



31 August 2022

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

Half-year Report

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with an investigational drug-device combination product for magnetic resonance imaging (MRI), announces its unaudited interim results for the six months ended 30 June 2022.

Highlights

- United States Food and Drug Administration ("FDA") acceptance of resubmission of Polarean's New Drug Application ("NDA") following the Complete Response Letter ("CRL") received in October 2021, with an established user fee goal date of 30 September 2022
- The Company is responding to FDA questions and requests as FDA reviews the resubmitted NDA
- Research system placements at McMaster University in Ontario, Canada and Cincinnati Children's Medical Center
- Continued preparation for potential commercial launch of the Company's product in the U.S.
- Ongoing planning for a new clinical trial to seek FDA approval for label expansion into the high-value gas exchange applications of Polarean's technology
- Appointment of Frank Schulkes, Dan Brague and Marcella Ruddy, MD to the Board as Non-Executive Directors
- Appointment of Ken West as Non-Executive Chairman, following the retirement of Jonathan Allis
- Net cash of US\$22.7m as of 30 June 2022, which, based on strategic decisions, could finance the Company into 2024
- Research collaboration with Oxford University Hospitals NHS Trust for long-COVID
- New publications by top-tier academic researchers exploring the applications of Xenon MRI in Asthma, COPD, cardiopulmonary disease, endobronchial valve placement, and long-COVID
- Selection of Polarean as one of the featured companies surrounding novel developments in interstitial lung disease at the 2022 ATS Respiratory Innovation Summit
- Numerous presentations of new findings in various clinical scenarios presented by researchers using Polarean's Xenon Hyperpolarisation systems at the high-profile scientific conferences American Thoracic Society ("ATS"), International Society for Magnetic Resonance in Medicine ("ISMRM"), and Pulmonary Vascular Research Institute ("PVRI")

Richard Hullihen, CEO of Polarean, commented: "During the first half of this year, we have focused on the approval process of our NDA, and addressing the findings related to the CRL. The FDA processes are proceeding with question and answer and other interactions with the FDA as we approach our goal action date of 30 September 2022. We have also made appropriate progress on our commercialisation planning activities, which include medical engagement of pulmonology and radiology thought-leaders at scientific conferences, profiling of our target top-tier academic institutions, and reimbursement code investigation and applications. We are excited to welcome our latest new researchers and sites, while renewing the capabilities of existing users, which continue to increase clinical research momentum."

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, investigational drug-device combination companies operating in the high-resolution medical imaging research space.

The Group develops equipment that enables existing MRI systems to achieve an improved level of pulmonary function imaging and specialises in the use of hyperpolarised xenon gas (^{129}Xe) as an imaging agent to visualise ventilation. ^{129}Xe gas is currently being studied for visualisation of gas exchange regionally in the smallest airways of the lungs, across the alveolar tissue membrane, and into the pulmonary bloodstream.

In October 2020, the Group submitted a New Drug Application ("NDA") to the FDA for hyperpolarised ^{129}Xe used to evaluate pulmonary function and to visualise the lung using MRI. The Group received a complete response letter on 5 October 2021. On 30 March 2022, the Company filed the resubmission of its NDA with the US FDA and has received a goal action date of 30 September 2022.

The Group operates in an area of significant unmet medical need and the Group's technology provides a novel investigational diagnostic approach, offering a non-invasive and radiation-free functional imaging platform.

CEO Statement

Introduction

During the six month period ending 30 June 2022, Polarean's activities were largely focused on resubmitting the NDA for the Company's drug-device combination. The NDA resubmission was completed in March 2022 and the Company has received a goal action date of 30 September 2022. Post resubmission, the Company, its suppliers and providers are responding to questions and requests from the FDA.

