



2 September 2021

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 2021.

Highlights

- Raised £27 million gross proceeds in an oversubscribed financing, including continued support of strategic investors, Bracco Imaging S.p.A and Nukem Isotopes GmbH as well as institutional investor Amati AIM VCT plc, joined by several new UK and US institutional investors.
- Appointment of Chief Financial Officer, Chuck Osborne, to the Board
- Additional research unit order for a 9820 Xenon Polariser system from the University of British Columbia in Vancouver, Canada
- Installation of its 9820 Xenon Polariser system for the University of Texas MD Anderson Cancer Center
- Presentation of data at both the American Thoracic Society ("ATS") and the International Society for Magnetic Resonance in Medicine ("ISMRM") virtual conferences
- Publication of first peer reviewed COVID-19 research by Professor Fergus Gleeson at the University of Oxford
- Net cash of US\$38.2m as of 30 June 2021

Post-period end

- Frequent interactions with the FDA as they review the NDA in advance of our target PDUFA goal date of 5 October 2021
- Preparation for launch of product including recruitment of employees into our sales and marketing organization
- Planning to broaden the awareness of Polarean technology through exhibitions at CHEST and RSNA 2021 and numerous topical conferences

Richard Hullihen, CEO of Polarean, commented: "During the first half of 2021 the Company raised its largest financing to date with its oversubscribed £27 million gross proceeds financing. We appreciate the continued support from our existing strategic, institutional and retail investors and welcome several new significant institutional investors. The proceeds from this round are being used to plan and execute the launch of our product in accordance with our current target PDUFA date of 5 October 2021. We continue to sell new polarisers systems for research use, as the amount of polarised Xenon research continues to increase. We look forward to providing our shareholders with updates regarding further progress and specifically the status of our target PDUFA date of 5 October 2021, and we thank them for their continued support on this exciting journey."

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.

Enquiries:

Polarean Imaging plc
Richard Hullihen, Chief Executive Officer
Jonathan Allis, Chairman

www.polarean.com / www.polarean-ir.com
Via Walbrook PR

Stifel Nicolaus Europe Limited (NOMAD and Sole Corporate Broker)

Nicholas Moore / Ben Maddison / Samira Essebiyea (Healthcare Investment Banking)
Nick Adams / Fred Walsh (Corporate Broking)

+44 (0)20 7710 7600

Walbrook PR

Paul McManus / Anna Dunphy

Tel: +44 (0)20 7933 8780 or polarean@walbrookpr.com

Mob: +44 (0)7980 541 893 / +44 (0)7879 741 001

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 barrier, 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. In December 2020, the Group received confirmation of acceptance of its NDA by the FDA, with a target PDUFA action date of 5 October 2021.

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. The annual burden of pulmonary disease in the US is estimated to be over US\$150 billion.

CEO Statement

Introduction

The six month period ending 30 June 2021 has seen Polarean make substantial progress towards its goal of seeking FDA approval for the Company's drug-device combination. As in the normal course, post submission, the Company has responded to the question and answer process with the FDA for our submission, while preparing itself and verifying the preparation of its suppliers and providers.

In January, the Company appointed a new Nominated Advisor and Broker, Stifel Nicolaus Europe Limited, which led to a successful placing, subscription, and open offer which was oversubscribed in every category, including its strategic investors Nukem Isotopes and Bracco. Then in February, Chuck Osborne, the existing CFO, was appointed to the Board in order to further leverage his extensive experience in early-stage life science company management, build out and fund raising.

During challenging times in healthcare and hospital utilization, we continued to take research orders from leading academic centres such as BC Children's hospital in Vancouver and also to build and deliver systems, completing the installation at MD Anderson Cancer Center in Houston.

Presentation at Medical Conferences and Studies Utilising our Technology

The Company's technology was once again prominent at the ATS and ISMRM virtual conference during May 2021 with over 50 abstracts related to the use of hyperpolarised ^{129}Xe accepted for presentation at the two conferences. The content of our publications and those of our customers, along with our participation is available on our website at www.polarean.com. The user base of our polarisers continues to expand and document the applications of our technology across the spectrum of pulmonary disease.

