24 September 2019

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

Half-year Report

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with a proprietary drug-device combination product for the magnetic resonance imaging (MRI) market, announces its unaudited interim results for the six months ended 30 June 2019.

Highlights

- Significant enrolment in Phase III FDA clinical trials (the "Clinical Trials") as Clinical Trials near completion
- Third trial site added at University of Cincinnati, in addition to Duke University and the University of Virginia, to improve enrolment rates for its Clinical Trials
- Three new orders for Polarean's 9820 Xenon Polariser system from the University of British Columbia, The Hospital for Sick Children ("SickKids") in Toronto and the University of Kansas.
- Third tranche of US$1m confirmed from US$3m Small Business Innovation Research ("SBIR") grant
- Second London Investor Symposium completed in June 2019
- Appointment of Charles ("Chuck") Osborne as the Company's new Chief Financial Officer
- Net cash of US$1.28m at 30 June 2019

Post-period end

- Raised £2.1m (gross) via a placing of 11,666,667 ordinary shares at a placing price of 18p per share in July 2019
- Enrolment for the Clinical Trials has now passed 98% in the lung transplant pathway and 87% in the lung lobe resection pathway, with a total of 80 patients targeted for enrolment
- Delivered and installed a 9820 Xenon Polariser system at SickKids
- Number of Xenon Polariser systems installed or on order is 25

Richard Hullihen, CEO of Polarean, commented*: "Our continued global engagement with the expanding base of clinicians and researchers, while extending our technology and discovering new techniques, reinforces our belief that pulmonary medicine patients and their doctors deserve the benefits of our unique three-dimensional, non-invasive, reproducible hyperpolarised xenon gas imaging technology. We have now entered a crucial period for the Company as the Clinical Trials near completion, with the top-line results of the Clinical Trials expected before the end of 2019. We remain confident and excited for the future of Polarean and are grateful to our shareholders and stakeholders for their continued support."*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

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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 drug-device combination companies operating in the high resolution functional magnetic resonance imaging market.

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 and gas exchange regionally in the smallest airways of the lungs, the tissue barrier between the lung and the bloodstream and in the pulmonary vasculature. Xenon gas exhibits solubility and signal properties that enable it to be imaged within other tissues and organs.

CEO Statement

Introduction

The six month period ending 30 June 2019 has seen Polarean make substantial progress towards its goal of completing the Clinical Trials for the Company's medical drug-device combination.

The first half of the financial year was committed to critically analysing the performance of the Clinical Trial sites and their protocols and processes for recruitment as the Clinical Trials progressed and enrolment rates increased. Despite having skilled academic site clinical trial organizations and contract research organizations (CROs), there is always a period of discovery and correction associated with any first of type trial, and we found and fixed several restrictions to our recruitment rates, working collaboratively with our CROs and academic sites.

Results overview

Our financial performance, with sales being made on a research-use-only basis to academic institutions in the US and Europe, remains in-line with management expectations. Revenues for the first half decreased from US$1.0m to US$0.4m, with gross profits US $0.32m (H1 2018: US$0.75m). This is primarily attributable to the timing of polariser sales. We received three high value polariser orders, during H1 2019, one of which was installed during September 2019. The other two polarisers are anticipated to be delivered during Q4 2019. Gross operating margins remain at over 50%. Administrative Expenses were flat for the period. Our overall loss before tax increased to US$3.4m from US$2.7m in the same comparable period, due to the lower revenue during the period. Cash controls within the business remain robust and as at 30 June 2019 we held US US$1.28m in net cash or cash equivalents.

