	1.8
Sunrise Medical	Platinum Equity	Jun-24	Wheelchairs/mobility	n/a	n/a	n/a
Healthium	KKR	Jun-24	Surgical products	839	86.2	9.7
HuFriedyGroup	Peak Rock Capital	Apr-24	Dental instruments	788	n/a	n/a

Source: Bloomberg, Companies, Press, CAG Research.

Nevertheless, taking the values derived in Figure 23 as the upper and lower limits, Figure 24 sets out the implied equity valuation ranges for Polarean, based on the revenue generation shown in Figure 22.

Figure 24: 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.

In sterling terms, the market capitalisation of Polarean can be justified on current management revenue guidance for FY24 and an 8x multiple. Based on our FY25 revenue forecast, which will include no contribution for sales linked to FDA approval of XENOVIEW® for gas exchange, Polarean's valuation indicates large scale upside on all but the lowest revenue multiples. Assuming sales reflect FDA approval for gas exchange from FY28, Polarean could have a valuation many times even the lowest revenue multiple and exceeding US$350m/£280m based on a 10x multiple, well above the historic peak market capitalisation achieved by the company (Figure 21).

Figure 25 translates the results shown in Figure 24 into percentage upside relative to the current market capitalisation of Polarean.

Figure 25: Polarean valuation upside, based on revenue multiples

Prem/Discount to mkt cap	FY24E	FY25E	FY26E	FY27E	FY28E
2x	-76%	-52%	-9%	58%	202%
4x	-52%	-5%	81%	217%	504%
6x	-28%	43%	172%	375%	805%
8x	-3%	90%	262%	533%	1,107%
10x	21%	138%	353%	692%	1,409%

Source: Polarean, CAG Research.

As a means of cross-checking the valuations derived from our revenue forecasts and visible deal multiples, we have also constructed a simple NPV analysis.

Using the assumptions underlying our profit forecast, we calculate a net present value for consumables based on one scan per week over a ten-year period which computes to US$125k, applying a 10% discount rate. The key assumptions are a Xenon-129 gas cylinder value of US$50k giving 100 doses with other consumables at 20% of the value of the gas and an overall gross margin of 65%. We can then derive an overall discounted cash flow value for consumables based on the average scans per week and the number of clinical units installed, discounted appropriately for the year of installation. To this we add the net revenue per clinical installation multiplied by the number of installations per year, again discounted for the year of installation.

Based on these assumptions we can derive a total NPV based on a range of assumptions for the capital value of each installation and the associated margin. We have calculated values based on our explicit five-year forecasts through FY28 only, and on a nominal basis for a further five years. In FY28, we assume that 25 of Polarean's Xenon MRI systems are installed and for each subsequent year we assume an additional five sales so by 2033, installations are running at 50 per year.

Based on the assumptions described above, either five or ten scans per week, held flat, and a range of capital unit sales values and margins, we estimate NPVs ranging from US$36m to US$73m, over a five-year period and US$114m-US$233m using a more realistic ten-year period (Figure 26).

Figure 26: NPV valuation (US$m), and upside to current mkt cap

			Vs mkt cap	
	5yr NPV	10yr NPV	5yr NPV	10yr NPV
Systems value, 5 scans/week				
Unit value US$500k, 30% margin	36	114	52%	386%
Unit value US$500k, 40% margin	38	121	62%	418%
Unit value US$500k, 50% margin	40	128	72%	449%
Unit value US$675k, 30% margin	38	121	63%	420%
Unit value US$675k, 40% margin	41	131	76%	462%
Unit value US$675k, 50% margin	44	141	89%	504%
Systems value, 10 scans/week				
Unit value US$500k, 30% margin	64	205	175%	779%
Unit value US$500k, 40% margin	67	213	185%	810%
Unit value US$500k, 50% margin	69	220	195%	842%
Unit value US$675k, 30% margin	67	213	185%	812%
Unit value US$675k, 40% margin	70	223	199%	854%
Unit value US$675k, 50% margin	73	233	212%	897%

Source: Polarean, CAG Research.

As for the revenue valuation approach, the NPV based valuations of the new clinical units we assume to be sold through FY28 generate values very substantially higher than the current market capitalisation of Polarean, roughly equivalent to a 6x through 8x multiple valuation on our FY25E or FY26E revenue forecasts. Naturally, assuming the business continues to grow after FY28, a much more likely assumption, given probable FDA approval for gas exchange, the valuations range from US$114m to US$233m. That is roughly equivalent to a 10x multiple on FY26 estimated revenue through mid-higher multiples on FY27 and FY28 revenue estimates.

While these calculations do not adjust for corporate costs, they also ignore potential growth beyond the time horizon and higher potential utilisation. Nor do they include any component for international expansion outside North America.

Structure, management, and shareholders

Polarean listed on the AIM market in 2018. Current CEO, Dr Christopher von Jako has a particular personal interest in Polarean's technology as his father, an eminent surgeon, succumbed to Idiopathic Pulmonary Fibrosis which could not be diagnosed with the technology available at the time. The Board of Polarean comprises seven Directors, including a Non-Executive Chairman, two Executive Directors and four additional Non-Executive Directors. The company's two largest shareholders are NUKEM Isotopes (NUKEM) and Bracco Imaging (Bracco) which hold interests of 19.0% and 14.4%, respectively. NUKEM has long been a key supply partner to Polarean for the raw Xenon-129 gas used in XENOVIEW®. Bracco is a leading family-owned player in the field of diagnostic imaging.

Polarean Imaging (Polarean) was incorporated in England and Wales on 24th October 2016 with company registration number 10442853.

Polarean was floated on the AIM market in March 2018 and is not listed on any other market. Polarean is a member of the AIM All Share Index.

Polarean was formed through the merger of a company co-founded by Dr Bastiaan Driehuys, who held key patents in hyperpolarisation technology, and which had acquired the assets and rights related to hyperpolarised MRI technology which GE HealthCare had developed for an investment of cUS$40m, and a company which had leading technology in the radiofrequency coils used in MRI scanning (Figure 11). This transaction was completed in 2017, ahead of flotation.

Dr Driehuys was a Director of Polarean until June 2024 and remains Chief Scientific Officer of Polarean as well as being Professor of Radiology and Professor of Biomedical Engineering at Duke University School of Medicine where he leads research into Xenon MRI scanning.

Dr Christopher von Jako became CEO of Polarean in June 2023 on the retirement of Richard Hullihen, who had led Polarean from IPO, seeing the company through its initial FDA approval for the use of Xenon MRI scanning for ventilation.

Dr von Jako has a particular personal interest in Polarean's technology as his father, an eminent surgeon, succumbed to Idiopathic Pulmonary Fibrosis which could not be diagnosed with the technology available at the time, but which could have been properly identified, diagnosed, and its treatment monitored utilising the XENOVIEW® system.

Polarean's Directors recognise the value of good corporate governance in every part of its business and have adopted the requirements of the Quoted Companies Alliance's Corporate Governance Code (the "QCA Code"), to the extent that they consider it appropriate having regard to the Company's size, board structure, stage of development and resources.

Within the Industry Classification Benchmark classification system, Polarean is categorised under Health Care, sub-categorised under Medical Equipment & Services, and Medical Equipment. Under the Bloomberg Industry Classification Standard, Polarean is listed under Health Care, nested within Medical Equipment & Devices, Medical Equipment, Radiation Equipment, Imaging Equipment.

The Board of Polarean comprises seven Directors, including a Non-Executive Chairman, two Executive Directors and four additional Non-Executive Directors (NEDs). Polarean considers all the NEDs to be independent,

although we note that the Chairman was formerly an Executive Director of Polarean while Jeurgen Laucht was previously associated with NUKEM and Cyrille Petit is associated with Bracco. NUKEM and Bracco are significant shareholders of Polarean. Neither Frank Schulkes nor Daniel Brague have prior association with Polarean. All of the Directors are male. Polarean has not designated any of the NEDs as a senior NED.

The Board of Polarean has established Audit and Remuneration Board Committees comprising only the Chair and NEDs but has not established a Nominations Committee the role of which is undertaken by the full Board.

The Directors, Board Committees and their current composition are set out in Figure 27.

Figure 27: Directors, Board Committees, and membership

			Committee/membership	
Member	**Position**	**Date appt**	**Audit**	**Remuneration**
Kenneth West	Chairman[1]	Mar-18		X
Christopher von Jako	CEO	Jun-23		
Charles Osborne	CFO	Feb-21[2]		
Jeurgen Laucht	NED	Mar-18	X	X
Cyrille Petit	NED	Jun-20	X	
Frank Schulkes	NED	Apr-22	Chair	
Daniel Brague	NED	May-22		Chair

Source: Polarean, CAG Research. 1) Non-executive.

Directors

Kenneth West – Non-Executive Chairman

Kenneth 'Ken' West has been involved with Polarean since flotation when he was Chief Operating Officer before retiring from executive duties to become a NED in December 2020, subsequently being appointed Chairman in May 2022. Mr West has a history of senior management in three venture-capital backed start-ups as well as building two US subsidiaries of European medical device companies into multi-million-dollar businesses with direct sales forces to physician offices and hospitals.

Dr Christopher von Jako – Chief Executive Officer

Dr Christopher 'Chris' von Jako was appointed CEO of Polarean in June 2023. Dr von Jako has over 30 years of healthcare leadership experience, having led both private and publicly listed business, with five entities resulting in M&A. Dr von Jako has a proven track record of commercialisation and has experience across a multitude of healthcare sectors, including radiology, pulmonology, and various surgical interventions. Dr von Jako serves as an Independent Director on the Board of nView medical Inc.

Charles Osborne – Chief Financial Officer

Charles 'Chuck' Osborne was appointed CFO of Polarean in April 2019, joining the Board in February 2021. Having initially qualified as an accountant with Deloitte & Touche, Mr Osborne served as CFO at Innocrin Pharmaceuticals Inc, a privately held oncology therapeutics company from 2015. From 2003, Mr Osborne served as CFO of Scynexis Inc, a publicly traded anti-infective company, prior to joining Innocrin.

Jeurgen Laucht - NED

Juergen Laucht has sat on the Board of Polarean since flotation when he was then Managing Director of NUKEM. Mr Laucht has over 40 years' experience in the chemical engineering industry, including at Siemens and at Reactor Brennelement Union.

Cyrille Petit - NED

Cyrille Petite joined the Board of Polarean in June 2020 when he was and remains Chief Corporate Development Officer and Head of Strategic Initiatives of Bracco. Mr Petit started his career at Goldman Sachs before working for GE for 15 years, subsequently joining Smith & Nephew as Chief Corporate Development Officer.

Frank Schulkes – NED

Frank Schulkes was appointed as a NED in April 2022. Mr Schulkes had a 27-year career with GE, mainly in GE's HealthCare division where he held the role of VP and CFO of GE HealthCare for eight years. From 2017 to 2022, Mr Schulkes was CFO of Convatec. Mr Schulkes is the CFO of Distalmotion, a privately held Swiss surgical robotics company.

Daniel Brague - NED

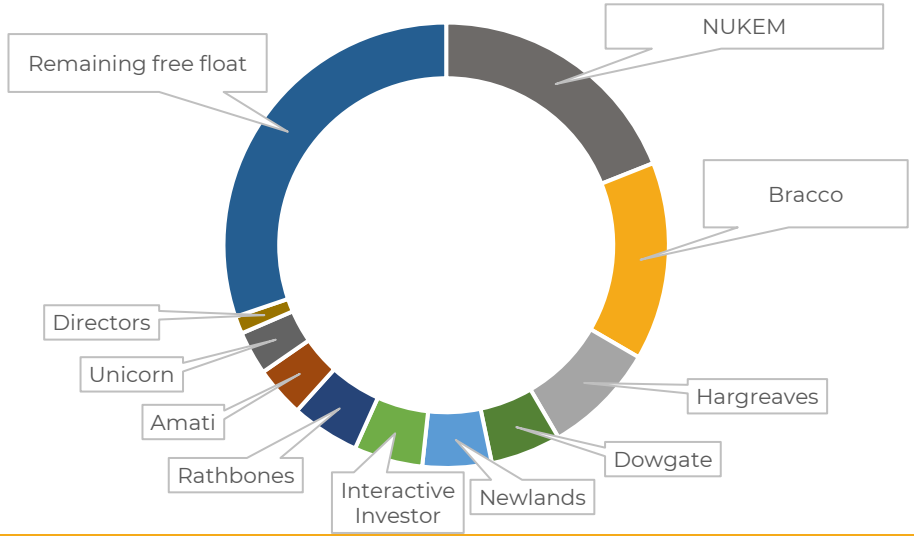
Daniel 'Dan' Brague was appointed as a NED in May 2022. Mr Brague has over 25 years' experience in the Healthcare sector including 22 years in the global diagnostic imaging industry. Most recently, Mr Brague was the North America Chief Executive Officer of Curium Pharma, the world's largest nuclear medicine company.

Shareholders

Polarean has 1,207m shares outstanding and a free float of 60.5%. The company's two largest shareholders are NUKEM and Bracco which hold interests of 19.0% and 14.4%, respectively. NUKEM has long been a key supply partner to Polarean for the raw Xenon-129 gas used in XENOVIEW® and held a 13.4% interest in the company on its Admission to AIM. Bracco is a leading family-owned player in the field of diagnostic imaging and initially took a 7.6% interest in Polarean in the March 2020 equity raise (Figure 19). Both NUKEM and Bracco were key supporters in the most recent fundraise, accounting for over a third of the funds raised.

Besides NUKEM and Bracco, retail shareholder platforms account for significant stakes but the company also has key investors well know for investing in healthcare and technology including Dowgate, Newlands, Rathbones, Amati and Unicorn (Figure 28). The Directors hold 1.3% of the shares.

Figure 28: Shareholders



Source: Bloomberg, Polarean, CAG Research.

Risks

Polarean's risk profile reflect the nature of its business and stage of development. In our view, the key risk to the delivery of the company's growth strategy lies in its ability to convince existing and potential hospital clients to invest in and utilise the company's technology which is linked to the company's ability to navigate Phase III clinical approval for the use of XENOVIEW® in gas exchange, which we believe should be a relatively low risk proposition, given the company's existing FDA approval of XENOVIEW® for use in ventilation and the unique capability of Xenon MRI scanning to image gas exchange.

Polarean lists 13 identified risks (Figure 29). In our view, none of the identified risks are unique to Polarean but rather reflect the fact that it is a pre-profit clinical device developer operating in a focused segment of medical imaging whose primary target market is the US, and which is reliant on outsourced manufacturing and the supply of critical components.

Figure 29: Identified risks

#	Identified risk	CAG view
1	Early stage of operations	Generic
2	Regulatory approvals & compliance	Generic/market specific
3	Access to funding	Generic
4	Dependence on key personnel	Generic
5	Intellectual property & proprietary technology	Generic but critical
6	Technology and products	Generic/market specific
7	Research and development risk	Generic
8	Competition	Generic
9	Reliance on third parties	Generic to business model
10	Manufacturing	Generic to business model
11	Product development timelines	Generic/market specific
12	General legal and regulatory issues	Generic/market specific
13	Healthcare pricing environment	Generic/market specific

Source: Polarean, CAG Research.

For each of the identified risks, Polarean has set out clear and credible mitigation strategies, in our view.

Polarean has unique and extensive experience in the field of xenon hyperpolarisation and its use in Xenon MRI scanning with no direct competitors in the field. That history includes the establishment of well developed supply chains, including the participation of NUKEM, its supplier of raw Xenon-129 gas, as a significant and supportive shareholder (see Structure, management, and shareholders).

While covered in the general rubrics rather than specifically, in our view, the key risk to the delivery of the company's growth strategy lies in its ability to convince existing and potential hospital clients to invest in and utilise the company's technology. Hospital acquisition of capital equipment is a notoriously lengthy process, with an average time from introduction to sales closing of between 18 to 24 months in the US and is partly dependent on physician driven demand. Developing that precursor demand requires convincing the medical establishment of the merits of Xenon MRI scanning to satisfy unmet clinical need that cannot be satisfied by the current standard of care or where the XENOVIEW® system offers a significant and cost-effective improvement in the current standard of care. Polarean has recently beefed up its sales capacity, but it remains a relatively, small and under-resourced

company. However, it is notable that following FDA clearance for ventilation and establishment of the requisite reimbursement codes last year, the company is on track to deliver four clinical systems in FY24, more than twice as many as average annual system deliveries since FY18, all of which were for research purposes.

A key component in driving demand and a focus of Polarean is achieving FDA approval for the use of XENOVIEW® in gas exchange which would more than double the potential TAM in the US, adding to demand for new systems and opening the door to higher rates of utilisation. Given the general experience of successfully concluding Phase III trials and Polarean's own experience, this is a lengthy, costly, and uncertain process. However, FDA approval of the XENOVIEW® system for use in imaging ventilation confirms that there is low to negligible risk that approval would be turned down on the basis of patient safety, and Xenon MRI scanning has demonstrated the ability to measure gas exchange in the lung in numerous academic and pharmaceutical company research studies So, this would appear to be a comparatively low risk Phase III trial which simply needs to demonstrate formally that the XENOVIEW® system can be used to measure gas exchange in a controlled clinical trial better than the current standard of care.

Polarean continues to engage with the FDA on the design of the trial, which is expected to be finalised in the first half of 2025 (See Financials). In addition, the FDA is actively reviewing Polarean's submission to approve reducing the age at which XENOVIEW® can be used for ventilation in paediatric care from twelve years to six years.

The nature of Polarean's business and offering is critically dependent on its intellectual property (IP) which includes both internally developed patents and patents exclusively licensed from Duke University. The company's portfolio covers four broad types of patents:

- Imaging methods
- Hyperpolarisation methods
- Hyperpolarisation equipment
- RF coil patents

Polarean is actively developing further IP, both internally and through licensing arrangements with third parties. Given the company's extensive patent portfolio and leading market position, Polarean is an attractive licensing partner for academic research institutions that are interested in outlining related IP.

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.

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 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)	0	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)**
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.

The lung

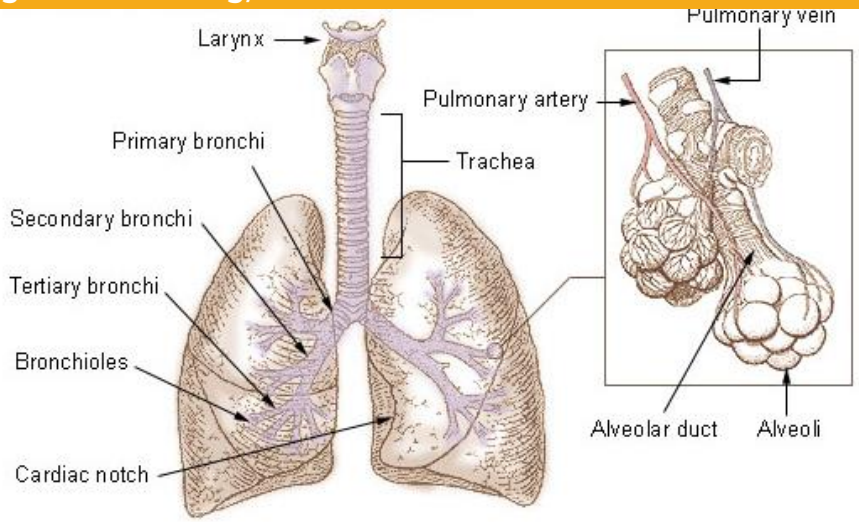
The function of the lung is to enable oxygenation of the blood. Air is inhaled through the bronchial tree to the alveoli where oxygen diffuses across the alveolar membrane into the capillary blood supply while carbon dioxide transfers in the other direction and is expelled on exhalation. The process of breathing air into and out of the alveoli is called ventilation while the actual process of gas exchange is called diffusion. Lung disease affects tens of millions of people in the US and hundreds of millions of people worldwide.

The function of the lung is to bring oxygen, contained in the air we breathe, into the body to oxygenate the blood and for the removal of carbon dioxide generated from the chemical usage of the oxygen in the body.

Humans and almost all air breathing animals, apart from snakes, have two lungs. In humans, the lungs are divided into lobes, the right lung having three lobes and the left lung two lobes, in order to provide space for the heart.

The lungs contain a highly branched network of airways known as the bronchial tree. This starts with the trachea (windpipe) and then splits into the left and right bronchi serving the left and right lungs with multiple further sub-divisions into bronchi and bronchioles, terminating in the alveoli where the magic of gas exchange happens. Humans have around 300 million alveoli (Figure 30).

Figure 30: The lung, with alveoli detail



Source: National Cancer Institute, CAG Research.

The alveoli are 200-300 microns across – about the thickness of two to three human hairs. In healthy lungs, inhaled air fills the lungs flowing into the alveoli where oxygen diffuses across the alveolar membrane, just one micron thick, into the capillary blood supply while carbon dioxide transfers in the other direction and is expelled when we exhale.

The process of breathing air into and out of the alveoli is called ventilation while the actual process of gas exchange is called diffusion.

This gas exchange process is critical to life and the effects of poor lung health range from impaired well being to death. Many lung diseases are chronic and subject to deterioration over time.

Common lung diseases caused by obstruction developing within the structure of the lung include asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, and emphysema.

Common lung diseases caused by tissue disease include fibrosis and unexplained breathlessness. Then there is cancer.

In the US, airway disease affects over 40 million people, tissue disease over 14 million people, pulmonary hypertension (high blood pressure) and microvascular disease over one million people with over 200k annual procedures for lung cancer. According to the National Library of Medicine, US expenditure on respiratory diseases accounted for 6.3% of total US health care expenditure in 2016.

Over half a billion people globally suffer from chronic respiratory disease. COPD is the fourth leading cause of death worldwide, causing 3.5 million deaths in 2021, according to the World Health Organisation

Imaging the lung

As the lung is 85%-90% air, it is extremely hard to image, particularly in the 'silent zone' of airways less than 2mm across. None of the existing methods used to measure or analyse lung performance can match the imaging capacity of the XENOVIEW® system used in Xenon MRI scanning, particularly for gas exchange, while both scintigraphy and CT scans bring radiation risk.

While the structure of the lung is evidently complex, in volume terms it is 85%-90% air. That makes it extremely hard to image as air does not reflect x-rays or radio waves and will not easily hold effective nuclear markers.

Before Polarean perfected Xenon MRI scanning there was no way to properly image lung function and in particular to image the 'silent zone' which are those airways less than 2mm across, roughly corresponding to the 10th subdivision and on of the 23 divisions in the bronchial tree, where the bronchi become bronchioles.

Prior to Xenon MRI, lung function was measured by Spirometry, DLCO, Scintigraphy or by Computed Tomography (CT scan).

Spirometry works by measuring how much air a patient can breathe out in one forced breath using a device called a spirometer, which is a small machine attached to a mouthpiece. It is a relatively simple and cheap form of test for ventilation, but it provides no direct image of the lungs, does not distinguish between the lungs, and is dependent on the effort the patient can muster. That renders spirometry relatively insensitive, and it provides no insight into the silent zone.

Lung diffusion testing (DLCO) tests for how well gas exchange is working in the lungs. The test requires breathing in a special gas mixture including carbon monoxide. Based on measuring how much carbon monoxide is breathed out, the quantity absorbed in the blood can be calculated and a measure of gas exchange performance estimated. While DLCO is used to test for gas exchange rather than ventilation performance, its limitations are similar to spirometry.

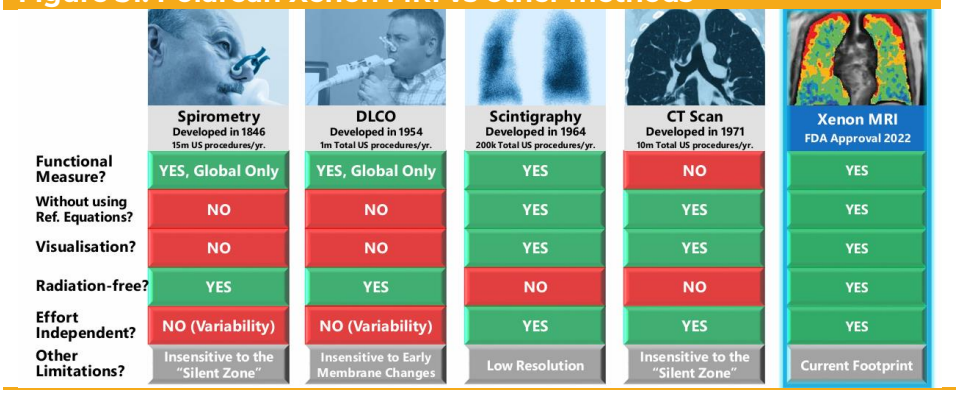
Scintigraphy involves inhaling a radionuclide which emits gamma rays which are recorded and converted into an image. However, the resolution is low, the image is of structure only, not function, and the use of radioactivity is a drawback as it limits the ability to carry out ongoing testing.

A CT scan uses multiple X-ray images processed by computer to build a 3-D image. When used to image lungs, the scan is clearer than for scintigraphy, but it is insensitive to the silent zone and also suffers from being another form of nuclear medicine, carrying radiation risk.

An MRI scan uses strong magnets to align the protons in the body with the magnetic field. When a radio frequency current is then pulsed through the patient, the protons are stimulated but realign when the current is pulsed off resulting in measurable radio signals which can be processed to form an image. The air in the lung does not respond to MRI scanning but does so when the air is replaced with Polarean's proprietary hyperpolarised Xenon-129, XENOVIEW® gas mix. The image provided by this process is sharp, provides clear information about both ventilation and also gas exchange performance for each individual lung, and carries no radiation risk. That makes it a uniquely capable tool for understanding lung performance and meeting unmet need in patient care.

The merits of Polarean's XENOVIEW® are clear from Figure 31.

Figure 31: Polarean Xenon MRI vs other methods

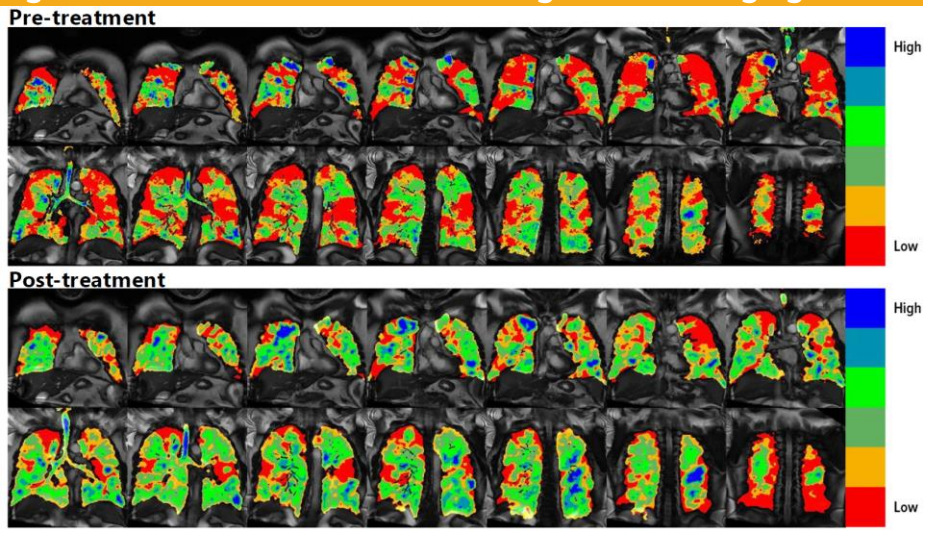


	Spirometry Developed in 1846 15m US procedures/yr.	DLCO Developed in 1954 1m Total US procedures/yr.	Scintigraphy Developed in 1964 200k Total US procedures/yr.	CT Scan Developed in 1971 10m Total US procedures/yr.	Xenon MRI FDA Approval 2022
Functional Measure?	YES, Global Only	YES, Global Only	YES	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.

The clarity and real time nature of the images generated with Xenon MRI scanning enable hitherto unsurpassed imaging of the lung and any disease issues together with response to treatment (Figure 32).

Figure 32: XENOVIEW® enables full lung function imaging

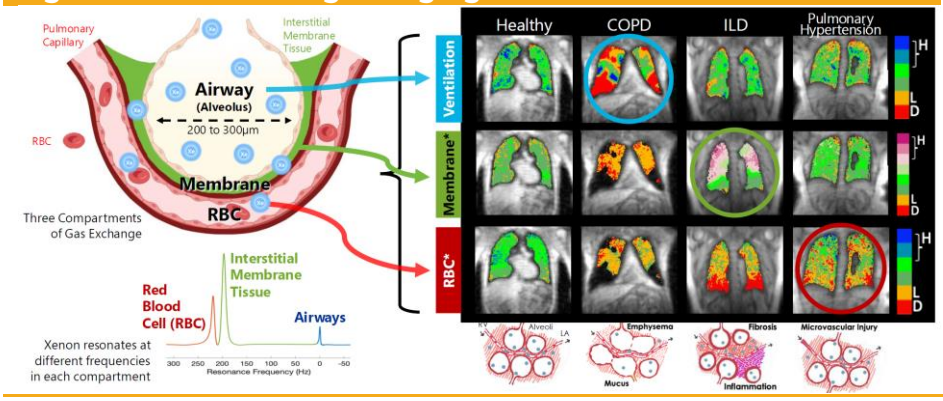


Source: Polarean, CAG Research.

From the perspective of cancer treatment, XENOVIEW® allows a much more precise estimate of lung functionality post-surgery enabling both better pre-operative surgical choices to be made and improved post-operative care.

The current FDA approval for XENOVISION® is for clinical use in ventilation, representing a US$2bn TAM. However, Xenon MRI imaging provides a unique MRI signal both for gas exchange across the alveoli membrane and take up in the capillary system, as well as in evaluating ventilation (Figure 33). There is simply no other methodology available that can provide the granularity of understanding about lung performance for either ventilation or gas exchange than the XENOVIEW® system used with MRI scanning and which really excels compared to potential alternative methods in the analysis of gas exchange.

Figure 33: Gas exchange imaging



Source: Polarean, CAG Research.

This gas exchange analysis aspect has additional significant market potential, estimated at US$3bn (see Business). However, FDA approval for clinical use in gas exchange is subject to a Phase III clinical trial against the current standard of care which is DLCO. In practice, the majority of the hospitals using the XENOVIEW® system for research purposes already use it to research gas exchange as well as ventilation, and physicians can use it for this purpose clinically on an 'off label' basis. However, that comes with significant administrative hurdles which act as a strong barrier to general use.

Based on the performance of XENOVIEW® used in imaging ventilation performance and the absence of radiation concerns, this Phase III trial for approval in gas exchange should be a low-risk proposition. Nevertheless, FDA approval will require a separate, successful Phase III trial to unlock the full potential of this market (see Business).

Capital Access Group
32 Cornhill
London
EC3V 3SG
www.capitalaccessgroup.co.uk