Importantly, the first peer reviewed article on COVID-19 Long Haul patients visualised using ^{129}Xe have now been published (<https://pubs.rsna.org/doi/10.1148/radiol.2021210033>). Additional investigator-initiated government research grants are underway to study the use of our technology to assess the long-term effects of COVID-19 infection in patients.

Results overview

Group revenues for the first half were US\$0.6m (2020: US\$0.3m) and were largely derived from the sale of a polariser system to MD Anderson, in contrast to the H1 2020 revenue, which was largely from our collaboration with the University of Cincinnati for work under our SBIR grant, which has now been completed. 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 2021 (US\$5.5m) increased from H1 2020 (US\$3.4m), as Selling and Distribution Expenses (H1 2021 US\$1.8m, H1 2020 US\$0.4m) increased as we are executing our plans for commercial launch. During H1 2021, the Company recognized Finance Income of US\$0.4m due to the strengthening of the British pound, which more than offset the US\$0.3m forgivable loan under the US Paycheck Protection Program ("PPP") we received and recognized as Finance Income in H1 2020. Our overall loss before tax increased from US\$3.2m to US\$4.9m in the same comparable period, due primarily to the commercial launch preparation expenses. The Company completed a £27m (~\$37m) fundraise during H1 2021 via the issue of new equity and as at 30 June 2021 we held US\$38.2m in net cash or cash equivalents.

Post-period end events

FDA review of NDA

We continue to interact with the FDA as they review our NDA with a target date PDUFA date of 5 October 2021.

Preparation for launch

We continue to prepare for the potential launch of our drug device combination post FDA approval. In particular, we have been building a sales and marketing organization with the recent recruitment of several sales positions.

Planning for conference exhibitions

We are continuing to increase the awareness of Polarean technology with exhibitions at CHEST in October 2021 and RSNA in December 2021.

Research polarisers

Researchers continue to apply for and receive grants to purchase our polariser systems, most recently BC Children's Hospital in Vancouver, BC. This system has been delivered and is proceeding to installation. We are in discussions with several research institutions and anticipate additional possible orders during calendar year 2021.

Outlook

We continue to demonstrate that Polarean's technology has the potential to be of tremendous benefit to patients and a powerful new tool for clinicians in discovering and characterising treatable traits in pulmonary medicine. In addition, our latest new techniques lead us into the field of 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.

This is an exciting time for the Company, as we enter the final stages of submitting our NDA and look towards a potential commercial launch before the end of 2021.

Richard Hulihan

Chief Executive Officer

2 September 2021

POLAREAN IMAGING PLC

Consolidated unaudited statement of comprehensive income

for the six months ended 30 June 2021

		Unaudited 6 months ended 30.6.21 US\$	Unaudited 6 months ended 30.6.20 US\$	Audited 12 months ended 31.12.20 US\$
	Note			
Revenue		621,874	327,896	1,056,766
Cost of sales		(323,185)	(41,387)	(346,300)
Gross profit		298,689	286,509	710,466
Administrative expenses		(2,915,214)	(2,724,411)	(5,049,246)
Depreciation		(81,320)	(73,204)	(150,224)
Amortisation		(375,861)	(359,677)	(734,058)
Selling and distribution expenses		(1,799,324)	(351,754)	(917,783)
Share based payment expense		(367,397)	(213,906)	(474,716)
Loss from operations		(5,240,427)	(3,436,443)	(6,615,562)
Finance expense		(8,261)	(9,647)	(19,730)
Finance income		393,392	267,155	100,769
Loss on ordinary activities before taxation	3	(4,855,296)	(3,178,935)	(6,534,523)
Taxation		-	-	-
Loss and total other comprehensive expense		(4,855,296)	(3,178,935)	(6,534,523)
Basic and fully diluted loss per share (US\$)	3	(0.026)	(0.023)	(0.044)