The Company held its second Investor Symposium in London on 12 June 2019. Attendance was significantly higher than it was at our first investor symposium which we held in June 2018, and the feedback from the 2019 symposium was positive. We conducted a review of the latest technology breakthroughs, as well as presentations by Key Opinion Leaders from two sites: Dr. Jason Woods from Cincinnati Chilldren's Hospital speaking on Cystic Fibrosis, and Dr. Sudarshan Rajagopal from Duke University speaking on pulmonary vascular disease. The video of the symposium can be viewed here: http://www.polarean-ir.com/content/investors/videos.asp

Post-period end events

Placing to raise £2.1m (gross) at 18p completed

On the 22 July 2019 Polarean announced the completion of a placing to raise an additional £2.1m (gross) at a placing price of 18 pence per share in response to strong demand from institutional and EIS/VCT investors. We are encouraged with the support shown by new and existing shareholders and these additional funds will further support our Clinical Trials in the US, preparation of our New Drug Application ("NDA") for submission to the US Food and Drug Administration ("FDA"), preparations for commercial launch and the improvements we continue to make to our polarisers.

Delivery of Xenon Polarisers

Whilst we seek clinical approval for our medical drug-device combination we continue to expand our installed base of systems through additional sales of research units to academic institutions.

Post-period end, we delivered and installed a new system at the SickKids Hospital Toronto. This is an additional system for SickKids who is a long-term collaborator and customer of the Company.

In February and July 2019, we received orders for additional Polarean 9820 Polariser systems. We anticipate shipping these two systems to the customers in the second half of 2019. The number of systems installed or on order is currently 25*.

* Inadvertently reported as 24 in the RNS dated 10 September 2019 which omitted the system ordered by KUMC as per the RNS dated 11 July 2019.

Outlook

We continue to demonstrate and reinforce our belief that Polarean's technology can be a tremendous benefit to patients and a powerful new tool for clinicians in discovering and demonstrating 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 upside potential of our technology. There are 40 clinical trials currently ongoing into the use of ^{129}Xe MRI accruing to the FDA website.

The burden of pulmonary disease in the USA is approximately US$150bn, with pulmonary disease widespread and growing, affecting nearly 40 million Americans. Given the limitations of existing methods of diagnosis and lung disease monitoring, we believe that there is a significant unmet need for non-invasive, quantitative, and cost-effective image-based diagnosis technology. We believe that our unique medical drug-device combination utilizing 129Xe offers the ideal solution for improving pulmonary disease diagnosis and we are confident that this will be borne out during the Company's Clinical Trials.

Richard Hullihen
Chief Executive Officer

23 September 2019

Consolidated unaudited statement of comprehensive income
for the six months ended 30 June 2019

	Note	Unaudited 6 months ended 30.6.19 US$	Unaudited 6 months ended 30.6.18 US$	Audited 12 months ended 31.12.18 US$
Revenue		399,639	1,026,926	2,439,139
Cost of sales		(75,185)	(279,455)	(633,463)
Gross profit		**324,454**	**747,471**	**1,805,676**
Administrative expenses		(3,068,371)	(3,106,922)	(6,161,916)
Depreciation		(4,661)	(4,489)	(10,140)
Amortisation		(341,937)	(308,426)	(616,852)
Selling and distribution expenses		(147,821)	(20,998)	(31,766)
Share based payment expense		(139,886)	(87,400)	(251,790)
Loss from operations		**(3,378,222)**	**(2,780,764)**	**(5,266,788)**
Finance expense		(22,356)	(52,654)	(188,055)
Finance income		274	27	184
Loss on ordinary activities before taxation	**4**	**(3,400,304)**	**(2,833,391)**	**(5,454,659)**
Taxation		-	-	-
Loss and total other comprehensive expense		**(3,400,304)**	**(2,833,391)**	**(5,454,659)**
Basic and fully diluted loss per share (US$)	**4**	**(0.034)**	**(0.057)**	**(0.078)**

