7 September 2023

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

Half-year Report

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced magnetic resonance imaging ("MRI") of the lungs, announces its unaudited interim results for the six months ended 30 June 2023.

Highlights

- Secured the first order for a xenon gas blend cylinder for the production of XENOVIEW™ (xenon Xe 129 hyperpolarised) from Cincinnati Children's Hospital Medical Center leading to the first clinical scan in North America, representing a key milestone in the execution of the commercial plan
- 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 prior to 30 June 2024 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
- Selected as one of the featured companies at the American Thoracic Society's 2023 Respiratory Innovation Summit
- Appointed Christopher von Jako, Ph.D. as new Chief Executive Officer and Board Director
- Net cash of US$9.9m as of 30 June 2023, which based on strategic decisions, is now expected to fund the Company until the end of Q2 2024

Post-period end

- 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
- Received 510(k) clearance from the FDA for the Company's specialised MRI chest coil to now include Philips 3.0T MRI scanners for the visualisation of 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

Christopher von Jako, Ph.D., CEO of Polarean, commented: *"Today marks 80 days since I joined the dynamic Polarean team, and I am very excited about our life-altering imaging platform technology and how we can help individuals suffering from lung disease. Over the past two months, we began revisiting all our strategic business initiatives with the intent of creating increased focus on key business drivers. As a result, we have identified five specific growth initiatives, which include driving utilisation at our newly established clinical sites, expanding to our highest priority targeted clinical sites, developing key industry partnerships, establishing reimbursement coverage and payment, and expanding our current FDA indication to include the even higher value interstitial lung and pulmonary vascular diseases.*

"I am also delighted that we received a final determination from CMS that our new C-code is linked to a new technology APC 1551, which corresponds to a payment range of between US$1,201 to US$1,300. This reimbursement code should be helpful as we market XENOVIEW for the evaluation of ventilation, which is highly useful in obstructive lung diseases like asthma, COPD, and cystic fibrosis.

"Our new focus will also result in reduced operating expenses going forward which allows us to extend our cash runway until the end of Q2 2024. All our initiatives are guided by our belief and desire to revolutionise pulmonary and cardio-pulmonary medicine."

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 (www.polarean.com)

The Company and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue-generating, medical imaging technology companies operating in the high-resolution medical imaging space. Polarean aspires to revolutionise pulmonary medicine by bringing the power and safety of MRI to the respiratory healthcare community in need of new solutions to evaluate lung ventilation, diagnose disease, characterise disease progression, and monitor response to treatment. By researching, developing, and commercialising novel imaging solutions with a non-invasive and radiation-free functional imaging platform. Polarean's vision is to help address the global unmet medical needs of more than 500 million patients worldwide suffering with chronic respiratory disease. Polarean is a leader in the field of hyperpolarisation science and has successfully developed the first and only hyperpolarised MRI contrast agent to be approved in the United States. The Company also commercialises systems (such as the HPX hyperpolarisation system), accessories (such as Xe-specific chest coils and phantoms), and FDA-cleared post-processing software (to support ventilation defect analysis), to support fully integrated modern respiratory imaging operations.

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

CEO Statement

Introduction

I am excited to have recently joined Polarean, and was initially attracted to the Company's promising functional imaging technology, the large clinical unmet need that it addresses, and the business model. I am confident that our technology will be clinically useful for the pulmonary diseases covered by the current FDA approval in ventilation, including asthma, COPD, and cystic fibrosis. In addition, it has even greater potential as we expand into the high-value areas of interstitial lung and pulmonary vascular disease. The XENOVIEW MRI technology has the potential to transform the visualisation and measurement of pulmonary and cardio-pulmonary disease.

I have spent the last two months working with the team to understand the technology and the commercial opportunities. I am very encouraged by the scientific and medical community's appreciation for the large unmet medical need in the pulmonary functional imaging space, and we are in the process of refining our commercialisation strategy to deploy XENOVIEW. My long tenure in the medical device industry, particularly focused on large capital products, will be very valuable as we look to ramp up commercial sales.

Results overview

Polarean received FDA approval in December 2022, which enabled the Company to start selling its products to the clinical market. As per US regulations, we could not start to market the system and services until we received FDA approval. Our efforts during the first half of 2023 were mainly focused on preparing our legacy research sites for the conversion to clinical scanning, obtaining the required state drug licenses, and beginning the commercial launch process. Whilst we have been encouraged by the successful clinical conversion of two of our prominent research sites, and the highly positive response from physicians in both existing and prospective new sites, the process has gone more slowly than the Company had originally hoped. The slower-than-expected early commercial sales are primarily due to the hospital contracting process, which we continue to actively address. From my perspective, the early results from this type of first-in-class medical imaging technology launch are not different than in my past experiences.

