

HEALTHCARE CONDITIONS



Non-Independent Research; Marketing & Sales Commentary - MiFID II exempt information – see disclaimer below

Company Update: 23 December 2020

Polarean Imaging (POLX.L): Acceptance of NDA by the US FDA

Share price: 75p; Market capitalisation: £121.4m

- Polarean Imaging, the developer of a drug-device combination for lung imaging, announced that the US Food and Drug Administration (FDA) has accepted the Group's New Drug Application (NDA) for its drug-device system.
- The NDA concerns marketing approval for the clinical use of hyperpolarised ¹²⁹Xenon gas to evaluate pulmonary function and to visualise the lung using MRI.
- The NDA will progress under the FDA standard review timeline with a targeted PDUFA action date of 5 October 2021.
- The Group also notes the planned retirement of Ken West, current Chief Operating Officer of the Company.
- Mr West will transition to a Non-Executive Director position and will continue to be involved with the Company as a consultant.

The acceptance of the NDA marks a further milestone towards the regulatory approval of the Group's platform for clinical use. Polarean submitted an NDA and request for Priority Review in October 2020 after the technology successfully met the primary endpoints in Phase 3 trials which read out earlier in the year. Although the Group's request for Priority Review was not accepted, the Company is continuing its commercialisation plans as per its original timelines. With a regulatory approval decision expected by 5 October 2021, the Group has just over 9 months to finalise its commercialisation plans prior to the platform's anticipated launch. Within this period we expect the Group to continue to expand its installed base of polarisers for research use only. This should increase awareness within the medical community regarding the use of the technology and support a successful clinical launch.

**SP Angel acts as Nomad and Broker to Polarean. One of the authoring analysts has an interest in Polarean shares*

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Recommendations are based on a 12-month time horizon as follows:

Buy - Expected return >15%

Hold - Expected return range -15% to +15%

Sell - Expected return < 15%