POLAREAN IMAGING PLC

Consolidated unaudited statement of financial position
As at 30 June 2019

		Unaudited As at 30.6.19 US$	Unaudited As at 30.6.18 US$	Audited As at 31.12.18 US$
Assets	Note			
Non-current assets				
Property, plant and equipment		13,091	23,403	17,752
Intangible assets		3,735,973	4,352,824	4,044,398
Right-of-use asset		131,773	-	-
Trade and other receivables		5,539	12,536	12,539
		3,886,376	4,388,763	4,074,689
Current assets				
Inventories		1,233,039	1,069,342	651,781
Trade and other receivables		1,094,988	1,148,306	4,226,585
Cash and cash equivalents		1,277,195	1,374,866	875,601
		3,605,222	3,592,514	5,753,967
Total assets		**7,491,598**	**7,981,277**	**9,828,656**
Equity				
Share capital	**5**	49,767	36,396	49,427
Share premium		11,200,461	6,432,812	11,063,075
Group reorganisation reserve		7,813,337	7,813,337	7,813,337
Share-based payment reserve		1,218,221	913,945	1,078,335
Accumulated losses		(15,619,993)	(9,591,499)	(12,212,767)
Total equity		**4,661,793**	**5,604,991**	**7,791,407**
Liabilities				
Non-current liabilities				
Deferred income		87,029	-	70,726
Borrowings	**6**	83,168	-	-
Contingent consideration		316,000	316,000	316,000
		486,197	316,000	386,726
Current liabilities				
Trade and other payables		1,604,792	1,908,079	1,590,482
Borrowings	**6**	82,716	149,878	5,213
Deferred income		656,100	2,329	54,828
		2,343,608	2,060,286	1,650,523
Total equity and liabilities		**7,491,598**	**7,981,277**	**9,828,656**

Consolidated unaudited statement of changes in equity

As at 30 June 2019

	Share capital	Share premium	Group re-organisation	Other equity	Share-based payment reserve	Accumulated losses	Total equity
Balance as at 31 December 2017 (audited)	**23,291**	**1,448,037**	**7,813,337**	**87,305**	**826,545**	**(6,758,108)**	**3,440,407**
Loss and total comprehensive income for the period	-	-	-	-	-	(2,833,391)	(2,833,391)
Transaction with owners							
Issue of shares	13,105	5,124,897	-	(87,305)	-	-	5,050,697
Share issue costs	-	(140,122)	-	-	-	-	(140,122)
Share-based payments	-	-	-	-	87,400	-	87,400
Balance as at 30 June 2018 (unaudited)	**36,396**	**6,432,812**	**7,813,337**	-	**913,945**	**(9,591,499)**	**5,604,991**
Loss and total comprehensive income for the period	-	-	-	-	-	(2,621,268)	(2,621,268)
Transaction with owners							
Issue of shares	13,031	5,036,577	-	-	-	-	5,049,608
Share issue costs	-	(406,314)	-	-	-	-	(406,314)
Share-based payments	-	-	-	-	164,390	-	164,390
Balance as at 31 December 2018 (audited)	**49,427**	**11,063,075**	**7,813,337**	-	**1,078,335**	**(12,212,767)**	**7,791,407**
Change in accounting policy	-	-	-	-	-	(6,922)	(6,922)
Restated total equity at 1 January 2019	**49,427**	**11,063,075**	**7,813,337**	-	**1,078,335**	**(12,219,689)**	**7,784,485**
Loss and total comprehensive income for the period	-	-	-	-	-	(3,400,304)	(3,400,304)
Transaction with owners							
Issue of shares	340	137,386	-	-	-	-	137,726
Share-based payments	-	-	-	-	139,886	-	139,886
Balance as at 30 June 2019 (unaudited)	**49,767**	**11,200,461**	**7,813,337**	**-**	**1,218,221**	**(15,619,993)**	**4,661,793**