The Company continued to strengthen its Board of Directors, with the addition of three independent Directors with significant industry experience. Frank Schulkes joined the Board as a Non-Executive Director and Chairman of the Audit Committee in April 2022. Daniel Brague joined the Board as a Non-Executive Director and Chairman of the Remuneration Committee in May 2022. On 25 August 2022, Marcella Ruddy, MD was appointed Non-Executive Director to the Board. Also in May 2022, Jonathan Allis retired from the Board and the Remuneration Committee. Kenneth West was appointed Chairman.

During the six month period ending 30 June 2022, we continued to sell our polariser systems for research purposes. We completed installations at McMaster University in Ontario, Canada and Cincinnati Children's Medical Center.

Increasing Awareness of Company's Technology

Polarean's technology was highlighted at the ATS and the ISMRM conferences during May 2022 with numerous abstracts related to the research use of hyperpolarised ¹²⁹Xe accepted for presentation at the two conferences. The academic research user base of our polarisers continues to expand and document the research applications of our technology across the spectrum of pulmonary disease.

In May 2022, the Company, and Oxford University Hospitals NHS Foundation Trust ("OUH") announced that they have entered into a research collaboration to study the long-term effects of COVID-19 in patients who are still experiencing difficulty breathing months after the virus infection is gone, as part of the upcoming EXPLAIN study. Under the terms of the collaboration, Polarean will provide its investigational xenon polariser system to OUH for their research. In turn, OUH will work with Polarean to optimise the imaging workflow and analyse the datasets coming from the newly enrolling EXPLAIN study. Through novel analyses of gas-exchange images, Polarean and OUH hope to better characterise long COVID and improve patient care.

Results overview

Group revenues for the first half were US\$0.8m (2021: US\$0.6m), largely derived from the sale of polariser systems to McMaster University in Ontario, Canada and Cincinnati Children's Medical Center. We continue to sell our polariser systems on a research-use-only basis to academic institutions in the US, Canada and Europe. Operating expenses for H1 2022 (US\$7.0m) increased from H1 2021 (US\$5.5m), as regulatory costs increased to support the resubmission of the NDA and administrative costs increased as we built infrastructure to support the launch of our product, and non-cash share-based costs increased due to the expense related to stock options issued in H2 2021 and H1 2022. During H1 2022, the Company recognised Finance Expense of US\$0.2m due to the weakening of the British pound during the period versus Finance Income of \$0.4m in H1 2021 due to the strengthening of the British pound during that period. Our overall loss before tax increased from US\$4.9m to US\$6.9m in the same comparable period, due to the higher operating expenses and weakening of the British pound described above. As of 30 June 2022, we held US\$22.7m in net cash or cash equivalents.

Post-period end events

FDA review of NDA

We, and our suppliers and providers, continue to interact with the FDA as they review our NDA and we move through the process toward our goal action date of 30 September 2022.

Preparation for launch and future indications

We continue to prepare for the potential launch of our drug device combination post FDA approval. In addition, we have begun clinical trial preparation for the study most likely to be required for approval of future high-value gas exchange indications to expand the clinical applications of our technology.

Publications and planning for conference exhibitions

As the research use of our technology continues to grow, there have been new publications by top-tier academic researchers exploring the applications of Xenon MRI in long-COVID and fibrotic lung disease.

We plan to utilise conference exhibitions to increase the awareness of Polarean's technology with exhibitions planned at the American College of Chest Physicians ("CHEST") conference in October 2022 and the Radiologic Society of North America ("RSNA") conference in November 2022.

Outlook

We continue to believe that Polarean's technology has the potential to be of tremendous benefit to patients and clinicians for discovering and characterising treatable traits in pulmonary medicine. In addition, our latest new techniques lead us into the field of research for cardiology and pulmonary vascular disease which is one example of the further potential of our technology. We also look forward to evaluating new uses of our technology in pharmaceutical drug development.

