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):
November 19, 2026

NEONC TECHNOLOGIES HOLDINGS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-42567	**92-1954864**
(Commission File Number)	(IRS Employer Identification No.)
23975 Park Sorrento, Suite 205 Calabasas, CA	**91302**
(Address of Principal Executive Offices)	(Zip Code)

(818) 570-6844
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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 (*see* General Instruction A.2. below):

☐ 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 registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value $0.0001	NTHI	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01. Regulation FD Disclosure.

On November 19, 2026, NeOnc Technologies Holdings, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has rescheduled the Company's End-of-Phase 1 Type B meeting concerning oral NEO212 from the previously announced date of November 17, 2026, to Monday, November 23, 2026. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 24, 2026, the Company issued a press release announcing that it met with the FDA on November 23, 2026, and reached agreement on the design of a single randomized, controlled study of oral NEO212 intended to support marketing approval for recurrent glioblastoma. Based on the Company's understanding of the End-of-Phase 1 Type B meeting, the FDA also agreed to an accelerated approval pathway using a planned interim analysis, with continued follow-up in the same study intended to verify clinical benefit. A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, Exhibit 99.1 and Exhibit 99.2 furnished hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 19, 2026
99.2	Press Release, dated November 24, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Dated: November 24, 2026

NeOnc Technologies Holdings, Inc.

By: /s/ Amir Heshmatpour
Name: Amir Heshmatpour
Title: Chief Executive Officer, President and Executive Chairman

Exhibit 99.1

NeOnc Technologies Announces FDA Rescheduled NEO212 End-of-Phase 1 Type B Meeting to November 23

Meeting will address Phase 2 study design and potential regulatory pathways for oral NEO212

CALABASAS, Calif., Nov. 19, 2026 -- NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) ("NeOnc" or the "Company"), a clinical-stage biopharmaceutical company developing therapies for central nervous system (CNS) cancers, today announced that the U.S. Food and Drug Administration (FDA) has rescheduled the Company's End-of-Phase 1 Type B meeting concerning oral NEO212 from the previously announced date of November 17, 2026, to Monday, November 23, 2026.

At the meeting, NeOnc intends to seek FDA feedback on its NEO212 clinical development program, including the proposed patient population, trial design, endpoints and dose selection for the Phase 2 portions of the NEO212-01 trial, as well as potential regulatory pathways for NEO212. The meeting provides an opportunity for discussion; its scheduling does not establish FDA agreement on a trial design or eventual approval of NEO212.

The meeting follows completion of the Phase 1 dose-escalation portion of the NEO212-01 Phase 1/2 clinical trial. NeOnc previously reported that dose escalation was discontinued following a dose-limiting toxicity at 810 mg, administered once daily on Days 1 through 5 of a 28-day cycle, and that 610 mg was selected as the recommended Phase 2 dose. In September 2025, FDA authorized the Company to proceed with the Phase 2a and Phase 2b portions of NEO212-01.

NeOnc has also reported encouraging clinical activity observed during the Phase 1 portion of the trial. In one patient with recurrent IDH1 wild-type, MGMT-methylated glioblastoma (GBM), treatment with NEO212 resulted in a partial response, including an approximately 60% reduction in tumor size, followed by prolonged disease control lasting 21 treatment months. In a second patient with lung cancer metastatic to the brain who had previously received and progressed following multiple lines of therapy, including immune checkpoint inhibitors, treatment with NEO212 was associated with stable disease lasting approximately 16 months. While these individual patient outcomes do not establish efficacy and require confirmation in larger studies, they provide the clinical rationale for further evaluation of NEO212 in the Phase 2 portions of the NEO212-01 trial.

"We believe the durable activity NEO212 showed in Phase 1, together with a well-defined recommended Phase 2 dose, gives us a compelling foundation for the next stage of development," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "We look forward to discussing our Phase 2 plans with the FDA as we work to advance NEO212 for patients with CNS cancers who urgently need new options."

Management anticipates hosting an investor webinar following issuance and receipt of the FDA's official meeting minutes to discuss the Agency's feedback and the Company's anticipated next steps for the NEO212 development program. The Company expects to announce the webinar date, time and registration details separately.

