



22 August 2018

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 2018.

Highlights

- Successful admission to trading on AIM on 29 March 2018
- £3m (gross) raised via a placing of 20,000,000 ordinary shares at a placing price of 15p in March 2018
- Delivery of Xenon Polariser to Cincinnati Children's Hospital and University of Virginia
 - *University of Virginia Polariser to be used exclusively for Phase III Clinical Trials*
- Financial performance in-line with management expectations:
 - *Revenues of US \$0.75m (H1 '17: US \$0.17m);*
 - *Operating gross margins, including grants, at over 70% margin*
- Net cash at 30 June 2018 of US \$1.22m

Post-period end

- Completion of successful Pilot Study prior to commencement of Phase III Trials
- Phase III FDA Clinical Trials to commence shortly
- US Patent Notice of Allowance received for polarization enhancing technology
- Placing to raise £0.8m (gross) at 16p completed on 10 July 2018

Richard Hullihen, CEO of Polarean, commented: *"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 our Phase III trials."*

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.

CEO Statement

Introduction

The six month period ending 30 June 2018 has seen Polarean make substantial progress towards its goal of undertaking and completing our Phase III Clinical Trials for our medical drug-device combination. This combination enables existing MRI systems to achieve an improved level of pulmonary function imaging through the use of hyperpolarised 129-Xenon gas (129Xe) as an imaging contrast agent.

Our Phase III trials will be used to demonstrate that our medical drug-device combination using 129Xe is capable of sharing the same claims as the approved comparator 133-Xenon (133Xe) gas scintigraphy. If the trials are successful the Company's ultimate goal will be to submit a New Drug Application ("NDA") with the same claim as 133Xe and seek FDA approval, allowing the launch of clinically approved systems to be used "for the evaluation of pulmonary function, for imaging the lungs" in early 2020.

The first half of the financial year was focussed on putting in place the funding, contracts, agreed protocols, equipment and supply agreements necessary to undertake our Phase III trials and details of these milestones were outlined in our Final Results statement announced in June. We expect the clinical trials to commence shortly and the data collection for the trials is expected to be completed during Q3 of 2019.

Admission to AIM

In March we successfully completed a £3m fundraising (before expenses) and the listing of our shares on the AIM Market of the London Stock Exchange. These funds provide us with the funding security needed to complete our Phase III clinical trials. In addition, the funds raised from our recent £0.8m (gross) placing will further support the clinical trials and support improvements to the Company's polarisers.

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 increased significantly from US \$0.21m to US \$0.75m, with gross profits hitting US \$0.47m (H1 '17: US \$0.17m). Gross operating margins remain at well over 50%. With a sizeable uplift in Administrative Expenses, due in the main to fees associated with our AIM admission, our overall loss before tax increased to £3.1m from £1.4m in the same comparable period. Cash controls within the business remain robust and as at 30 June 2018 we held US \$1.22m in net cash or cash equivalents.

The development of stronger recurring revenues are clearly targeted for the business, assuming FDA approval is achieved. In addition, the Company's longer term strategy is for our polarisers to be operational beyond the academic research market that Polarean currently serves.

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.

In May 2018 we announced the delivery of the latest model of our Xenon polariser to the Center for Pulmonary Imaging Research at the Cincinnati Children's Hospital Medical Center, with whom we hold a Small Business Innovation Research grant awarded by the National Heart, Lung and Blood Institute.

Cincinnati Children's, a non-profit academic medical center globally-renowned for its paediatric teaching and research, is a recognized leader in using hyperpolarized 129Xe for paediatric pulmonary imaging through advanced imaging techniques.

Similarly in June 2018 we were pleased to announce the delivery of our latest polariser to the University of Virginia Health System (UVa), the site of one of our Phase III Clinical Trials. UVa has been a key clinical collaborator with

Polarean and, as a result of this collaboration, the Department of Radiology & Medical Imaging at UVa now has three latest-generation 129Xe Polarean polarisers installed at their site with the latest system to be used exclusively for our Phase III clinical trials.

We now have 15 Polarean Xenon polarisers in use at research institutions across the US and Europe.

Post-period end events

Following the close of the first half we provided shareholders with an update on additional progress made in preparation for the imminent start of our clinical trials, as well as additional patent protection and further funding support.

(i) Completion of successful Pilot Study prior to Phase III Clinical Trials

In last month's update we announced the completion of a Pilot Study at one of our trial sites, which validated the study design and the proposed analytical methods that will be used in the trials. The successful conclusion of the pilot has provided us with the confidence that the chosen methodology, agreed with the FDA, is appropriate and should maximise the probability that both the primary and secondary endpoints of our trials should clearly demonstrate non-inferiority of 129Xe against 133Xe.

