

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On April 8, 2025, Outlook Therapeutics, Inc. announced that the U.S. Food and Drug Administration (the “FDA”) had acknowledged receipt of its resubmission of the Biologics License Application (the “BLA”) for ONS-5010 (bevacizumab-vikg). The FDA determined that the BLA is a Class 2 review, which results in a six-month review period from the date of resubmission. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of August 27, 2025.

SIGNATURES

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 hereunto duly authorized.

Outlook Therapeutics, Inc.

Date: April 8, 2025

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Financial Officer and Interim Chief Executive Officer
