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Polarean Imaging PLC
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Polarean Imaging Plc

("Polarean" or the "Company")

2024 Polarean Strategy Update

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced magnetic resonance imaging ("MRI") of the lungs, provides an update on the Company's plans for 2024.

Company Update

- The Company continues to make substantial progress toward the implementation of the five-pillar growth strategy outlined in its half-year report.
    - **Drive utilisation:** When new medical devices are introduced, hospital physicians need to be educated on their benefits in order to drive utilisation. The Polarean commercial team has been regularly visiting the Company's initial two clinical sites, Cincinnati Children's Hospital Medical Center and the University of Missouri Health Care, educating pulmonologists and radiologists on the benefits of the XENOVIEW™ technology. The number of scans at these sites has been steadily increasing.
    - **Grow user base:** Hospital acquisition of capital equipment is a notoriously lengthy process, with an average time from introduction to sales closing of between 18 to 24 months. The Company has been actively navigating obstacles to transition multiple research sites to clinical status, alongside engagement of new sites to introduce the Polarean pulmonary functional MRI technology as a solution to their unmet diagnostic needs. Both existing customers and potential clients are becoming increasingly aware of the technology's value in lung ventilation diagnostics as well as its significant future growth opportunities in gas exchange and cardiopulmonary applications.
    - **Broaden reimbursement coverage:** In adopting new diagnostic technologies, US-based hospitals look carefully at the return on investment, driven by the reimbursement rates of private and government insurers. Following the Centers for Medicare & Medicaid Services issuance of the reimbursement code for XENOVIEW scans and the associated reimbursement rate of between $1,201 and $1,300 in October 2023, hospitals are steadily recognising the economic benefits of integrating the XENOVIEW technology into the clinical care pathway for patients with lung disease. Medicare (the U.S. government-funded health insurance for people aged 65 and older) coverage is important in the elderly population suffering from chronic lung diseases that XENOVIEW is tailored to address. Polarean has further confirmed evidence that the initial clinical sites have attained reimbursement by both private insurers and Medicaid (the U.S. government-funded programme providing health coverage to low-income individuals and families). The Company is working to broaden reimbursement coverage with additional private U.S. health insurers to strengthen the value proposition for the adoption of XENOVIEW.
    - **Expand total addressable market:** In its initial regulatory approval, the FDA outlined specific requirements to expand the approved patient age range for XENOVIEW from twelve to six years old, marking a significant milestone in the product's accessibility to younger patients. The Company has made notable progress in meeting these FDA requirements. Additionally, the Company is incorporating insights gathered from the October 2023 FDA meeting to support a development plan for the approval of new indications to include gas exchange and cardiopulmonary applications. With XENOVIEW's safety demonstrated in the prior Phase 3 clinical trials combined with over a decade of research and publications on gas exchange and cardiopulmonary applications, the Company is confident that a forthcoming clinical trial required to expand the indications for XENOVIEW has been considerably de-risked.
    - **Further develop partnerships:** The Company's existing strategic partners Philips (a leading MRI company), VIDA (a leading clinical lung imaging intelligence company), and NUKEM Isotopes (a leading medical stable isotope supplier), remain involved and instrumental in helping advance the XENOVIEW technology. Additionally, Polarean has been actively engaging multiple pharmaceutical ("Pharma") and medical

technology ("MedTech") companies to increase awareness and adoption of the Polarean technology. Currently, clinicaltrials.gov lists numerous clinical trials underway that utilize Xenon MRI technology to evaluate the effectiveness of existing and new pharmaceutical treatments. In January 2024, the Company participated in the annual Xenon-129 MRI Clinical Trials Consortium Meeting. This meeting also brought together other representatives from the Pharma and MedTech sectors, like GE HealthCare, Genentech, Philips, and Siemens, to share insights and advancements of Xenon MRI.

- The Company remains committed to fortifying its intellectual property portfolio to further consolidate its position as a market leader. Alongside existing patents predating 2023, the Company has recently secured two new patents, one in the US and the other in Japan. This development ensures the extension of Polarean's patent protection from 2032 and beyond, bolstering its competitive advantage. Moreover, the Company currently has over 15+ patent applications pending, underlining its dedication to innovation and future growth.
- In August 2023, the Company implemented strict cost control measures. These measures resulted in a cash balance of $6.1m on 31 December 2023 (unaudited), extending the cash runway into October 2024 (previously June 2024).
- For the Company to continue to make commercial and strategic progress, additional financing will be required as set forth below.