Group revenues for the first half were US$0.1m (H1 2022: US$0.8m), based on sales of xenon gas blend cylinders and parts and service for polarisers installed at our customer locations. Operating expenses for H1 2023 (US$7.7m) increased from H1 2022 (US$7.0m), as we incurred commercialisation costs to launch our products. In H1 2023, the Company recognised finance income of US$0.2m (H1 2022: US$nil), due to interest earned on our bank deposits. Other gains / (losses) of US$0.1m (H1 2022: US$(0.2m)) were due to the strengthening of the British pound during the 2023 period versus a weakening of the British pound during the 2022 period. The overall loss before tax increased to US$7.4m in H1 2023 (H1 2022: US$6.9m), due to higher operating expenses, partially offset by the interest income and foreign exchange gain described above. As of 30 June 2022, the Company held US$9.9m in net cash or cash equivalents.

Commercialisation plans

We are in the market development phase of our novel functional imaging technology. In order for hospital administrators to embrace our technology, we need to focus on the most compelling clinical use cases that lead to meaningful outcomes for patients. We are working with our experienced research user-base to continue generating case studies, while also equipping them to utilise the technology in their clinical practice setting. In addition, we are in conversations with our highest-priority early adopter sites for new placements, and exploring ways for them to acquire polariser systems that they can use for both research and clinical uses of our technology. The recent reimbursement code issuance should aid the market adoption of the polariser systems.

An important part of our strategy will be to seek industry partners, which includes pharmaceutical and medical device companies as well as specific disease advocacy organisations to expand the uses of our technology and

provide potential sources of resources and funding. In June 2023, we announced that we had entered into a collaboration with Philips, a global leader in health technology. The collaboration was featured at the 2023 International Society for Magnetic Resonance in Medicine Annual Meeting in Toronto, and facilitates the sharing of technical data and marketing materials to jointly advance the field of Xenon MRI into the clinical realm. The collaboration was shortly followed by Polarean receiving an additional 510(k) from the FDA for our specialised MRI chest coil to now include Philips 3.0T MRI scanners. This was an important milestone, not only highlighting the value that Philips sees in the XENOVIEW MRI technology in furthering pulmonary imaging but also in growing the number of healthcare systems that are able to utilise XENOVIEW MRI.

Outlook

As I approach my three-month mark as CEO, I strongly believe that the novel Polarean imaging platform holds the potential to bring significant benefits to both patients and clinicians. The technology will revolutionise the landscape of diagnosis and longitudinal monitoring in the fields of pulmonary and cardio-pulmonary medicine. The recent milestone approval of a new C-code, which is linked with a new technology APC code featuring a payment range of US$1,201 to US$1,300, represents another significant achievement by our Company. This accomplishment establishes a solid foundation for our reimbursement endeavors within our two targeted fields.

In my 30-year career in high-tech medical devices, I have seen the early days of several minimally invasive disruptive technologies that have since changed the course of medicine in their respective fields. Each experience has taught me the importance of focus and cash efficiency while continuing to build value. In my experience of selling large capital equipment, I have found that early sales are often irregular and difficult to forecast whilst the commercialisation process is still evolving. Therefore, while I am confident in the demand for our product and its ability to gain commercial traction, we feel it is sensible to withdraw the previously stated commercial targets at this time. We will, however, be providing renewed guidance at a suitable time.

We are focusing our efforts and expenditures on activities that we believe can deliver important milestones within our current cash runway. These activities have led to the identification of specific growth initiatives, which include:

1) Driving utilisation at our newly established clinical sites;
2) Expanding to our highest-priority targeted clinical sites;
3) Establishing reimbursement coverage and payment;
4) Developing key industry partnerships; and
5) Planning for the expansion of our current FDA labeling to include visualisation and measurement of gas exchange

The Company is funded until the end of Q2 2024, and the continued progress on the above initiatives will help support future financing at the appropriate time.

I look forward to leading Polarean through this exciting journey and developing this large potential market for our employees and investors. Together, we are committed to successfully increasing access to the XENOVIEW MRI technology because so many people are counting on this technology to improve patients' lives.