Consolidated unaudited cash flow statement
for the six months ended 30 June 2019

	Unaudited 6 months ended 30.6.19 US$	Unaudited 6 months ended 30.6.18 US$	Audited 12 months ended 31.12.18 US$
Cash flows from operating activities			
Loss for the period before taxation	(3,400,304)	(2,833,391)	(5,454,659)
Adjustments for non-cash/non-operating items:			
Depreciation of plant and equipment	4,661	4,489	10,140
Amortisation of intangible assets	341,937	308,426	616,852
Share based compensation	139,886	87,400	251,790
Interest paid	22,356	52,654	188,055
Interest received	(274)	(27)	(184)
	(2,891,738)	(2,380,449)	(4,388,006)
Changes in working capital:			
Increase in inventories	(581,257)	(419,482)	(1,921)
Increase in trade and other receivables	(301,448)	(659,448)	(69,517)
(Decrease)/increase/ in trade and other payables	36,955	10,026	(315,894)
Increase/(decrease) in deferred revenue	617,575	(24,233)	98,992
Net cash flows used from operating activities	**(3,119,913)**	**(3,473,586)**	**(4,676,346)**
Cash flows from investing activities			
Purchase of plant and equipment	-	(6,551)	(6,551)
Net cash used in investing activities	**-**	**(6,551)**	**(6,551)**
Cash flows from financing activities			
Repayment of loans		(116,126)	(307,623)
Issue of shares	3,577,509	4,063,539	5,093,775
Interest paid	(22,356)	(52,654)	(188,055)
Interest received	274	27	184
Principal elements of lease payments	(42,793)	-	-
Interest elements of lease payments	8,873	-	-
Net cash generated from financing activities	**3,521,507**	**3,894,786**	**4,598,281**
Net increase in cash and equivalents	401,594	414,649	(84,616)
Cash and equivalents at beginning of period	875,601	960,217	960,217
Cash and equivalents at end of period	1,277,195	1,374,866	875,601

NOTES TO THE INTERIM ACCOUNTS

1. Basis of preparation

The accounting policies adopted are consistent with those of the previous financial year ended 31 December 2018.

This interim consolidated financial information for the six months ended 30 June 2019 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 2018, 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 2019 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 2018 are also unaudited.

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

2. Changes in accounting policies

The Group has initially adopted IFRS 16 Leases from 1 January 2019. IFRS 16 introduced a single, on-balance sheet accounting model for leases. As a result, the Group, as a lessee, has recognised right-of-use assets representing its rights to use the underlying assets and lease liabilities representing its obligation to make lease payments.

The Group has applied IFRS 16 using the modified retrospective approach, under which the cumulative effect of initial application is recognised in retained earnings at 1 January 2019. Accordingly, the comparative information presented for 2018 has not been restated – i.e. it is presented, as previously reported, under IAS 17 and related interpretations. The details of the changes in accounting policies are disclosed below.

Definition of a lease

Previously, the Group determined at contract inception whether the arrangement was or contained a lease under IFRIC 4 Determining Whether an Arrangement contains a Lease. The Group now assesses whether a contract is or contains a lease based on the new definition of a lease. Under IFRS 16, a contract is, or contains, a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration.

On transition to IFRS 16, the Group elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 only to contracts that were previously identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed.

Significant accounting policies

The Group recognises a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated amortisation and impairment losses, and adjusted for certain measurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payments made. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, a change in estimate of the amount expected to be payable under a residual value guarantee, or as appropriate, changes in the assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

The Group has applied judgement to determine the lease term for some lease contracts in which it is a lease that include renewal options. The assessment of whether the Group is reasonably certain to exercise such options impacts the lease term, which significantly affects the amount of lease liabilities ad right-of-use assets recognised.

Transition

Previously, the Group classified property leases as operating lease under IAS 17. At transition, for leases classified as operating leases under IAS 17, lease liabilities were measured at the present value of the remaining lease payments, discounted at the Group's incremental borrowing rate as at 1 January 2019. Right-of-use assets are measured at their carrying value as if IFRS 16 has been applied since the commencement date, discounted using the lessee's incremental borrowing rate at the date of initial application.

The Group used the following practical expedients when applying IFRS 16 to leases previously classified as operating leases under IAS 17:

- Applied the exemption not to recognise right-of-use assets and liabilities for leases with less than 12 months of lease term;
- Excluded the initial direct costs from measuring the right-of-use asset at the date of initial application; and
- Used hindsight when determining the lease term if the contract contains options to extend or terminate the lease.

Impact on transition

The impact (increase/(decrease)) on the statement of financial position as at 1 January 2019 as a result of adopting IFRS 16 is as follows:

	US$
Right-of-use assets	165,284
Accumulated losses	(6,922)
Borrowings	191,361
Trade and other payables	(19,155)

When measuring lease liabilities for leases that were classified as operating leases, the Group discounted the lease payment using its incremental borrowing rate at 1 January 2019. The weighted-average rate applied is 10%.