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

at 30 June 2021

		Unaudited As at 30.6.21 US\$	Unaudited As at 30.6.20 US\$	Audited As at 31.12.20 US\$
Assets	Note			
Non-current assets				
Property, plant and equipment		233,044	312,287	271,264
Intangible assets		2,502,268	3,119,120	2,810,694
Right-of-use asset		116,778	224,414	184,213
Trade and other receivables		5,539	5,539	5,539
		<u>2,857,629</u>	<u>3,661,360</u>	<u>3,271,710</u>
Current assets				
Inventories		1,246,311	950,674	977,924
Trade and other receivables		397,473	522,625	348,067
Cash and cash equivalents		38,197,203	9,190,862	6,282,665
		<u>39,840,987</u>	<u>10,664,161</u>	<u>7,608,656</u>
Total assets		<u>42,698,616</u>	<u>14,325,521</u>	<u>10,880,366</u>
Equity				
Share capital	4	101,545	77,518	78,200
Share premium		59,003,465	23,573,058	23,840,571
Group reorganisation reserve		7,813,337	7,813,337	7,813,337
Share-based payment reserve		2,212,848	1,584,640	1,845,450
Accumulated losses		(29,699,500)	(21,488,616)	(24,844,204)
Total equity		<u>39,431,695</u>	<u>11,559,936</u>	<u>8,733,354</u>
Liabilities				
Non-current liabilities				
Deferred income		219,954	192,817	219,954
Lease liability	5	21,017	149,487	91,609
Contingent consideration		316,000	316,000	316,000
		<u>556,971</u>	<u>658,304</u>	<u>627,563</u>
Current liabilities				
Trade and other payables		2,549,096	1,985,828	1,348,866
Lease liability	5	137,589	102,213	129,819
Deferred income		23,265	19,239	40,763
		<u>2,709,950</u>	<u>2,107,280</u>	<u>1,519,449</u>
Total equity and liabilities		<u>42,698,616</u>	<u>14,325,521</u>	<u>10,880,366</u>

POLAREAN IMAGING PLC
Consolidated unaudited statement of changes in equity

at 30 June 2021

	Share capital	Share premium	Group re-organisation	Share-based payment reserve	Accumulated losses	Total equity
Balance as at 31						
December 2019 (audited)	55,776	13,659,912	7,813,337	1,370,734	(18,309,681)	4,590,078
Loss and total comprehensive income for the period	-	-	-	-	(3,178,935)	(3,178,935)
Issue of shares	21,742	10,427,537	-	-	-	10,449,279
Share issue costs	-	(514,391)	-	-	-	(514,391)
Share-based payments	-	-	-	213,906	-	213,906
Balance as at 30 June 2020 (unaudited)	77,518	23,573,058	7,813,337	1,584,640	(21,488,616)	11,559,937
<i>Comprehensive income</i>						
Loss and total comprehensive income for the period	-	-	-	-	(3,355,588)	(3,355,588)
<i>Transactions with owners</i>						
Issue of shares	682	275,836	-	-	-	276,518
Share issue costs	-	(8,323)	-	-	-	(8,323)
Share-based payments	-	-	-	260,810	-	260,810
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

POLAREAN IMAGING PLC**Consolidated unaudited cash flow statement**

for the six months ended 30 June 2021

	Unaudited 6 months ended 30.6.21 US\$	Unaudited 6 months ended 30.6.20 US\$	Audited 12 months ended 31.12.20 US\$
Cash flows from operating activities			
Loss for the period before taxation	(4,855,296)	(3,178,935)	(6,534,522)
Adjustments for non-cash/non-operating items:			
Depreciation of plant and equipment	81,320	73,204	150,224
Amortisation of intangible assets	375,861	359,677	734,058
Share based compensation	367,398	213,906	474,716
Interest paid	-	-	19,730
Interest received	(470)	(92)	(100,769)
	(4,031,187)	(2,532,240)	(5,256,563)
Changes in working capital:			
Increase in inventories	(268,387)	(396,462)	(423,093)
Increase in trade and other receivables	(49,406)	114,157	288,096
Increase/(decrease) in trade and other payables	1,310,426	189,407	(424,714)
Increase/(decrease) in deferred revenue	(127,696)	(27,085)	21,576
Net cash flows used from operating activities	(3,166,250)	(2,652,223)	(5,794,698)
Cash flows from investing activities			
Purchase of plant and equipment	(43,099)	(29,534)	(65,531)
Net cash used in investing activities	(43,099)	(29,534)	(65,531)
Cash flows from financing activities			
Issue of shares	37,283,856	10,449,279	10,725,797
Cost of issue	(2,097,617)	(514,391)	(522,714)
Interest paid	-	-	-
Interest received	470	92	100,769
Funds received from PPP loan	-	22,840	-
Principal elements of lease payments	(71,083)	(56,717)	(103,097)
Interest elements of lease payments	8,261	9,647	(19,730)
Net cash generated from financing activities	35,123,887	9,910,750	10,181,025
Net increase in cash and equivalents	31,914,538	7,228,993	4,320,796
Cash and equivalents at beginning of period	6,282,665	1,961,869	1,961,869
Cash and equivalents at end of period	38,197,203	9,190,862	6,282,665

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 2020.