(ii) Phase III Clinical Trials scheduled to start this month and due to complete in Q3 2019

In addition, we were also able to announce that our 'head to head' non-inferiority trials against 133Xe scintigraphy, a 40 year old nuclear medicine technique using radioactive ¹³³Xe and gamma cameras, will commence very shortly. We expect to provide an announcement to investors as soon as the trial starts.

The Phase III Trials will evaluate two patient populations – candidate patients for lung lobe resection, and candidates for lung transplant procedures – and will encompass a total of 80 patients, across two sites: the University of Virginia and Duke University. We currently expect data collection for the Phase III Trials to complete during Q3 of 2019 and if successful, we will submit our NDA with the same claim as 133Xe soon after.

(iii) US Patent Notice of Allowance received

We also were pleased to announce receipt of a Notice of Allowance for the U.S. Patent covering "*Hyperpolarized Noble Gas Production Systems with Nanocluster Suppression, Detection, and/or Filtering and Related Methods and Devices*" to which we have the exclusive rights. This patent, together with our know-how, has led to increasing levels of polarisation for our MRI gas-hyperpolarisation platform and is key to advancing image quality, exploring new applications and increasing the overall efficiency of our systems. This patent adds to our IP portfolio of 29 patents with a broad area of coverage around our technology and extending into 2034.

(iv) Placing to raise £0.8m (gross) at 16p completed

On the 10 July we announced the successful completion of a Placing to raise an additional £0.8 million at a price of 16 pence (before expenses) in response to strong demand from institutional and EIS/VCT investors. We are very pleased with support shown by new and existing shareholders and these additional funds will further support our clinical trials in the US and the improvements we continue to make to our polarisers.

(v) Delivery of Polariser to Duke for Clinical Trial

In August 2018 we were pleased to announce the delivery of our latest polariser to the Duke University (Duke), the site of one of our Phase III Clinical Trials. Duke has been a key technology and clinical collaborator with Polarean and, as a result of this collaboration, the Department of Radiology at Duke now has three 129Xe Polarean polarisers installed at their site with the latest system to be used exclusively for our Phase III clinical trials.

Outlook

I am excited that we will shortly start our FDA Phase III clinical trials and I look forward to updating shareholders once it commences and with our progress.

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 our Phase III trials.

Richard Hullihen
Chief Executive Officer

22 August 2018

Consolidated unaudited statement of comprehensive income
for the six months ended 30 June 2018

	Note	Unaudited 6 months ended 30.6.18 US\$	Unaudited 6 months ended 30.6.17 US\$	Audited 12 months ended 31.12.17 US\$
Revenue		1,026,926	205,085	1,237,163
Cost of sales		(279,455)	(33,712)	(297,215)
Gross profit		747,471	171,373	939,948
Administrative expenses		(3,106,922)	(1,502,079)	(4,051,000)
Depreciation		(4,489)	(2,885)	(7,478)
Amortisation		(308,426)	(2,300)	(361,746)
Selling and distribution expenses		(20,998)	(15,474)	(28,752)
Share based payment expense		(87,400)	(402,007)	(414,866)
Loss from operations		(2,780,764)	(1,753,372)	(3,923,894)
Finance Charges		(52,654)	(7,160)	(34,056)
Finance Income		27	-	129
Loss on ordinary activities before taxation	3	(2,833,391)	(1,760,532)	(3,957,821)
Taxation		-	-	-
Loss and total other comprehensive expense		(2,833,391)	(1,760,532)	(3,957,821)
Basic and fully diluted loss per share (US\$)	3	(0.057)	(0.062)	(0.139)