Christopher von Jako, Ph.D.
Chief Executive Officer

7 September 2023

POLAREAN IMAGING PLC
Consolidated unaudited statement of comprehensive income
for the six months ended 30 June 2023

	Note	Unaudited 6 months ended 30 June 2023 US$	Unaudited 6 months ended 30 June 2022 US$	Audited 12 months ended 31 December 2022 US$
Revenue		142,384	834,087	1,033,008
Cost of sales		(60,484)	(539,247)	(684,732)
Gross profit		**81,900**	**294,840**	**348,276**
Administrative expenses		(1,865,084)	(1,480,119)	(2,839,544)
Research, development and regulatory expenses		(2,460,547)	(2,522,166)	(5,625,222)
Depreciation		(165,509)	(139,058)	(277,461)
Amortisation		(306,126)	(392,739)	(760,780)
Selling and distribution expenses		(2,453,477)	(1,738,265)	(3,310,592)
Share based payment expense		(433,892)	(701,832)	(1,205.247)
Total operating expenses		(7,684,635)	(6,974,179)	(14,018,846)
Loss from operations		**(7,602,735)**	**(6,679,339)**	**(13,670,570)**
Finance income		192,826	2,530	35,045
Finance expense		(8,945)	(12,944)	(23,762)
Other gains/(losses)-net		67,685	(228,378)	(246,309)
Loss on ordinary activities before taxation	**3**	**(7,351,169)**	**(6,918,131)**	**(13,905,596)**
Taxation		-	-	
Loss and total other comprehensive expense		**(7,351,169)**	**(6,918,131)**	**(13,905,596)**
Basic and fully diluted loss per share (US$)	**3**	**(0.035)**	**(0.033)**	**(0.066)**

POLAREAN IMAGING PLC
Consolidated unaudited statement of financial position
at 30 June 2023

	Note	Unaudited As at 30 June 2023 US$	Unaudited As at 30 June 2022 US$	Audited As at 31 December 2022 US$
Assets				
Non-current assets				
Property, plant and equipment		351,109	504,484	418,498
Intangible assets		1,275,465	1,887,717	1,581,591
Right-of-use asset		212,373	336,203	274,288
Trade and other receivables		413,539	5,539	437,539
		2,252,486	2,733,943	2,711,916
Current assets				
Inventories		2,061,931	1,571,100	1,711,419
Trade and other receivables		1,505,254	1,958,292	1,659,649
Cash and cash equivalents		9,879,595	22,690,308	16,454,241
		13,446,780	26,219,700	19,825,309
Total assets		**15,699,266**	**28,953,643**	**22,537,225**
Equity				
Share capital	**4**	103,861	103,194	103,463
Share premium		59,291,496	59,179,376	59,288,383
Group reorganisation reserve		7,813,337	7,813,337	7,813,337
Share-based payment reserve		5,299,471	4,362,164	4,865,579
Accumulated losses		(60,116,973)	(45,778,339)	(52,765,804)
Total equity		**12,391,192**	**25,679,732**	**19,304,958**
Liabilities				
Non-current liabilities				
Deferred income		99,596	157,702	128,704
Lease liability	**5**	147,667	285,493	216,691
Trade and other payables		300,000	-	360,000
Contingent consideration		316,000	316,000	316,000
		863,263	759,195	1,021,395
Current liabilities				
Trade and other payables		2,169,530	2,179,232	1,979,001
Lease liability	**5**	137,827	144,767	142,146
Deferred income		137,454	190,717	89,725
		2,444,811	2,514,716	2,210,872
Total equity and liabilities		**15,699,266**	**28,953,643**	**22,537,225**

POLAREAN IMAGING PLC
Consolidated unaudited statement of changes in equity
at 30 June 2023