Commercial and Strategy Update

Financing Plan

- To achieve the commercial targets below, the Company will need access to additional capital.
- The Company is exploring the appropriate financing options, with an anticipated launch in Q2-2024
    - Assuming a minimum financing of $10m, NUKEM Isotopes intends to commit $2.5m and Bracco intends to commit $2.0m to a prospective fundraise in the future
    - The Company has obtained advanced assurance from His Majesty's Revenue & Customs (HMRC) to confirm £2.5m ($3.1m) of Enterprise Investment Scheme availability
- A minimum of $10m in financing would allow the Company to:
    - Expand and develop the sales team to achieve meaningful commercial traction
    - Finalise the FDA plan for the anticipated gas exchange trial
    - Further develop strategic relationships
    - Fund the Company into Q1-2026
- The Company is still in discussions with NUKEM Isotopes and Bracco about the terms and conditions of this potential financing opportunity. There can be no certainty that a financing will take place this year nor as to the terms and conditions of any such financing. A further announcement will be made in due course.
- Any financing agreement with NUKEM Isotopes would constitute a related party transaction.
- Future financing and/or strategic relationships are needed to fund the future FDA clinical trial and grow the Company to profitability
    - Profitability projected for late 2027, post-gas exchange FDA approval
    - Total of $30m to $35m, inclusive of money raised in the anticipated 2024 financing, from investment and strategic deals needed to fund the Company to profitability, investment focused on:
        - Resources to enhance and accelerate commercialisation efforts
        - Product development, including the FDA Phase III clinical trial to drive the commercialisation of the gas exchange label expansion and continuous improvement of the system

Commercial Plan

- Given the progress on the five-pillar growth strategy outlined above, the Company is poised to achieve the following commercial targets:
    - End of 2024
        - Total installed clinical base of five to seven systems
        - Sites performing three to four scans per week, which potentially enables sites to earn a positive return on investment on the Polarean technology
        - Revenue of $2m to $3m, as compared to less than $1m (unaudited) in 2023
    - End of 2025
        - Total installed clinical base of 12 to 14 systems
        - Sites performing five to six scans per week
        - Revenue of $5m to $6m
    - 2026 through 2028
        - Profitable at $25m to $30m revenue (post-gas exchange FDA approval)
        - 2028 projected revenue of $35m to $40m
        - Total installed clinical base of 60 to 70 systems at end of 2028

- Sites performing over 10 scans per week in 2028

Christopher von Jako, Ph.D., CEO of Polarean, said *"We have made important headway in 2023, and we anticipate this positive momentum to continue into 2024 and beyond. Clinicians and healthcare providers in the U.S. are increasingly recognising the potential of our technology in aiding disease characterisation, providing visual and quantitative assessments of response to therapy, and guiding interventions for various challenging lung diseases. We are confident in our abilities to execute this plan, and additional financing will enable us to meet our milestones effectively.*

"I extend my gratitude to our strategic investors, loyal customers, and the outstanding Polarean team for their unwavering support. Together, we look forward to a positive 2024."

Daniel Plumpe, Managing Director of NUKEM Isotopes,said: *We are very excited to see such a positive update from Polarean. Our faith in the Polarean team is evident as we recently increased our investment to over 10%, making us the largest shareholder in the Company. We have a long-standing relationship with Polarean as a provider of their xenon-129 gas, a critical component of the Company's pulmonary functional MRI product, and we look forward to seeing continued progress as they look to increase their number of sites."*

Fulvio Renoldi Bracco, Bracco Imaging CEO said: *"As a significant shareholder in Polarean, it is encouraging to see the work that has been done to date, and the focus the Company has had and continues to have on delivering value. We remain a strong supporter of the business and truly believe in the technology and the value it brings to patients."*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014, as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

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About Polarean

Polarean is a revenue-generating medical imaging technology company revolutionizing pulmonary medicine through direct visualization of lung function by introducing the power and safety of MRI to the respiratory healthcare community. This community is in desperate need of modern solutions to accurately assess lung function. The Company strives to optimize lung health and prevent avoidable loss by illuminating hidden disease, addressing the global unmet medical needs of more than 500 million patients worldwide suffering from chronic respiratory disease. Polarean is a leader in the field of hyperpolarization science and has successfully developed the first and only hyperpolarized Xenon MRI inhaled contrast agent, XENOVIEW™, which is now FDA-approved in the United States. Polarean is dedicated to researching, developing, and commercialising innovative imaging solutions with its non-invasive and radiation-free pulmonary functional MRI platform. This comprehensive drug-device platform encompasses the proprietary Xenon gas blend, gas hyperpolarization system, as well as software and accessories, facilitating fully integrated modern respiratory imaging operations. Founded in 2012, with offices in Durham, NC, and London, United Kingdom, Polarean is committed to increasing global awareness of and broad access to its XENOVIEW MRI technology platform. For the latest news and information about Polarean, please visit www.polarean.com.

XENOVIEW IMPORTANT SAFETY INFORMATION

Indication

XENOVIEW™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Limitations of Use

XENOVIEW has not been evaluated for use with lung perfusion imaging.

CONTRAINDICATIONS

None.

Warnings and Precautions

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen desaturation and symptoms of hypoxemia and treat as clinically indicated.

Adverse Reactions

Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness. Adverse Reactions in Pediatric and Adolescent Patients: In published literature in pediatric patients aged 6 to 18, transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate was reported following hyperpolarized xenon Xe 129 administration. XENOVIEW is not approved for use in pediatric patients less than 12 years of age.

Please see full prescribing information at www.xenoview.net

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