This interim consolidated financial information for the six months ended 30 June 2021 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 2020, which have been prepared in accordance with International Financial Reporting 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 for the six months ended 30 June 2021 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 2020 are also unaudited.

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

2. Going concern

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

The Directors consider the going concern basis of preparation to be appropriate in preparing the financial statements. 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 financial information.

3. Loss per share

The basic and diluted loss per share for the period ended 30 June 2021 was US\$0.026 (2020: US\$0.023) The calculation of loss per share is based on the loss of US\$4,855,296 for the period ended 30 June 2021 (2020: loss of US\$3,178,935) and the weighted average number of shares in issue during the period for calculating the basic profit per share of 184,552,681 shares (2020: 137,598,239).

4. Called up share capital

	Unaudited 30.6.21 US\$	Unaudited 30.6.20 US\$	Audited 31.12.20 US\$
Allotted, issued and fully paid			
Ordinary Shares	<u>101,545</u>	<u>77,518</u>	<u>78,200</u>

The number of shares in issue was as follows:

	Number of shares
Balance at 1 January 2020	114,438,600
Issued during the period	11,666,667
Exercised warrants	<u>766,410</u>
Balance at 30 June 2020	161,830,007
Issued during the period	1,318,800
Exercised warrants	<u>64,128</u>
Balance at 31 Dec 2020	163,212,935
Issued during the period	44,932,142
Exercised warrants	<u>928,089</u>
Balance at 30 June 2021	<u>209,073,166</u>

5. Borrowings

	Unaudited 30.6.21 US\$	Unaudited 30.6.20 US\$	Audited 31.12.20 US\$
Non-current			
Lease liability	<u>21,017</u>	<u>149,487</u>	<u>91,609</u>
Current			
Lease Liability	<u>137,589</u>	<u>102,213</u>	<u>129,819</u>
Total	<u>158,606</u>	<u>251,700</u>	<u>221,428</u>

6. Share based payments

Share Options

The Company grants share options as 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 at the year-end are as follows:

	Number of share options	Weighted average exercise price (US\$)
Outstanding at 1 January 2021	16,884,322	0.19
Granted during period	1,250,000	1.12
Outstanding at 30 June 2021	18,134,322	0.26
Exercisable at 30 June 2021	12,699,615	0.14

There were 1,250,000 options granted in the period to 30 June 2021. No options were exercised or forfeited during the period.

The weighted average contractual life of the share options outstanding at the reporting date is 4 years and 361 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 for the warrants exercised, lapsed and outstanding at the period ending 30 June 2021 are as follows:

	Number of share warrants	Weighted average exercise price (US\$)
Outstanding at 1 January 2021	3,994,165	0.09
Exercised during the period	(928,089)	0.20
Forfeited during the period	(11,947)	0.20
Outstanding at 30 June 2021	3,054,129	0.01
Exercisable at 30 June 2021	3,054,129	0.01

On 24 February 2021, 61,563 new ordinary shares were issued in the Company following the exercise of warrants at an exercise price of 15 pence per warrant. On 25 March 2021, the Company issued a further 358,713 new ordinary shares following an exercise of warrants at an exercise price of 15 pence per warrant. On 16 April 2021 and 17 May 2021, an additional 467,733 and 40,080, respectively, new ordinary shares were issued in the Company following the exercise of warrants at an exercise price of 15 pence per warrant.

The weighted average contractual life of the share warrants outstanding at the reporting date is 2 years and 122 days.

7. Events after the reporting period

On 7 July 2021, the Company granted options over a total of 5,250,000 ordinary shares of £0.00037 each in the capital of the Company to certain Directors and employees of the Company. The options vest over four years and have an exercise price of 93 pence per share.