	US$
Operating lease commitment at 31 December 2018 as disclosed in the Group's consolidated financial statements	183,421
Plus additional lease payments	34,814
Operating lease commitment	218,235
The discounted lease liability recognised at 1 January 2019 after using the incremental borrowing rate	191,361

Impact for the period

As a of result of initially applying IFRS 16, in relation to the leases that were previously classified as operating leases, the Group recognised amortisation and interest costs, instead of operating lease expense. During the six months ended 30 June 2019, the Group recognised US$33,511 of amortisation charges and US$8,873 of interest costs from these leases.

3. Going concern

The interim consolidated financial information for the six months ended 30 June 2019 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.

4. Loss per share

The basic and diluted loss per share for the period ended 30 June 2019 was US$0.034 (2018: US$0.057) The calculation of loss per share is based on the loss of US$3,400,304 for the period ended 30 June 2019 (2018: loss of US$2,833,391) and the weighted average number of shares in issue during the period for calculating the basic profit per share of 101,087,330 shares (2017: 49,432,227).

5. Called up share capital

	Unaudited 30.6.19 US$	Unaudited 30.6.18 US$	Audited 31.12.18 US$
Allotted, issued and fully paid			
Ordinary Shares	49,767	36,396	49,427

The number of shares in issue was as follows:	Number of shares
Balance at 1 January 2018	1,814,003
Effect of share split	46,656,158
Issued during the period	24,939,303
Balance at 30 June 2018	73,409,464
Issued during the period	22,382,126
Issue of shares upon converting loans	4,939,303
Balance at 31 December 2018	100,730,893
Exercised warrants	(705,040)
Balance at 30 June 2019	101,435,933

On 31 March 2019, the warrants were exercised that resulted in the conversion of an addition 705,040 ordinary shares.

6. Borrowings

	Unaudited 30.6.19 US$	Unaudited 30.6.18 US$	Audited 31.12.18 US$
Non-current			
Lease liability	83,168	-	-
Current			
Related Party Loans	-	7,936	-
Bank Overdraft	8,443	141,942	5,213
Lease Liability	74,273	-	-
Total	82,716	149,878	5,213

7. 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 2019	15,560,560	0.13
Forfeited during the period	(550,941)	0.20
Granted during the period	1,200,000	0.20
Outstanding at 30 June 2019	16,209,619	0.14

The fair value of options granted has been calculated using the Black Scholes model which has given rise to fair values per share of US$0.09. This is based on risk-free rates of 1.41% and volatility of 40.84%.

The weighted average contractual life of the share options outstanding at the reporting date is 7.41 years.

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 2019 are as follows:

	Number of share warrants	Weighted average exercise price (US$)
Outstanding at 1 January 2019	7,023,539	0.09
Lapsed during the period	(157,796)	0.20
Exercised during the period	(705,040)	0.20
Outstanding at 30 June 2019	6,160,703	0.08
Exercisable at 30 June 2019	6,160,703	0.08

On 2 April 2019, the Company issued 705,040 new ordinary shares of £0.00037 each in the capital of the Company at the exercise price of 15 pence per share, following the exercise of warrants. The total consideration received by the Company pursuant to the warrant exercise was £105,756. An additional 157,796 warrants lapsed on 31 March 2019.

The weighted average contractual life of the share warrants outstanding at the reporting date is 4.14 years.

8. Subsequent events

On 22 July 2019, the Company announced it had raised a total of £2.1million (before expenses) via the placing of total of 11,666,667 ordinary shares at a price of 18p per share with institutional investors. The net proceeds of the placing will be used to further support the Company's Clinical Trials, the preparation and submission of the NDA, provide additional working capital to build new polarisers for future orders and to further support the preparation for market launch following submission of the NDA and the development of relationships with strategic partners of the Company.

On 24 July 2019, the Company issued 1,336,000 new ordinary shares of £0.00037 each in the capital of the Company at the exercise price of 15 pence per share, following the exercise of warrants.