	Share capital	Share premium	Group re-organisation	Share-based payment reserve	Accumulated losses	Total equity
Balance as at 31 December 2021 (audited)	**101,642**	**59,022,919**	**7,813,337**	**3,660,332**	**(38,860,208)**	**31,738,022**
Loss and total comprehensive income for the period	-	-	-	-	(6,918,131)	(6,918,131)
Transactions with owners						
Issue of shares	1,552	156,457	-	-	-	158,009
Share-based payments	-	-	-	701,832	-	701,832
Balance as at 30 June 2022 (unaudited)	**103,194**	**59,179,376**	**7,813,337**	**4,362,164**	**(45,778,339)**	**25,679.732**
Comprehensive income						
Loss and total comprehensive income for the period	-	-	-	-	(6,987,465)	(6,987,465)
Transactions with owners						
Issue of shares	269	109,007	-	-	-	109,276
Share-based payments	-	-	-	503,415	-	503,415
Balance as at 31 December 2022 (audited)	**103,463**	**59,288,383**	**7,813,337**	**4,865,579**	**(52,765,804)**	**19,304,958**
Loss and total comprehensive income for the period	-	-	-	-	(7,351,169)	(7,351,169)
Transactions with owners						
Issue of shares	398	3,113	-	-	-	3,511
Share-based payments	-	-	-	433,892	-	433,892
Balance as at 30 June 2023 (unaudited)	**103,861**	**59,291,496**	**7,813,337**	**5,299,471**	**(60,116,973)**	**12,391,192**

POLAREAN IMAGING PLC
Consolidated unaudited cash flow statement
for the six months ended 30 June 2023

	Unaudited 6 months ended 30 June 2023 US$	Unaudited 6 months ended 30 June 2022 US$	Audited 12 months ended 31 December 2022 US$
Cash flows from operating activities			
Loss for the period before taxation	(7,351,169)	(6,918,131)	(13,905,596)
Adjustments for non-cash/non-operating items:			
Depreciation of property, plant and equipment	103,594	139,058	277,461
Amortisation of intangible and right-of-use assets	368,041	392,739	760,780
Loss on disposal of property, plant and equipment	-	1,927	2,766
Share based payment expense	433,892	701,832	1,205,247
Net foreign exchange (gains)/losses	(67,685)	228,378	246,309
Finance expense	8,945	12,944	23,762
Finance income	(192,826)	(2,530)	(35,045)
	(6,697,208)	(5,443,783)	(11,424,316)
Changes in working capital:			
Increase in inventories	(350,512)	(144,290)	(284,609)
Decrease/(increase) in trade and other receivables	57,587	(987,325)	(1,120,681)
Increase in trade and other payables	227,538	435,439	607,887
Increase/(decrease) in deferred revenue	42,421	106,358	(36,312)
Net cash flows used in operating activities	**(6,720,174)**	**(6,033,601)**	**(12,258,031)**
Cash flows from investing activities			
Purchase of property, plant and equipment	(36,205)	(10,689)	(63,946)
Interest received	**192.826**	**2,530**	**35,045**
Net cash generated from (used in) investing activities	**156,621**	**(8,159)**	**(28,901)**
Cash flows from financing activities			
Issue of shares	3,511	158,009	267,285
Interest paid on lease liabilities	(8,945)	(12,944)	(23,762)
Principal elements of lease payments	(73,344)	(59,527)	(130,949)
Net cash generated from (used in)financing activities	**(78,778)**	**85,538**	**112,574**
Net decrease in cash and equivalents	(6,642,331)	(5,956,222)	(12,174,358)
Cash and equivalents at beginning of period	16,454,241	28,874,908	28,874,908
Effect of foreign exchange rate changes on cash and cash equivalents	67,685	(228,378)	(246,309)
Cash and equivalents at end of period	**9,879,595**	**22,690,308**	**16,454,241**

NOTES TO THE INTERIM ACCOUNTS

1. Basis of presentation

This interim consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with AIM rule 18, *'Half yearly reports and accounts'*. This interim consolidated financial information is not the Group's statutory financial statements within the meaning of section 434 of the Companies Act 2006 (and information as required by section 435 of the Companies Act 2006) and should be read in conjunction with the annual financial statements for the year ended 31 December 2022, which have been prepared in accordance with UK-adopted International Accounting Standards (UK IFRS) and have been delivered to the Registrar of Companies. The auditors have reported on those accounts; their report was unqualified but drew attention to a material uncertainty related to going concern. It did not contain statements under section 498(2) or (3) of the Companies Act 2006.

The interim consolidated financial information has been prepared in accordance with the accounting policies adopted in the Group's most recent annual financial statements for the year ended 31 December 2022. A number of amendments to IFRS accounting standards have become applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these amended standards.

The judgements, estimates and assumptions applied in the interim condensed consolidated financial information, including the key sources of estimation uncertainty, were the same as those applied in the Group's last annual financial statements for the year ended 31 December 2022.

The interim consolidated financial information for the six months ended 30 June 2023 is unaudited. In the opinion of the Directors, the interim consolidated financial information presents fairly the financial position, and results from operations and cash flows for the period. Comparative numbers for the six months ended 30 June 2022 are also unaudited.