The burden of pulmonary disease in the USA is approximately US\$150bn and is widespread and growing, affecting nearly 40 million Americans and 500 million worldwide, with post COVID patients comprising a new segment approaching the scale of asthma. Given the limitations of existing methods of diagnosis and lung disease monitoring, we estimate that there is a significant unmet need for safe, non-invasive, quantitative, and cost-effective image-based diagnosis technology. We believe that our unique medical drug-device combination utilising ¹²⁹Xe offers the ideal solution for improving pulmonary disease diagnosis.

As we enter the final stages of the NDA review process, we look towards a potential commercial launch before the end of 2022.

Richard Hullahen

Chief Executive Officer

30 August 2022

POLAREAN IMAGING PLC**Consolidated unaudited statement of comprehensive income**

for the six months ended 30 June 2022

	Unaudited 6 months ended 30 June 2022 US\$	Unaudited 6 months ended 30 June 2021 US\$	Audited 12 months ended 31 December 2021 US\$
	Note		
Revenue	834,087	621,874	1,185,427
Cost of sales	(539,247)	(323,185)	(677,402)
Gross profit	294,840	298,689	508,025
Administrative expenses	(1,480,119)	(1,224,162)	(3,024,123)
Research, development and regulatory expenses	(2,522,166)	[1,691,052]	(3,493,273)
Depreciation	(139,058)	(81,320)	(177,349)
Amortisation	(392,739)	(375,861)	(757,016)
Selling and distribution expenses	(1,738,265)	(1,799,324)	(5,557,829)
Share based payment expense	(701,832)	(367,397)	(1,814,882)
Total operating expenses	(6,974,179)	(5,539,116)	(14,824,472)
Loss from operations	(6,679,339)	(5,240,427)	(14,316,447)
Finance expense	(241,322)	(8,261)	(21,101)
Finance income	2,530	393,392	321,544
Loss on ordinary activities before taxation	3 (6,918,131)	(4,855,296)	(14,016,004)
Taxation	-	-	-
Loss and total other comprehensive expense	(6,918,131)	(4,855,296)	(14,016,004)
Basic and fully diluted loss per share (US\$)	3 (0.033)	(0.026)	(0.071)

POLAREAN IMAGING PLC**Consolidated unaudited statement of financial position**

at 30 June 2022

		Unaudited As at 30 June 2022 US\$	Unaudited As at 30 June 2021 US\$	Audited As at 31 December 2021 US\$
Assets	Note			
Non-current assets				
Property, plant and equipment		504,484	233,044	634,779
Intangible assets		1,887,717	2,502,268	2,193,843
Right-of-use asset		336,203	116,778	422,816
Trade and other receivables		5,539	5,539	5,539
		<u>2,733,943</u>	<u>2,857,629</u>	<u>3,256,977</u>
Current assets				
Inventories		1,571,100	1,246,311	1,426,810
Trade and other receivables		1,958,292	397,473	970,968
Cash and cash equivalents		22,690,308	38,197,203	28,874,908
		<u>26,219,700</u>	<u>39,840,987</u>	<u>31,272,686</u>
Total assets		<u>28,953,643</u>	<u>42,698,616</u>	<u>34,529,663</u>
Equity				
Share capital	4	103,194	101,545	101,642
Share premium		59,179,376	59,003,465	59,022,919
Group reorganisation reserve		7,813,337	7,813,337	7,813,337
Share-based payment reserve		4,362,164	2,212,848	3,660,332
Accumulated losses		(45,778,339)	(29,699,500)	(38,860,208)
Total equity		<u>25,679,732</u>	<u>39,431,695</u>	<u>31,738,022</u>
Liabilities				
Non-current liabilities				
Deferred income		157,702	219,954	145,747
Lease liability	5	285,493	21,017	358,837
Contingent consideration		316,000	316,000	316,000
		<u>759,195</u>	<u>556,971</u>	<u>820,584</u>
Current liabilities				
Trade and other payables		2,179,232	2,549,096	1,731,114
Lease liability	5	144,767	137,589	130,949
Deferred income		190,717	23,265	108,994
		<u>2,514,716</u>	<u>2,709,950</u>	<u>1,971,057</u>
Total equity and liabilities		<u>28,953,643</u>	<u>42,698,616</u>	<u>34,529,663</u>

