**30 September 2020**

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

**Half-year Report**

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with a proprietary investigational drug-device combination diagnostic for magnetic resonance imaging ("MRI"), announces its unaudited interim results for the six months ended 30 June 2020.

**Highlights**

- Positive results from Phase III trials (the "Clinical Trials") announced in January 2020
- Raised gross proceeds of £8.4m in April 2020, which included a £2.2m subscription from new strategic investor Bracco Imaging S.p.A. ("Bracco")
- Appointment of former NED Jonathan Allis as Chairman in February 2020
- Appointment of Cyrille Petit as Non-Executive Director and representative of Bracco in June 2020
- Net cash of US$9.2m as of 30 June 2020

**Post-period end**

- Significant progress toward submission of New Drug Application ("NDA")
    - Small Business Waiver of Human Drug Application Fee granted by the United States Food and Drug Administration ("FDA") on 28 September 2020
    - NDA to be submitted in early October 2020
- Presentation of data at the American Thoracic Society and the International Society for Magnetic Resonance in Medicine virtual conferences
- Installed a 9820 Xenon Polariser system at University of Kansas Medical Center ("KU Medical Center")
- Government COVID-19-related grants are being applied for and received by our current device users, including a recent award for a multi-center initiative coordinated by Western Ontario Professor Grace Parraga PhD to better understand the long-term effects of COVID-19 using hyperpolarised 129Xe MRI in combination with computed tomography (CT)

**Richard Hullihen, CEO of Polarean, commented:** *"During the period under review, Polarean achieved one of its most important milestones to date, the positive readout from our Phase III Clinical Trials. We subsequently undertook an £8.4m fundraising and welcomed our new strategic investor Bracco to our share register, alongside several new institutional investors. We are also grateful for the continued support we received from our existing long-term investors and partners. The installation of new polarisers has continued and users of our systems are publishing research at an increased rate, expanding and deepening the knowledge base of the use of hyperpolarised 129Xe in pulmonary medicine, while further validating Polarean's technology. We look forward to providing our shareholders with updates regarding further progress and specifically the imminent submission of the Company's NDA to the FDA."*

*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 medical 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.

The Group operates in an area of significant unmet medical need and the Group's technology provides a novel diagnostic approach, offering a non-invasive and radiation-free functional imaging platform which is more accurate and less harmful to the patient than current methods. The annual burden of pulmonary disease in the US is estimated to be over US$150 billion.

The Group also develops high performance MRI radiofrequency (RF) coils which are a required component for imaging $^{129}$Xe in the MRI system. The development of these coils by the Group facilitates the adoption of the Xenon technology by providing application-specific RF coils which optimise the imaging of $^{129}$Xe in MRI equipment for use as a medical diagnostic as well as a method of monitoring the efficacy of therapeutic intervention.

**CEO Statement**

**Introduction**

The six month period ending 30 June 2020 has seen Polarean make substantial progress towards its goal of seeking FDA approval for the Company's drug-device combination. After successfully completing two Phase III Clinical Trials in Q4 2019, the Company announced positive top line results of these Clinical Trials on 29 January 2020. During the first half of 2020, the Company performed the post trial in depth analysis of the results of the Clinical Trials and initiated work associated with the construction of both the drug and device components of our NDA submission.

Despite the challenging market conditions in the first half of 2020, the Company closed a financing that resulted in gross proceeds of US$10.4m (£8.4m). This financing included a new strategic investor, Bracco Imaging S.p.A., several new institutional investors and the continued support of previous VCT and EIS investors. We are encouraged with the support shown by new and existing shareholders and these additional funds will further support our preparation of our NDA for submission to the FDA, focus on preparations for commercial launch and continue development of our polariser system.

Also, during the period, former NED Jonathan Allis was appointed Chairman of Polarean after the sale of his former company, Blue Earth Diagnostics, to Bracco. We also welcomed Cyrille Petit to the Board, as a result of the Bracco investment.