This interim consolidated financial information is presented in US Dollars (US$).

2. Going concern

The interim consolidated financial information for the six months ended 30 June 2023 have been prepared on the going concern basis.

In considering the appropriateness of this basis of preparation, the Directors have reviewed the Group's working capital forecasts. It is anticipated that additional capital will need to be raised by the end of the second quarter of 2024 in order to continue to fund the Group's activities at their planned levels beyond this date. This represents a material uncertainty that may cast significant doubt about the Group's and Company's ability to continue as a going concern. However, the Directors have a reasonable expectation that this uncertainty can be managed to a successful outcome, and based on that assessment, the Group has adequate resources to continue for the foreseeable future. Thus, they continue to adopt the going concern basis of accounting in preparing these financial statements.

3. Loss per share

The basic and diluted loss per share for the period ended 30 June 2023 was US$0.035 (2022: US$0.033) as the warrant and options have an anti-dilutive effect in the current and prior period. The calculation of loss per share is based on the loss of US$7,351,169 for the period ended 30 June 2023 (2022: loss of US$6,918,131) and the weighted average number of shares in issue during the period for calculating the basic loss per share of 213,052,247 shares (2022: 210,921,193).

4. Called up share capital

	Unaudited 30 June 2023 US$	Unaudited 30 June 2022 US$	Audited 31 December 2022 US$
Allotted, issued and fully paid			
Ordinary Shares	103,861	103,194	103,463

The number of shares in issue was as follows:	Number of shares
Balance at 1 January 2022	209,249,966
Issued during the period	
Exercised options	3,190,024
Balance at 30 June 2022	212,439,990
Issued during the period	
Exercised options	607,519
Balance at 31 Dec 2022	213,047,509
Issued during the period	
Exercised warrants	852,822
Balance at 30 June 2023	213,900,331

5. Borrowings

	Unaudited 30 June 2023 US$	Unaudited 30 June 2022 US$	Audited 31 December 2022 US$
Non-current			
Lease liability	147,667	285,493	216,691
Current			
Lease Liability	137,827	144,767	142,146
Total	285,494	430,260	358,837

6. Share based payments

Share Options

The Company grants share options at its discretion to Directors, management and employees. These are accounted for as equity settled transactions. Should the options remain unexercised after a period of ten years from the date of grant the options will expire unless an extension is agreed to by the Board. Options are exercisable at a price equal to the Company's quoted market price on the date of grant or an exercise price to be determined by the Board.

Details of share options granted, exercised, forfeited and outstanding in the period ended 30 June 2023 are as follows:

	Number of share options	Weighted average exercise price (US$)
Outstanding at 1 January 2023	19,384,571	0.51
Granted during period	5,650,000	0.37
Exercised during period	-	-
Forfeited during period	(329,166)	0.87
Outstanding at 30 June 2023	24,705,405	0.48
Exercisable at 30 June 2023	14,740,960	0.37

There were 5,650,000 options granted in the period to 30 June 2023. There were no options exercised and 329,166 options forfeited in the period to 30 June 2023.

The weighted average contractual life of the share options outstanding at the reporting date is 5 years and 84 days.

Share Warrants
The Company grants share warrants at its discretion to Directors, management, employees, advisors and lenders. These are accounted for as equity settled transactions. Terms of warrants vary from agreement to agreement.

Details of warrants granted, exercised, forfeited and outstanding in the period ended 30 June 2023 are as follows:

	Number of share warrants	Weighted average exercise price (US$)
Outstanding at 1 January 2023	3,054,129	0.01000
Exercised during the period	(852,822)	0.00412
Forfeited during the period	(3,400)	0.18000
Outstanding at 30 June 2023	**2,197,907**	0.02000
Exercisable at 30 June 2023	**2,197,907**	0.02000

There were 852,822 warrants exercised and 3,400 warrants forfeited in the six months ended 30 June 2023. There were no warrants granted during this period.

The weighted average contractual life of the share warrants outstanding at the reporting date is 1 year and 180 days.

7. Related party transactions

The Company paid US$11,650 of consulting fees to board member Daniel Brague in the six months ending 30 June 2023.

8. Events after the reporting period

On 4 August 2023, the Company issued a total of 1,948,262 shares upon the exercise of warrants with an exercise price of US$0.00749 per share for total proceeds of US$14,583.