POLAREAN IMAGING PLC

Consolidated unaudited statement of financial position

As at 30 June 2018

		Unaudited As at 30.6.18 US\$	Unaudited As at 30.6.17 US\$	Audited As at 31.12.17 US\$
Assets	Note			
Non-current assets				
Property, plant and equipment		23,403	16,398	21,341
Intangible assets		4,352,824	5,020,696	4,661,250
Trade and other receivables		12,536	5,539	12,539
		<u>4,388,763</u>	<u>5,042,633</u>	<u>4,695,130</u>
Current assets				
Inventories		1,069,342	392,932	649,860
Trade and other receivables		1,148,306	22,209	488,861
Cash and cash equivalents		1,374,866	1,712,073	960,217
		<u>3,592,514</u>	<u>2,127,214</u>	<u>2,098,938</u>
Total assets		<u>7,981,277</u>	<u>7,169,847</u>	<u>6,794,068</u>
Equity				
Share capital	4	36,396	23,291	23,291
Share premium		6,432,812	1,808,587	1,448,037
Group reorganisation reserve		7,813,337	7,813,337	7,813,337
Other equity		-	-	87,305
Share based payment reserve		913,945	813,686	826,545
Retained losses		(9,591,499)	(4,560,819)	(6,758,108)
Total equity		<u>5,604,991</u>	<u>5,898,082</u>	<u>3,440,407</u>
Liabilities				
Non-current liabilities				
Deferred revenue		-	36,152	-
Contingent consideration		316,000	316,000	316,000
		<u>316,000</u>	<u>352,152</u>	<u>316,000</u>
Current liabilities				
Trade and other payables		1,908,079	521,719	1,906,376
Borrowings	5	149,878	379,541	1,104,723
Deferred revenue		2,329	18,353	26,562
		<u>2,060,286</u>	<u>919,613</u>	<u>3,037,661</u>
Total equity and liabilities		<u>7,981,277</u>	<u>7,169,847</u>	<u>6,794,068</u>

Consolidated unaudited statement of changes in equity

As at 30 June 2018

	Share capital	Share premium	Group re-organisation	Other equity	Share based payment reserve	Retained earnings	Total equity
Balance as at 31 December 2016 (audited)	1	-	1,976,367	-	238,172	(2,800,287)	(585,747)
Loss and total comprehensive income for the year	-	-	-	-	-	(3,957,821)	(3,957,821)
<i>Transaction with owners</i>							
Issue of shares	2,970	1,982,094	-	-	-	-	1,985,064
Share issue costs	-	(534,057)	-	-	173,507	-	(360,550)
Share-based payments	-	-	-	-	414,866	-	414,866
Group re-organisation	20,320	-	5,836,970	-	-	-	5,857,290
Convertible loans	-	-	-	87,305	-	-	87,305
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)
<i>Transaction with owners</i>							
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

Consolidated unaudited cash flow statement
for the six months ended 30 June 2018

	Unaudited 6 months ended 30.6.18 US\$	Unaudited 6 months ended 30.6.17 US\$	Audited 12 months ended 31.12.17 US\$
Cashflows from operating activities			
Loss for the period before taxation	(2,833,391)	(1,760,532)	(3,957,821)
Adjustments for non-cash/non-operating items:			
Depreciation of plant and equipment	4,489	2,884	7,478
Amortisation of intangible assets	308,426	2,300	361,746
Increase in provision for contingent consideration	-	-	-
Share based compensation	87,400	402,007	414,866
Interest paid	52,654	2,160	34,056
Interest received	(27)	-	(129)
Write off of share issuance costs	-	156,953	-
	<u>(2,380,449)</u>	<u>(1,194,228)</u>	<u>(3,139,804)</u>
Changes in working capital:			
(Increase) in inventories	(419,482)	(71,271)	(328,199)
(Increase) in trade and other receivables	(659,448)	(7,753)	(440,931)
Increase/(decrease) in trade and other payables	10,026	(12,121)	1,343,861
Decrease in deferred revenue	(24,233)	(22,675)	(50,618)
	<u>-</u>	<u>-</u>	<u>-</u>
Taxation	-	-	-
Net cash flows used from operating activities	<u>(3,473,586)</u>	<u>(1,308,048)</u>	<u>(2,615,691)</u>
Investing activities			
Purchase of plant and equipment	(6,551)	(7,298)	(16,834)
Net cash used in investing activities	<u>(6,551)</u>	<u>(7,298)</u>	<u>(16,834)</u>
Financing activities			
(Repayment of) proceeds from borrowings	(116,126)	275,000	1,047,014
Issue of shares	4,063,539	2,656,732	2,481,808
Interest paid	(52,654)	(2,160)	(34,056)
Interest received	27	-	129
Net cash from financing activities	<u>3,894,786</u>	<u>2,929,572</u>	<u>3,494,895</u>
Net increase in cash and equivalents	414,649	1,614,226	862,370
Cash and equivalents at beginning of period	960,217	97,847	97,847
Cash and equivalents at end of period	1,374,866	1,712,073	960,217

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 2017.

This interim consolidated financial information for the six months ended 30 June 2018 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 2017, 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 2018 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 2017 are also unaudited.

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

IFRS15 – Accounting Policies and Transition

The directors have reviewed the way that the group accounts for revenues from contracts with customers and has adopted the new reporting standard on revenue recognition, IFRS 15. Following that review, the directors did not consider it necessary to change the group's accounting policies with respect to revenue recognition. There have been no changes to recognition or measurement of revenue or to the consolidated statements of comprehensive income or financial position as a consequence of adopting IFRS15.