**Results overview**

Group revenues for the first half were US$0.3m (2019: US$0.4m) and were largely derived from our collaboration with the University of Cincinnati where work under our SBIR grant has been completed. We continue to sell our polariser systems on a research-use-only basis to academic institutions in the US, Canada and Europe. Due to COVID-19, we were unable to complete the installation of a polariser system we had delivered to KU Medical Center during December 2019. The system installation completed recently as per the Company's announcement on 18 September 2020. Operating expenses for H1 2020 (US$3.4m) were flat compared with H1 2019 (US$3.4m), as Administrative Expenses (H1 2020 US$2.7m, H1 2019 US $3.1m) decreased after we completed the Clinical Trials and Selling and Distribution Expenses (H1 2020 US$0.4m, H1 2019 US $0.1m) increased as we began preparations for commercial launch. During H1 2020, the Company received a US$0.3m forgivable loan under the US Paycheck Protection Program ("PPP"), which was recognised as Finance Income. Our overall loss before tax decreased from US$3.4m to US$3.2m in the same comparable period, due to the PPP proceeds. The Company completed the £8.4m fundraise during H1 2020 via the issue of new equity and as at 30 June 2020 we held US US$9.2m in net cash or cash equivalents.

**Post-period end events**

**Presentation at Medical Conferences and Studies Utilising our Technology**

The Company's technology was prominent at the American Thoracic Society and International Society of Magnetic Resonance in Medicine virtual conferences during August 2020. Over 40 abstracts related to the use of hyperpolarised $^{129}$Xe were presented at the two conferences, including the Company's Clinical Trial results. The content of our publications and those of our customers, along with our participation is available on our website at www.polarean.com . The users of our polarisers continue to expand and document the applications of our technology across the spectrum of pulmonary disease.

The "$^{129}$Xe MRI Clinical Trials Consortium" continues to discuss the application of our technology to the case of post infection COVID-19 patients to assess the long-term effects and case management of these

patients. Investigator-initiated government research grants have been submitted to study the use of our technology to assess the long-term effects of COVID-19 post infection in patients. Some of these grants have been awarded and COVID-19-related clinical research has begun.

**Installation 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. We recently completed the installation of a new system at the KU Medical Center, which is starting up a research programme under the guidance of a veteran researcher in the field of hyperpolarised 129Xe imaging.

Researchers continue to apply for and receive grants to purchase our polariser systems. We are in discussions with several potential customers and anticipate additional orders during calendar year 2020. The number of systems currently installed is 23.

**NDA Submission**

We have continued to compile the components of the NDA submission. On 28 September 2020, the Company was granted a Small Business Waiver of Human Drug Application Fee (the "Waiver") by the FDA. The Waiver exempts the Company from having to pay the US$2.9m filing fee for our NDA submission. We anticipate submitting our NDA to the FDA in early October 2020.

**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. There are currently 40 clinical trials ongoing into the use of $^{129}$Xe MRI according to the FDA website.

The burden of pulmonary disease in the USA is approximately US$150bn and is widespread and growing, affecting nearly 40 million Americans. Given the limitations of existing methods of diagnosis and lung disease monitoring, we estimate 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 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 Hullihen**
*Chief Executive Officer*

30 September 2020

**POLAREAN IMAGING PLC**
**Consolidated unaudited statement of comprehensive income**
for the six months ended 30 June 2020

| | Note | Unaudited 6 months ended 30.6.20 US$ | Unaudited 6 months ended 30.6.19 US$ | Audited 12 months ended 31.12.19 US$ |
|---|---|---|---|---|
| **Revenue** | | 327,896 | 399,639 | 2,301,093 |
| Cost of sales | | (41,387) | (75,185) | (925,612) |
| **Gross profit** | | **286,509** | **324,454** | **1,375,481** |
| Administrative expenses | | (2,724,411) | (3,068,371) | (6,010,119) |
| Depreciation | | (73,204) | (4,661) | (63,121) |
| Amortisation | | (359,677) | (341,937) | (683,873) |
| Selling and distribution expenses | | (351,754) | (147,821) | (324,791) |
| Share based payment expense | | (213,906) | (139,886) | (305,747) |
| **Loss from operations** | | **(3,436,443)** | **(3,378,222)** | **(6,012,170)** |
| Finance expense | | (9,647) | (22,356) | (91,678) |
| Finance income | | 267,155 | 274 | 508 |
| **Loss on ordinary activities before taxation** | **3** | **(3,178,935)** | **(3,400,304)** | **(6,103,340)** |
| Taxation | | - | - | - |
| **Loss and total other comprehensive expense** | | **(3,178,935)** | **(3,400,304)** | **(6,103,340)** |
| **Basic and fully diluted loss per share (US$)** | **3** | **(0.023)** | **(0.034)** | **(0.057)** |

