Business Update

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Celadon Pharmaceuticals PLC
22 June 2022

Celadon Pharmaceuticals Plc
("Celadon" or the "Company")

Business Update

Progress against IPO milestones

London, UK, 22 June 2022: Celadon Pharmaceuticals Plc (AIM: CEL), a UK-based pharmaceutical company focused on the development and supply of natural, cannabis-based medicines, is pleased to announce an update on its business and operations following the Company's Admission to AIM on 28 March 2022.

Highlights

- Successfully completed sixth harvest from its Phase 1 grow facility, with initial results from the selected test batches showing high quality, consistent growing of pharmaceutical grade, high THC medical cannabis
- Nearing completion of all preparatory work ahead of GMP inspection by MHRA, having undertaken extensive internal audits and independent third-party testing
- High level of new patient enquiries to LVL clinic for participation in the chronic pain study, with feedback from initial patients reporting improvements in quality of life
- Phase 2 grow facility build on track and expected to become operational in Q1 2023, following which the Company will aim to expand its high THC medical cannabis grow capacity to three tonnes per year

James Short, CEO of Celadon, commented:

"*We are pleased to report on our significant progress since Admission, which has seen Celadon advance all the necessary preparatory work to be in position for an MHRA inspection and continue the preliminary works for the build-out of its Phase 2 grow facilities. Alongside our grow activity, I am delighted to report that LVL has been experiencing significant levels of new enquiries from those looking to participate in the chronic pain study. The LVL team is working hard to keep pace with patient onboarding as we continue to advance towards our objective of conducting what we believe would be the UK's only MHRA approved clinical trial exploring the use of medical cannabis for the treatment of chronic pain.*

"We believe that our highly regulated, pharmaceutical approach is the most effective route to ensuring that patient needs are met. With our focus on evidence-based data, facilitated by our medical cannabis study and MHRA conditionally approved medical cannabis trial, we hope to demonstrate the safety and efficacy of cannabis-based medicines, underpinning the case for regulatory approval and, in turn, reimbursement by the NHS."

Business update

Phase 1 grow

In May 2022, the Company completed its sixth harvest of test batches of high THC medical cannabis from the Phase 1 grow rooms for the purpose of supporting its application for MHRA registration as a manufacturer of medicinal product Active Pharmaceutical Ingredients ("APIs"). The harvested product has since undergone rigorous internal and initial independent testing of certain of the cannabis flower to assess its consistency, quality, purity and cannabinoid profile. The results of the independent third party testing confirmed that the cannabis flower tested has consistently met Good Agricultural and Collection Practice ("GACP") / pharmaceutical grade standards for medical cannabis, demonstrating a consistent and high level of THC, well within all testing tolerances. Ahead of an MHRA inspection, independent third party testing will also be undertaken on Celadon's processed cannabis oil.

The harvested high THC cannabis is currently being stored and processed by the Company for the purposes of its MHRA inspection, which is noted in more detail below, as part of its Good Manufacturing Practice ("GMP") certified medical grade cannabis application.

GACP & MHRA preparatory work and grow facility fit out

The Company is in the final stages of completing all necessary preparatory work to be in a position for an MHRA inspection of the Celadon facility. This has included successfully running internal audits conducted via third party professional advisers and the independent third party testing of its batches from its analytical testing partner, in order to ensure the business is in a prime position to receive its MHRA registration. The Company continues to engage with the MHRA on its progress and potential timings for the inspection, which it expects will now be during H2 2022.

On the basis of a successful MHRA inspection and subsequent receipt of MHRA registration and the grant of a further licence from the Home Office permitting supply for manufacture into finished medicinal products, the Directors believe that the Company will become one of the first organisations in the UK to be licensed to sell GMP standard API, high THC medical cannabis from its Midlands facility, and one of a limited number of GMP approved medical cannabis facilities in the world.

Celadon has made significant progress in the development of its cannabis cultivation and processing capacity. The Company is on track for its Phase 2 facility to become operational by Q1 2023, which will see the fit out of the facility's second grow space for the cultivation of high THC medical cannabis. Following completion of the Phase 2 fit out, the Directors believe that the Company has the potential to achieve an annualised yield of approximately three tonnes of dry flower. Although the Company has not been immune to inflationary cost pressures across the economy attaching to the vast majority of building materials and labour, Celadon is aiming to mitigate certain rising cost pressures where it can, to ensure the build programme remains on track by bringing inhouse the project management activity and rephasing certain aspects of the build.

The Company has been working closely with the Home Office and has been successful in its application to expand its Home Office licence, which now allows for increased permitted storage of cannabis products at its Midlands based facility, and has received the necessary approvals to export its cannabis products for the purposes of analytical testing.

Commencement of feasibility study in chronic pain by LVL Health ("LVL")

As set out in the Company's admission document, LVL, the Company's private pain clinic subsidiary, received approval from Research Ethics Committee ("REC") allowing for a 100-patient feasibility study of medical cannabis in patients with non-cancer chronic pain. The feasibility study is designed to demonstrate the ability to engage and retain patients and will allow LVL to carry out an in-depth evaluation of the patient pathway.

The Company has commenced the enrolment of patients on to the feasibility study. Enquiries from patients interested in participating in the feasibility study have surpassed the Company's expectations with approximately 1,500 potential leads currently being screened for eligibility. There have been some delays in onboarding certain patients due to the volume of enquiries being processed, however the Company is working to resolve this. This initial patient onboarding data will be used in the feasibility study, and in due course the MHRA conditionally approved patient trial, for presentation to the National Institute for Clinical Excellence ("NICE"). Initial feedback from patients who have received treatment has been positive, with improvements in quality of life being noted.

LVL also received Care Quality Commission approval for its physical clinic on Harley Street in London in order to operate that clinic, and the physical clinic is now able to see patients face to face.

Commercialisation

Whilst the Company is required to obtain both MHRA registration and a subsequent Home Office licence before it can sell cultivated medical cannabis commercially, Celadon is pleased to report that there have been a number of positive preliminary discussions regarding sales of bulk cannabis flower both in the UK and internationally.

Enquiries:

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About Celadon Pharmaceuticals Plc

Celadon Pharmaceuticals Plc is a UK based pharmaceutical company focused on the research, cultivation, manufacturing, and supply of natural cannabis-based medicines. Its primary focus is on improving quality of life for chronic pain sufferers, as well as exploring the potential of cannabis-based medicines for other conditions such as autism. Its 100,000 sq ft UK facility comprises a laboratory designed to meet GMP standards, and capacity for a large indoor hydroponic growing facility that has received a Home Office Licence for the legal cultivation of high-THC medicinal cannabis for the purpose of producing test batches of cannabis oil to support its application to the MHRA. The Company's subsidiary, LVL, owns an MHRA conditionally approved cannabis trial using cannabis based medicinal products to treat chronic pain in the UK.

For further information please visit our website www.celadonpharma.com

This announcement contains inside information for the purposes of article 7 of the Market Abuse Regulation (EU) 596/2014 as amended by regulation 11 of the Market Abuse (Amendment) (EU Exit) Regulations 2019/310. With the publication of this announcement, this information is now considered to be in the public domain.

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