2. Going concern

The interim consolidated financial information for the six months ended 30 June 2018 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

On 16 February 18, the Company sub-divided its share capital on the basis of 26.71999:1. The loss per share has been restated for the subdivision in the comparatives presented for the six months ended 30 June 17 and the year ended 31 December 17.

The basic and diluted loss per share for the period ended 30 June 2018 was US\$0.057 (2017: US\$0.062) The calculation of loss per share is based on the loss of US\$2,833,391 for the period ended 30 June 2018 (2017: loss of US\$1,760,532) and the weighted average number of shares in issue during the period for calculating the basic profit per share of 49,432,227 shares (2017: 28,497,296).

4. Called up share capital

	Unaudited 30.6.18 US\$	Unaudited 30.6.17 US\$	Audited 31.12.17 US\$
Allotted, issued and fully paid			
Ordinary Shares	<u>36,396</u>	<u>23,291</u>	<u>23,291</u>

The number of shares in issue was as follows:

	Number of shares
Balance at 1 January 2017	1
Effect of share split	99
Issued during the period	1,813,903
Balance at 30 June 2017	<u>1,814,003</u>
Issued during the period	-
Balance at 31 December 2017	<u>1,814,003</u>
Effect of share split	46,656,158
Issued during the period	24,939,303
Balance at 30 June 2018	<u>73,409,464</u>

On 16 February 18, the Company sub-divided its existing share capital on the basis of 26.71999:1, resulting in the issue of 46,656,158 ordinary shares. The Company then issued 24,939,303 new ordinary shares on the 29 March, comprising of 20,000,000 shares issued as part of the admission to AIM and 4,939,303 shares issued repay a convertible loan and accrued interest.

5. Borrowings

	Unaudited 30.6.18 US\$	Unaudited 30.6.17 US\$	Audited 31.12.17 US\$
Related Party Loans	7,936	104,451	47,086
Notes Payable	-	275,000	265,750
Bank Overdraft	141,942	-	-
Convertible Loan Notes	-	-	791,887
Total	<u>149,878</u>	<u>379,541</u>	<u>1,104,723</u>

In the interim period to June 2018, an unsecured convertible loan note that was issued for a principal amount of US\$903,000 (£647,147) was converted with accrued interest, into 4,939,303 ordinary shares in the Company at a conversion price equal to 90 per cent. of the issue price of the ordinary shares upon admission.

During the interim period, an unsecured loan note for a principal amount of US\$250,000 was repaid. The conditions of the loan note detailed the Group was to receive the initial 50 per cent of the loan upon the completion of the loan agreement. Upon the completion of the mid-term project report, the Group will receive 40 per cent of the loan, while the remaining 10 per cent will be received upon completion of the project. At the point of settlement, the Group had received 50 per cent of the principal in accordance with the conditions in the agreement.

An unsecured promissory note that was issued in June 17 for a principal amount of US\$150,000, with an interest rate of 6 per cent per annum, was settled in full with all outstanding interest in April 2018.

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, lapsed and outstanding at the year-end are as follows:

	Number of share options	Weighted average exercise price(US\$)
Outstanding at 1 January 2018	5,156,960	0.02
Granted during the period	9,629,868	0.20
Outstanding at 30 June 2018	14,786,828	0.13
Exercisable at 30 June 2018	5,073,980	0.04

The opening balance of share options as at 1 January 18 has been adjusted to reflect the subdivision of share capital on a basis of 26.719999: 1.

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 1.14% and volatility of 40.84%.

The weighted average contractual life of the share options outstanding at the reporting date is 9.67 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 granted, exercised, lapsed and outstanding at the period ending 30 June 2018 are as follows:

	Number of share warrants	Weighted average exercise price (US\$)
Outstanding at 1 January 2018	9,065,428	0.16
Lapsed during the period	(2,618,373)	0.34
Granted during the period	253,400	0.20
Outstanding at 30 June 2018	6,700,455	0.08
Exercisable at 30 June 2018	6,229,709	0.07

The opening balance of share warrants as at 1 January 18 has been adjusted to reflect the subdivision of share capital on a basis of 26.719999: 1

The weighted average contractual life of the share options outstanding at the reporting date is 4.81 years.

7. Subsequent events

On 10 July 2018, the Company announced it had raised a total of £0.8million (before expenses) via the placing of total of 5,000,000 ordinary shares at a price of 16p per share with new and existing investors. The net proceeds of the placing will be used to further support the FDA Phase III clinical trials in the US and further support improvements on the Company's polarisers.