**POLAREAN IMAGING PLC**
**Consolidated unaudited statement of financial position**
at 30 June 2020

| | Note | Unaudited As at 30.6.20 US$ | Unaudited As at 30.6.19 US$ | Audited As at 31.12.19 US$ |
|---|---|---|---|---|
| **Assets** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | | 312,287 | 13,091 | 355,958 |
| Intangible assets | | 3,119,120 | 3,735,973 | 3,427,547 |
| Right-of-use asset | | 224,414 | 131,773 | 98,263 |
| Trade and other receivables | | 5,539 | 5,539 | 5,539 |
| | | 3,661,360 | 3,886,376 | 3,887,307 |
| **Current assets** | | | | |
| Inventories | | 950,674 | 1,233,039 | 554,211 |
| Trade and other receivables | | 522,625 | 1,094,988 | 636,783 |
| Cash and cash equivalents | | 9,190,862 | 1,277,195 | 1,961,869 |
| | | 10,664,161 | 3,605,222 | 3,152,863 |
| **Total assets** | | **14,325,521** | **7,491,598** | **7,040,170** |
| **Equity** | | | | |
| Share capital | **4** | 77,518 | 49,767 | 55,776 |
| Share premium | | 23,573,058 | 11,200,461 | 13,659,912 |
| Group reorganisation reserve | | 7,813,337 | 7,813,337 | 7,813,337 |
| Share-based payment reserve | | 1,584,640 | 1,218,221 | 1,370,734 |
| Accumulated losses | | (21,488,616) | (15,619,993) | (18,309,681) |
| **Total equity** | | **11,559,937** | **4,661,793** | **4,590,078** |
| **Liabilities** | | | | |
| **Non-current liabilities** | | | | |
| Deferred income | | 192,817 | 87,029 | 192,817 |
| Lease liability | **5** | 149,487 | 83,168 | 50,455 |
| Contingent consideration | | 316,000 | 316,000 | 316,000 |
| | | 658,304 | 486,197 | 559,272 |
| **Current liabilities** | | | | |
| Trade and other payables | | 1,985,828 | 1,604,792 | 1,773,582 |
| Lease liability | **5** | 102,213 | 82,716 | 70,914 |
| Deferred income | | 19,239 | 656,100 | 46,324 |
| | | 2,107,280 | 2,343,608 | 1,890,820 |
| **Total equity and liabilities** | | **14,325,521** | **7,491,598** | **7,040,170** |

**POLAREAN IMAGING PLC**
**Consolidated unaudited statement of changes in equity**
at 30 June 2020

| | Share capital | Share premium | Group re-organisation | Share-based payment reserve | Accumulated losses | Total equity |
|---|---|---|---|---|---|---|
| **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) |
| 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** |
| *Comprehensive income* | | | | | | |
| Share based payment – lapsed share options | **-** | **-** | - | (13,348) | 13,348 | - |
| Loss and total comprehensive income for the period | **-** | **-** | - | - | (2,703,036) | (2,703,036) |
| *Transaction with owners* | | | | | | |
| Issue of shares | 6,009 | 2,618,903 | - | - | - | 2,624,912 |
| Share issue costs | - | (159,452) | - | - | - | (159,452) |
| Share-based payments | - | - | - | 165,861 | - | 165,861 |
| **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** |