POLAREAN IMAGING PLC

Consolidated unaudited statement of changes in equity

at 30 June 2022

	Share capital	Share premium	Group re-organisation	Share-based payment reserve	Accumulated losses	Total equity
Balance as at 31 December 2020 (audited)	78,200	23,840,571	7,813,337	1,845,450	(24,844,204)	8,733,354
Loss and total comprehensive income for the period	-	-	-	-	(4,855,296)	(4,855,296)
Issue of shares	23,345	37,260,511	-	-	-	37,283,856
Share issue costs	-	(2,097,617)	-	-	-	(2,097,617)
Share-based payments	-	-	-	367,398	-	367,398
Balance as at 30 June 2021 (unaudited)	101,545	59,003,465	7,813,337	2,212,848	(29,699,500)	39,431,695
<i>Comprehensive income</i>						
Loss and total comprehensive income for the period	-	-	-	-	(9,160,708)	(9,160,708)
<i>Transactions with owners</i>						
Issue of shares	97	23,943	-	-	-	24,040
Share issue costs	-	(4,489)	-	-	-	(4,489)
Share-based payments	-	-	-	1,447,484	-	1,447,484
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)
Issue of shares	1,552	156,457	-	-	-	158,009
Share issue costs	-	-	-	-	-	-
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

POLAREAN IMAGING PLC
Consolidated unaudited cash flow statement
for the six months ended 30 June 2022

	Unaudited 6 months ended 30 June 2022 US\$	Unaudited 6 months ended 30 June 2021 US\$	Audited 12 months ended 31 December 2021 US\$
Cash flows from operating activities			
Loss for the period before taxation	(6,918,131)	(4,855,296)	(14,016,004)
Adjustments for non-cash/non-operating items:			
Depreciation of plant and equipment	139,058	81,320	177,349
Amortisation of intangible assets	392,739	375,861	757,015
Loss on disposal of property, plant and equipment	1,927	-	590
Loss on remeasurement of right-of-use assets	-	-	11,660
Share based compensation	701,832	367,398	1,814,882
Finance expense	241,322	8,261	21,101
Finance income	(2,530)	(470)	(321,544)
	(5,443,783)	(4,022,926)	(11,554,951)
Changes in working capital:			
Increase in inventories	(144,290)	(268,387)	(448,886)
Increase in trade and other receivables	(987,325)	(49,406)	(622,901)
Increase in trade and other payables	435,439	1,310,426	382,247
Increase/(decrease) in deferred revenue	106,358	(127,696)	(5,976)
Net cash flows used in operating activities	(6,033,601)	(3,157,989)	(12,250,467)
Cash flows from investing activities			
Purchase of plant and equipment	(10,689)	(43,099)	(541,454)
Net cash used in investing activities	(10,689)	(43,099)	(541,454)
Cash flows from financing activities			
Issue of shares	158,009	37,283,856	37,307,896
Cost of issue	-	(2,097,617)	(2,102,106)
Interest paid	(228,378)	-	-
Interest received	2,530	470	321,544
Principal elements of lease payments	(59,527)	(62,822)	(122,069)
Interest elements of lease payments	(12,944)	(8,261)	(21,101)
Net cash generated from (used in) financing activities	(140,310)	35,115,626	35,384,164
Net increase (decrease) in cash and equivalents	(6,184,600)	31,914,538	22,592,243
Cash and equivalents at beginning of period	28,874,908	6,282,665	6,282,665
Cash and equivalents at end of period	22,690,308	38,197,203	28,874,908

NOTES TO THE INTERIM ACCOUNTS

1. Basis of presentation

The accounting policies adopted are consistent with those of the previous financial year ended 31 December 2021.

