UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 28, 2024

Outlook Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37759**	**38-3982704**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

111 S. Wood Avenue, Unit #100 **Iselin, New Jersey**	**08830**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(609) 619-3990**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock	OTLK	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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 May 28, 2024, Outlook Therapeutics, Inc. ("Outlook") announced that the European Commission has granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma), an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) in the European Union (EU). LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU.

The application for European Commission Marketing Authorization of LYTENAVA™ (bevacizumab gamma) is a mixed application grounded on Article 8.3 of Directive 2001/83/EC and is based on the results from Outlook's wet AMD clinical program, which consists of three completed registration clinical trials – NORSE ONE, NORSE TWO and NORSE THREE – as well as studies and peer reviewed literature substituting or supporting certain tests and studies. This decision applies automatically in all 27 EU Member States and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, the Marketing Authorization grants Outlook an initial ten years of market exclusivity in the EU for LYTENAVA™ (bevacizumab gamma).

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: May 28, 2024

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer