28 June 2024

Polarean Imaging Plc
("Polarean" or the "Company")

Final Results and Directorate Changes
Notice of Annual General Meeting

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced Magnetic Resonance Imaging ("MRI") of lung function, announces its audited final results for the year ended 31 December 2023.

In addition, Polarean confirms that the Annual Report and Accounts for the year ended 31 December 2023, the Notice of the Annual General Meeting ("AGM") and a Form of Proxy are now available on the Company's website (http://www.polarean-ir.com/content/investors/annual-reports.asp) and will be posted to shareholders shortly.

The AGM will be held at 2500 Meridian Parkway, Suite 175, Durham, NC 27713, USA at 2:00 p.m. BST / 9:00 a.m. EDT on 24 July 2024.

Highlights

- Appointed Christopher von Jako, Ph.D. as new Chief Executive Officer and Board Director, following the retirement of Richard Hullihen
- Received first de novo XENOVIEW™ (Xenon Xe 129 hyperpolarised) polariser order from a top-tier U.S. academic medical centre located in the north-eastern region of the U.S.
- Secured first order for a Xenon gas blend cylinder for the production of XENOVIEW from Cincinnati Children's Hospital Medical Center, enabling the first clinical scan utilising the technology in the U.S.
- Upgraded the University of Missouri Health Care polariser system to a clinical configuration accompanied by the sale of an initial xenon gas blend cylinder for the production of XENOVIEW
- Entered into a collaboration agreement with multinational medical imaging technology company, Philips to advance the field of hyperpolarised Xenon MRI
- Submitted a post-marketing commitment plan to the US Food and Drug Administration ("FDA") to seek approval to expand the minimum current age of XENOVIEW MRI in children from twelve to six years
- Granted New Chemical Entity designation for XENOVIEW by the FDA, with a five-year market exclusivity period
- Received 510(k) clearance from the FDA for the Company's specialised MRI chest coil to now include Philips 3.0T MRI scanners for visualisation of the Xenon 129 nuclei
- New reimbursement C-code (C9791) from the US Centers for Medicare & Medicaid Services ("CMS") for the XENOVIEW MRI technology which corresponds to a payment range of between US$1,201 to US$1,300
- Requested and granted a formal Type B meeting in October 2023 with the FDA's Center for Drug Evaluation and Research division to seek guidance on the clinical plan related to the XENOVIEW indication expansion, which includes both regional visualisation and quantitative assessment of gas exchange and microvascular haemodynamics for both pulmonary and cardio-pulmonary diseases
- Partnered with VIDA Diagnostics ("VIDA") to further enable the Polarean Xenon 129 MRI platform to accelerate clinical and research use
- Net cash of $6.2 million as of 31 December 2023 (31 December 2022: $16.4 million)

Post period end highlights

- Successfully raised gross proceeds of US$12.6 million (£9.9 million), including participation of existing strategic partners NUKEM Isotopes GmbH and Bracco Imaging S.p.A., and certain Directors and management of the Company demonstrating their continued support and extending cash runway until at least Q1 2026
- Received first de novo XENOVIEW (Xenon Xe 129 hyperpolarised) polariser order from the University of Alabama at Birmingham, a top-tier academic hospital in the south-eastern region of the U.S.
- U.S. Patent granted for dynamic cardiopulmonary blood flow imaging with Xenon MRI
- Received an order from Cincinnati Children's Hospital Medical Center for a new polariser to upgrade its existing research system to provide additional flexibility for research and clinical scanning

- Bastiaan Driehuys, Ph.D., Marcella Ruddy, M.D. and William Blair notified the Company of their intention to resign from their roles as Directors of the Board, with effect from 24 July 2024. Dr. Driehuys will retain his role as Chief Scientific Officer. Departures will result in a seven-member Board, an appropriate size and skill set for the Company

Christopher von Jako, Ph.D., CEO of Polarean, commented: "*It is now one year since I joined the excellent team at Polarean and I am very pleased with the progress we have made so far. Most recently in May, we announced a successful Placing, Subscription and Open Offer where we raised gross proceeds of US$12.6 million (£9.9 million), which we will use to accelerate the commercialisation of XENOVIEW, support our continued investment in research and development including, amongst other developments, finalisation of the FDA plan to expand indications to gas exchange, and continue to develop strategic partnerships. The fundraise will enable us to substantially progress implementation of our five-pillar growth strategy in pursuit of its mission to revolutionise pulmonary medicine.*

"We also achieved a number of key milestones in 2023, making significant progress with the FDA and in pursuit of reimbursement, as well as through the signing of key partnerships in the pulmonary space. With a current total of approximately 17 installed sites, we will continue to work closely with existing and target hospitals to facilitate the adoption and consistent utilisation of our cutting-edge technology. Thus far in 2024, we have completed sales and received orders that could result in revenues of $2.5 million. We expect further sales and additional resulting revenue for the year, particularly with our ability to expand our commercial team as a result of a successful fundraise.

"On behalf of the Board and the whole Polarean team, I would like to extend my thanks to our shareholders for all their support and we look forward to further updating the market in due course. I would also like to take this opportunity to thank Bastiaan, Marcie and Bill, who will be stepping down from their Board roles next month, for their contributions to the Company."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014, as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

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About Polarean

Polarean is a revenue-generating medical imaging technology company revolutionizing pulmonary medicine through direct visualization of lung function by introducing the power and safety of MRI to the respiratory healthcare community. This community is in desperate need of modern solutions to accurately assess lung function. The Company strives to optimize lung health and prevent avoidable loss by illuminating hidden disease, addressing the global unmet medical needs of more than 500 million patients worldwide suffering from chronic respiratory disease. Polarean is a leader in the field of hyperpolarization science and has successfully developed the first and

only hyperpolarized Xenon MRI inhaled contrast agent, XENOVIEW™, which is now FDA-approved in the United States. Polarean is dedicated to researching, developing, and commercialising innovative imaging solutions with its non-invasive and radiation-free pulmonary functional MRI platform. This comprehensive drug-device platform encompasses the proprietary Xenon gas blend, gas hyperpolarization system, as well as software and accessories, facilitating fully integrated modern respiratory imaging operations. Founded in 2012, with offices in Durham, NC, and London, United Kingdom, Polarean is committed to increasing global awareness of and broad access to its XENOVIEW MRI technology platform. For the latest news and information about Polarean, please visit www.polarean.com

XENOVIEW IMPORTANT SAFETY INFORMATION

Indication
XENOVIEW™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Limitations of Use
XENOVIEW has not been evaluated for use with lung perfusion imaging.

CONTRAINDICATIONS
None.

Warnings and Precautions
Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen desaturation and symptoms of hypoxemia and treat as clinically indicated.

Adverse Reactions
Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness. Adverse Reactions in Pediatric and Adolescent Patients: In published literature in pediatric patients aged 6 to 18, transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate was reported following hyperpolarized xenon Xe 129 administration. XENOVIEW is not approved for use in pediatric patients less than 12 years of age.

Please see full prescribing information at www.xenoview.net

PLC-RNS-2334

Chairman's statement

2023 was a challenging year for the Company, but we accomplished some important milestones that we believe have set the Company up for future success.

With approval of XENOVIEW™ by the United States ("US") Food and Drug Administration ("FDA") in late December of 2022, we began the process of obtaining insurance reimbursement for our novel imaging procedure and also began the relatively lengthy hospital decision processes for the acquisition of new capital equipment and the incorporation of novel diagnostic methods into routine clinical practice. We have had success in achieving strong reimbursement and are seeing progress in accelerating the rate of clinical adoption.

To lead our Company's commercialisation effort, we recruited Dr. Christopher von Jako as CEO, upon the retirement of Richard Hullihen. Chris has extensive experience bringing novel MedTech products to market, and his training and expertise in radiology are an excellent fit for Polarean as we continue our dual strategy of achieving commercial sales of XENOVIEW™ and establishing strategic industry collaborations to accelerate growth worldwide. Chris has done an excellent job refining and implementing a strategy to enable the Company to achieve commercial success. The development and implementation of the five-pillar growth strategy announced with our Half-Year results RNS in September 2023 has brought focus and energy to the Company and is resulting in tangible results.

In June 2024, in a difficult environment for emerging companies, we closed on a financing with gross proceeds of $12.6 million. This financing will enable the Polarean team to continue execution of our commercial strategy until at least Q1-2026. I want to particularly thank NUKEM and Bracco for their significant support of the financing and our commercialisation efforts. Both groups have been long-term supportive partners to Polarean.

On behalf of the Board, I also want to thank our employees and business partners for their untiring efforts in the commercialisation of our products, and also our shareholders for their continued support.

Kenneth West

Non-Executive Chairman
27 June 2024

Chief Executive Officer's Statement

2023 – CEO Transition

I was pleased to join Polarean as Chief Executive Officer and Director in June 2023, succeeding Richard Hullihen upon his retirement. With over 30 years of global healthcare leadership experience, I have successfully led both private and publicly listed companies. My proven track record in commercialization, alongside developing and executing sound business and operational strategies, spans across multiple healthcare sectors, including radiology, pulmonology, and various surgical interventions.

I am excited to be with Polarean at this pivotal stage in the Company's development. I am confident that our current and future advanced imaging platform will significantly aid clinicians in managing their patients' lung conditions. I look forward to continuing to work with our team to expand the reach of the XENOVIEW™ technology.

Strategy Development and Implementation

As I joined the dynamic Polarean team, we revisited all our strategic business initiatives with the intent of creating an increased focus on key business drivers. As a result, we have identified five specific growth initiatives: driving utilisation at our newly established clinical sites, expanding to our highest priority targeted clinical sites, establishing reimbursement coverage and payment, expanding our total addressable market, and developing and fostering key industry partnerships.

In February 2024, we provided an update on our progress implementing our five-pillar growth strategy.

- **Drive utilisation:** When new medical devices are introduced, hospital physicians need to be educated on their benefits in order to drive utilisation. The Polarean commercial team has been regularly visiting the Company's initial two clinical sites, Cincinnati Children's Hospital and the University of Missouri Health Care, educating pulmonologists and radiologists on the benefits of the XENOVIEW technology. The number of scans at these sites has been steadily increasing.

- **Grow user base:** 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. The Company has been actively navigating obstacles to transition multiple research sites to clinical status, alongside engaging new sites to introduce the Polarean pulmonary functional magnetic resonance imaging ("MRI") technology as a solution to their unmet diagnostic needs. Both existing and potential customers are becoming increasingly aware of the technology's value in lung ventilation diagnostics and its significant future growth opportunities in gas exchange and cardiopulmonary applications.

- **Broaden reimbursement coverage:** In adopting new diagnostic technologies, US-based hospitals look carefully at the return on investment, driven by the reimbursement rates of private and government insurers. Following the Centers for Medicare & Medicaid Services issuance of the reimbursement code for XENOVIEW scans and the associated reimbursement rate of between US$1,201 and US$1,300 in October 2023, hospitals are steadily recognising the economic benefits of integrating the XENOVIEW technology into the clinical care pathway for patients with lung disease. Medicare (the U.S. government-funded health insurance for people aged 65 and older) coverage is important in the elderly population suffering from chronic lung diseases that XENOVIEW is tailored to address. Polarean has confirmed that the initial clinical sites have attained reimbursement by both select private insurers and Medicaid (the U.S. government-funded programme providing health coverage to low-income individuals and families). The Company is working to broaden reimbursement coverage with additional private U.S. health insurers to strengthen the value proposition for the adoption of XENOVIEW.

- **Expand total addressable market:** In its initial regulatory approval, the FDA outlined specific requirements to expand the approved patient age range for XENOVIEW from twelve to six years old, marking a significant milestone in the product's accessibility to younger patients. The Company has made notable progress in meeting these FDA requirements. Additionally, the Company is incorporating insights gathered from the October 2023 FDA meeting to support a development plan for the approval of new indications including gas exchange and cardiopulmonary applications. With XENOVIEW's safety demonstrated in the prior Phase 3 clinical trials combined with over a decade of research and publications on gas exchange and cardiopulmonary applications, the Company is confident that a forthcoming clinical trial required to expand the indications for XENOVIEW has been considerably de-risked.

- **Further develop partnerships:** The Company's existing strategic partners Philips (a leading MRI company), VIDA (a leading clinical lung imaging intelligence company), and NUKEM Isotopes (a leading medical stable isotope supplier), remain involved and instrumental in helping advance the XENOVIEW technology. Additionally, Polarean has been actively engaging multiple pharmaceutical ("Pharma") and medical technology ("MedTech") companies to increase awareness and adoption of the Polarean technology. Currently, clinicaltrials.gov lists numerous clinical trials underway that utilise Xenon MRI technology to evaluate the effectiveness of existing and new pharmaceutical treatments. In January 2024, the Company participated in the annual 129Xe MRI Clinical Trials Consortium Meeting. This meeting also brought together other representatives from the Pharma and MedTech sectors, like GE HealthCare, Genentech, Philips, and Siemens, to share insights and advancements of Xenon MRI.

In May 2024 we announced our second de novo system order of the year from The University of Alabama at Birmingham Hospital, a prestigious top-tier US academic facility. As described, hospital acquisition of new capital equipment can be a lengthy process, and so momentum continues to build for our sales success. Contingent on the installation of this polariser system, and the two additional previously announced system orders, the Company has completed sales and firm orders as of today that would result in 2024 revenue of approximately US$2.5M. We expect additional orders to come in this year that will result in additional 2024 revenue. We are very excited to see that our commercial growth strategy is yielding tangible results.

Financials

Sales for 2023 were below our original expectations, as the capital sales process at hospitals took longer than the Company had originally anticipated. Upon my appointment and subsequent review of the strategy, we reduced our sales forecasts and adjusted our spending plans to extend our cash runway. This prudent financial management allowed us to finish 2023 with a higher-than-anticipated cash balance of US$6.2 million.

On 18 June 2024, we announced the results of a financing with gross proceeds of US$12.6 million. This financing is expected to support the company financially until at least Q1-2026.

2024 and Beyond

As outlined earlier, we are laser-focused on executing our five-pillar growth strategy. With the recent financing closed, we are expanding our commercial team to achieve the sales targets set in our February 2024 Strategy Update RNS.

Our mission is revolutionizing pulmonary medicine through direct visualization of lung function, and our vision is to optimize lung health and prevent avoidable loss by illuminating hidden disease. These guiding principles drive our efforts as we strive to make a significant impact on pulmonary health.

I want to express my gratitude to the investors who participated in the recent financing for their support. I also extend my heartfelt thanks to our dedicated team of employees, consultants, and advisers who work

tirelessly on our mission. Their commitment is evident in the lives we are already improving, as our advanced imaging technology helps clinicians manage their patients more effectively.

Together, we are making a meaningful difference in lung health and advancing our mission to revolutionize pulmonary medicine.

Christopher von Jako, Ph.D.

Chief Executive Officer
27 June 2024

Consolidated Statement of Comprehensive Income

	Notes	2023 US$	2022 US$
Revenue	4	890,933	1,033,008
Cost of sales		(555,450)	(684,732)
Gross profit		335,483	348,276
Administrative expenses		(3,337,836)	(2,839,543)
Research, development and regulatory expenses		(4,194,006)	(5,625,223)
Depreciation	11	(208,786)	(277,461)
Amortisation	12	(728,411)	(760,780)
Selling and distribution expenses		(3,562,412)	(3,310,592)
Share-based payment expense	19	(860,195)	(1,205,247)
Total operating costs		(12,891,646)	(14,018,846)
Operating loss	6	(12,556,163)	(13,670,570)
Finance income	7	298,899	35,045
Finance expense	7	(15,990)	(23,762)
Other gains/(losses) – net	7	388,451	(246,309)
Loss before tax		(11,884,803)	(13,905,596)
Taxation	10	-	-
Loss for the year and total other comprehensive expense		(11,884,803)	(13,905,596)
Loss per share			
Basic and diluted (US$)	9	(0.055)	(0.066)

The results reflected above relate to continuing activities.

There are no items of Other Comprehensive Income (“OCI”) for the year other than the loss above and therefore no separate statement of other comprehensive income has been presented.

Consolidated Statement of Financial Position

	Notes	2023 US$	2022 US$
ASSETS			
Non-current assets			
Property, plant and equipment	11	288,627	418,498
Intangible assets	12	969,339	1,581,591
Right-of-use assets	24	158,129	274,288
Trade and other receivables	14	387,961	437,539
		1,804,056	2,711,916
Current assets			
Inventories	15	2,221,823	1,711,419
Trade and other receivables	14	685,117	1,659,649
Cash and cash equivalents	16	6,171,636	16,454,241
		9,078,576	19,825,309
TOTAL ASSETS		10,882,632	22,537,225
EQUITY AND LIABILITIES			
Equity attributable to holders of the parent			
Share capital	17	104,780	103,463
Share premium	18	59,305,160	59,288,383
Group re-organisation reserve	18	7,813,337	7,813,337
Share-based payment reserve	19	5,725,774	4,865,579
Accumulated losses	18	(64,650,607)	(52,765,804)
		8,298,444	19,304,958
Non-current liabilities			
Contract liabilities	21	67,032	128,704
Trade and other payables	22	240,000	360,000
Lease liability	24	74,846	216,691
Contingent consideration	20	-	316,000
		381,878	1,021,395
Current liabilities			
Trade and other payables	22	1,831,587	1,979,001
Lease liability	24	141,845	142,146
Contract liabilities	21	228,878	89,725
		2,202,310	2,210,872
TOTAL EQUITY AND LIABILITIES		10,882,632	22,537,225

Consolidated Statement of Changes in Equity

	Share capital US$	*Share premium US$*	*Share-based payment reserve US$*	*Group re-organisation reserve US$*	*Accumulated losses US$*	*Total equity US$*
As at 1 January 2022	101,642	59,022,919	3,660,332	7,813,337	(38,860,208)	31,738,022
Comprehensive income						
Loss for the year	-	-	-	-	(13,905,596)	(13,905,596)
Transactions with owners						
Issue of shares	1,821	265,464	-	-	-	267,285
Share issue costs						
Share-based payment expense	-	-	1,205,247	-	-	1,205,247
As at 31 December 2022 (audited)	103,463	59,288,383	4,865,579	7,813,337	(52,765,804)	19,304,958
Comprehensive income						
Loss for the year					(11,884,803)	(11,884,803)
Transactions with owners						
Issue of shares	1,317	16,777	-	-	-	18,094
Share-based payment expense	-	-	860,195	-	-	860,195
As at 31 December 2023	104,780	59,305,160	5,725,774	7,813,337	(64,650,607)	8,298,444

Consolidated Statement of Cash Flows

	2023 US$	*2022 US$*
Cash flows from operating activities		
Loss before tax	(11,884,803)	(13,905,596)
Adjustments for non-cash/non-operating items:		
Depreciation of property, plant and equipment	208,786	277,461
Amortisation of intangible assets and right-of use-assets	728,411	760,780
Loss on disposal of property, plant and equipment	-	2,766
Share-based payment expense	860,195	1,205,247
Net foreign exchange (gains)/losses	(72,451)	246,309
Writeback of contingent consideration	(316,000)	-
Finance expense	15,990	23,762
Finance income	(298,899)	(35,045)
Operating cash outflows before movements in working capital	(10,758,771)	(11,424,316)
Decrease/(Increase) in inventories	(510,404)	(284,609)
Decrease/(increase) in trade and other receivables	1,024,108	(1,120,681)
Increase/(decrease) in trade and other payables	(267,413)	607,887
Increase/(decrease) in contract liabilities	77,482	(36,312)
Net cash used in operations	(10,434,998)	(12,258,031)
Cash flows from investing activities		
Purchase of property, plant and equipment	(78,915)	(63,946)
Dividend and interest received	298,899	35,045
Net cash used in investing activities	219,984	(28,901)
Cash flows from financing activities		
Issue of shares	18,094	267,285
Interest paid on lease liabilities	(15,990)	(23,762)
Principal elements of lease payments	(142,146)	(130,949)
Net cash generated by financing activities	(140,042)	112,574
Net decrease in cash and cash equivalents	(10,355,056)	(12,174,358)
Cash and cash equivalents at the beginning of year	16,454,241	28,874,908
Effect of foreign exchange rate changes on cash and cash equivalents	72,451	(246,309)
Cash and cash equivalents at end of year	6,171,636	16,454,241

For access to the full notes on these statements, please click here for the Annual Report.