This interim consolidated financial information for the six months ended 30 June 2022 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 2021, which have been prepared in accordance with UK-adopted International Accounting Standards (IFRS) and have been delivered to the Registrar of Companies. The auditors have reported on those accounts; their report was unqualified, did not include references to any matters to which the auditors drew attention by way of emphasis of matter without qualifying their report and 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 2021. 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 2021.

The interim consolidated financial information for the six months ended 30 June 2022 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 2021 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 2022 have been prepared on the going concern basis.

The Directors consider the going concern basis of preparation to be appropriate in preparing the interim consolidated financial information. In considering the appropriateness of this basis of preparation, the Directors have received the Group's working capital forecasts for a minimum of 12 months from the date of the approval of this financial information. Based on their consideration the Directors have reasonable expectation that the Group has adequate resources to continue for the foreseeable future and that carrying values of intangible assets are supported. Thus, they continue to adopt the going concern basis of accounting in preparing this interim consolidated financial information.

3. Loss per share

The basic and diluted loss per share for the period ended 30 June 2022 was US\$0.033 (2021: US\$0.026) The calculation of loss per share is based on the loss of US\$6,918,331 for the period ended 30 June 2022 (2021: loss of US\$4,855,296) and the weighted average number of shares in issue during the period for calculating the basic profit per share of 210,921,193 shares (2021: 184,552,681).

4. Called up share capital

	Unaudited 30 June 2022 US\$	Unaudited 30 June 2021 US\$	Audited 31 December 2021 US\$
Allotted, issued and fully paid			
Ordinary Shares	103,194	101,545	101,642

The number of shares in issue was as follows:

	Number of shares
Balance at 1 January 2021	163,212,935
Issued during the period	44,932,142
Exercised warrants	928,089
Balance at 30 June 2021	209,073,166
Issued during the period	
Exercised options	176,800
Balance at 31 Dec 2021	209,249,966
Issued during the period	
Exercised options	3,190,024
Balance at 30 June 2022	212,439,990

5. Borrowings

	Unaudited 30 June 2022 US\$	Unaudited 30 June 2021 US\$	Audited 31 December 2021 US\$
Non-current			
Lease liability	285,493	21,017	358,837
Current			
Lease Liability	144,767	137,589	130,949
Total	430,260	158,606	489,786

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 2022 are as follows:

	Number of share options	Weighted average exercise price (US\$)
Outstanding at 1 January 2022	24,443,312	0.50
Granted during period	1,316,000	0.67
Exercised during period	(3,190,024)	0.05
Forfeited during period	(2,381,364)	1.03
Outstanding at 30 June 2022	20,187,924	0.47
Exercisable at 30 June 2022	12,330,672	0.18

There were 1,316,000 options granted in the period to 30 June 2022. There were 3,190,024 options exercised and 2,381,364 options forfeited in the period to 30 June 2022.

The weighted average contractual life of the share options outstanding at the reporting date is 6 years and 166 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 2022 are as follows:

	Number of share warrants	Weighted average exercise price (US\$)
Outstanding at 1 January 2022	3,054,129	0.01
Exercised during the period	-	-
Forfeited during the period	-	-
Outstanding at 30 June 2022	3,054,129	0.01
Exercisable at 30 June 2022	3,054,129	0.01

No warrants were granted, exercised or forfeited during the six months ended 30 June 2022.

The weighted average contractual life of the share warrants outstanding at the reporting date is 2 years and 19 days.

7. Events after the reporting period

Between 1 July 2022 and 31 July 2022, the Company issued a total of 607,519 new ordinary shares of 0.037 pence each in the capital of the Company upon the exercise of share options. The options had an exercise price of 15 pence per share.

On 25 August 2022, the Company granted options over a total of 573,000 ordinary shares of 0.037 pence each in the capital of the Company to a new Director and to a new employee of the Company.