**POLAREAN IMAGING PLC**
**Consolidated unaudited cash flow statement**
for the six months ended 30 June 2020

| | Unaudited 6 months ended 30.6.20 US$ | Unaudited 6 months ended 30.6.19 US$ | Audited 12 months ended 31.12.19 US$ |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Loss for the period before taxation | (3,178,935) | (3,400,304) | (6,103,340) |
| Adjustments for non-cash/non-operating items: | | | |
| Depreciation of plant and equipment | 73,204 | 4,661 | 63,121 |
| Amortisation of intangible assets | 359,677 | 341,937 | 683,873 |
| Share based compensation | 213,906 | 139,886 | 305,747 |
| Interest paid | - | 22,356 | 91,678 |
| Interest received | (92) | (274) | (508) |
| | (2,532,240) | (2,891,738) | (4,959,429) |
| Changes in working capital: | | | |
| Increase in inventories | (396,462) | (581,257) | (97,570) |
| Increase in trade and other receivables | 114,157 | (301,448) | (14,737) |
| (Decrease)/increase in trade and other payables | 189,407 | 36,955 | (285,074) |
| Increase/(decrease) in deferred revenue | (27,085) | 617,575 | 595,961 |
| **Net cash flows used from operating activities** | **(2,652,223)** | **(3,119,913)** | **(4,565,709)** |
| | | | |
| **Cash flows from investing activities** | | | |
| Purchase of plant and equipment | (29,534) | - | (401,327) |
| **Net cash used in investing activities** | **(29,534)** | **-** | **(401,327)** |
| | | | |
| **Cash flows from financing activities** | | | |
| Issue of shares | 10,449,279 | 3,577,509 | 6,373,919 |
| Cost of issue | (514,391) | | (159,452) |
| Interest paid | - | (22,356) | - |
| Interest received | 92 | 274 | 508 |
| Funds received from PPP loan | 22,840 | - | - |
| Principal elements of lease payments | (56,717) | (42,793) | (69,993) |
| Interest elements of lease payments | 9,647 | 8,873 | (91,678) |
| **Net cash generated from financing activities** | **9,910,750** | **3,521,507** | **6,053,304** |
| | | | |
| **Net increase in cash and equivalents** | 7,228,993 | 404,594 | (1,086,268) |
| **Cash and equivalents at beginning of period** | 1,961,869 | 875,601 | 875,601 |
| **Cash and equivalents at end of period** | 9,190,862 | 1,277,195 | 1,961,869 |

**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 2019.

This interim consolidated financial information for the six months ended 30 June 2020 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 2019, 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 2020 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 2019 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 2020 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 2020 was US$0.023 (2019: US$0.034) The calculation of loss per share is based on the loss of US$3,178,935 for the period ended 30 June 2020 (2019: loss of US$3,400,304) and the weighted average number of shares in issue during the period for calculating the basic profit per share of 137,598,239 shares (2019: 101,087,330).

**4. Called up share capital**

| | Unaudited 30.6.20 US$ | Unaudited 30.6.19 US$ | Audited 31.12.19 US$ |
|---|---|---|---|
| **Allotted, issued and fully paid** | | | |
| Ordinary Shares | 77,518 | 49,427 | 55,776 |

| The number of shares in issue was as follows: | Number of shares |
|---|---|
| **Balance at 1 January 2019** | 100,730,893 |
| Exercised warrants | 705,040 |
| **Balance at 30 June 2019** | 101,435,933 |
| Issued during the period | 11,666,667 |
| Exercised warrants | 1,336,000 |
| **Balance at 31 Dec 2019** | 114,438,600 |
| Issued during the period | 46,624,997 |
| Exercised warrants | 766,410 |
| **Balance at 30 June 2020** | 161,830,007 |

**5. Borrowings**

| | Unaudited 30.6.20 US$ | Unaudited 30.6.19 US$ | Audited 31.12.19 US$ |
|---|---|---|---|
| **Non-current** | | | |
| Lease liability | 149,487 | 83,168 | 50,455 |
| | | | |
| **Current** | | | |
| Bank Overdraft | - | 8,443 | - |
| Lease Liability | 102,213 | 74,273 | 70,917 |
| Total | 251,700 | 82,716 | 121,369 |

**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 2020 | 17,436,722 | 0.15 |
| Outstanding at 30 June 2020 | 17,436,722 | 0.15 |
| Exercisable at 30 June 2020 | 9,383,074 | 0.10 |

There have been no options granted in the period to 30 June 2020.

The weighted average contractual life of the share options outstanding at the reporting date is 6 years and 278 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 2020 are as follows:

| | Number of share warrants | Weighted average exercise price (US$) |
|---|---|---|
| Outstanding at 1 January 2020 | 4,824,703 | 0.09 |
| Exercised during the period | (766,410) | 0.10 |
| Outstanding at 30 June 2020 | 4,058,293 | 0.09 |
| Exercisable at 30 June 2020 | 4,058,293 | 0.09 |

On 2 March 2020, 232,010 new ordinary shares were issued by the Company following the exercise of warrants at an exercise price of 0.037 pence per warrant. On 1 June 2020, the Company issued a further 534,400 new ordinary shares following an exercise of warrants at an exercise price of 0.003 pence per warrant.

The weighted average contractual life of the share warrants outstanding at the reporting date is 3 years and 99 days.