

0001104659-24-1315476-K CASI Pharmaceuticals, Inc. 2024122620241226083016083016083016 0 0001104659-24-131547 6-K 1 20241226 20241226 20241226 CASI Pharmaceuticals, Inc. 0001962738 2834 000000000 E9 1231 6-K 34 001-41666 241576532 1701-1702, CHINA CENTRAL OFFICE TOWER 1 NO. 81 JIANGUO ROAD, CHAOYANG DISTRICT BEIJING F4 100025 86 10 6561 8789 1701-1702, CHINA CENTRAL OFFICE TOWER 1 NO. 81 JIANGUO ROAD, CHAOYANG DISTRICT BEIJING F4 100025 CASI Pharmaceuticals Holdings, Inc. 20230118 6-K 1 tm2431957d1_6k.htm FORM 6-K Â Â Â UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 Â FormÂ 6-K Â REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934 Â For the month of December, 2024 Â Commission File Number 001-41666 Â CASI PHARMACEUTICALS, INC. (Translation of registrantâ€™s name into English) Â 1701-1702, China Central Office Tower 1 No. 81 Jianguo Road, Chaoyang District Beijing, 100025 Peopleâ€™s Republic of China (Address of principal executive office) Â Â Indicate by check mark whether the registrant files or will file annual reports under cover FormÂ 20-F or FormÂ 40-F.Â FormÂ 20-FÂ Â xÂ FormÂ 40-FÂ Â Â Â Â Â Â Â CASI Pharmaceuticals Announces Clinical Hold of CID-103 for Antibody Mediated Rejection (AMR) of Kidney Transplant Â On December 26, 2024, CASI Pharmaceuticals, Inc., a Cayman Islands incorporated company (â€™CASIâ€™ or the â€™Companyâ€™) announced that the Company was informed via a teleconference with the FDA that CID-103, anti-CD38 antibody, Investigational New Drug (IND) for the treatment of AMR has been placed on clinical hold. FDA plans to provide a formal written response before the statutory deadline. The CID-103 IND application supporting a phase 1-2 study of CID-103 in adults with chronic Immune Thrombocytopenia (ITP) remains open and accrual to the study is expected to commence in Q1 2025. Â Forward-Looking Statements Â This 6-K contains forward-looking statements. These statements are made under the â€™safe harborâ€™ provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as â€™willâ€™, â€™expectsâ€™, â€™anticipatesâ€™, â€™futureâ€™, â€™intendsâ€™, â€™plansâ€™, â€™believesâ€™, â€™estimatesâ€™, â€™confidentâ€™ and similar statements. The Company may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the â€™SECâ€™), in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about the Companyâ€™s beliefs and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. A number of factors could cause actual results to differ materially from those contained in any forward-looking statement. All information provided herein is as of the date of this 6-K, and the Company undertakes no obligation to update any forward-looking statement, except as required under applicable law. We caution readers not to place undue reliance on any forward-looking statements contained herein. Â Â Â Â INCORPORATION BY REFERENCE Â The information included in this Report on Form 6-K is hereby incorporated by reference into the Company's Registration Statement[s] onÂ Form F-3Â (File No. 333-283998 [and File No. 333-281621]) (including any prospectuses forming a part of such registration statement[s]) and to be a part thereof from the date on which this Report on Form 6-K is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Â Â Â Â SIGNATURES Â Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized. Â Â CASI Pharmaceuticals, Inc. Â Â Â By: /s/ Wei-Wu He Â Name: Wei-Wu He Â Title: Chairman & CEO Â Â Date: December 26, 2024 Â Â Â Â Â