About NEO212

NEO212 is an investigational oral conjugate of temozolomide and NEO100. It is being studied for CNS cancers, including recurrent glioblastoma. Preclinical studies support further evaluation of its potential activity and delivery characteristics; clinical efficacy and safety have not been established. NEO212 is being developed under an FDA investigational new drug application.

About NeOnc Technologies Holdings, Inc.

NeOnc Technologies Holdings, Inc. is a clinical-stage biopharmaceutical company developing therapies for central nervous system cancers. Its investigational programs include intranasal NEO100 and oral NEO212. NEO212 has completed Phase 1 dose escalation and is advancing toward Phase 2 development. NeOnc exclusively licenses a worldwide portfolio of issued patents and pending applications from the University of Southern California related to NEO100, NEO212 and other drug candidates and delivery approaches. For more information, visit https://neonc.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the anticipated date and format of the FDA meeting, the topics to be discussed, issuance and receipt of the FDA's official meeting minutes, the anticipated investor webinar and its timing, future clinical trial design, potential regulatory pathways, the Company's clinical development programs and the clinical potential of NEO212. These statements reflect current expectations and involve risks and uncertainties. NEO212 is investigational and has not been approved by any regulatory authority. The scheduling of the FDA meeting does not establish FDA agreement on a development plan or eventual approval of NEO212. FDA feedback may differ from the Company's proposals; the meeting may be rescheduled or its format changed; issuance of the FDA's official meeting minutes may be delayed and the anticipated investor webinar may be delayed or may not occur; additional clinical, nonclinical or manufacturing work may be required; future studies may not demonstrate safety or efficacy; clinical development remains subject to applicable clinical, regulatory and institutional requirements; and no regulatory pathway or marketing approval is assured. The individual patient outcomes described in this release do not establish efficacy and require confirmation in larger studies. The Company will require substantial additional capital to fund its operations, which may not be available on acceptable terms or at all. Actual results may differ materially. Readers should consider the risk factors described in the Company's most recent filings with the Securities and Exchange Commission. These statements speak only as of the date of this release. The Company undertakes no obligation to update forward-looking statements except as required by law.

"NEO100" and "NEO212" are registered trademarks of NeOnc Technologies Holdings, Inc.

Contacts

Company Contact
info@neonc.com

Investor Contact
Jon Nugent
Jon Nugent Communications
jon@jonnugent.com
205-566-3026

Exhibit 99.2

NeOnc Announces FDA Agreement on Single Study Design and Accelerated Approval Pathway for NEO212

Interim analysis could support earlier marketing approval in recurrent glioblastoma, with continued follow-up in the same study intended to confirm clinical benefit

CALABASAS, Calif., November 24, 2026 -- NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) ("NeOnc" or the "Company"), a clinical-stage biopharmaceutical company developing therapies for central nervous system (CNS) cancers, today announced that it met with the U.S. Food and Drug Administration (FDA) on November 23, 2026, and reached agreement on the design of a single randomized, controlled study of oral NEO212 intended to support marketing approval for recurrent glioblastoma. Based on the Company's understanding of the End-of-Phase 1 Type B meeting, FDA also agreed to an accelerated approval pathway using a planned interim analysis, with continued follow-up in the same study intended to verify clinical benefit. The Company's summary of the meeting remains subject to the FDA's official meeting minutes.

The planned interim analysis would evaluate tumor response and duration of response to support a potential application for accelerated approval. This approach could allow NEO212 to reach patients sooner than waiting for the study's final clinical benefit results, provided the interim data are sufficient and FDA grants approval. Longer-term follow-up in the same study is intended to confirm clinical benefit. Study design agreement does not constitute approval of NEO212, and approval remains dependent on adequate safety and efficacy data and satisfaction of applicable FDA requirements.

"This meeting represents an important step toward our goal of bringing NEO212 to patients with recurrent glioblastoma," said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer of NeOnc. "Agreement on a single study design and an accelerated approval pathway gives us a clearer development plan. If the interim results meet FDA requirements, we could seek earlier marketing approval while continuing the same study to confirm clinical benefit. Our focus now is on advancing the program and executing the study with the rigor patients deserve."

Management anticipates hosting an investor webinar after the FDA's official meeting minutes are issued to discuss the Agency's feedback, the study design and the Company's next steps for NEO212. The Company expects to announce the webinar date, time and registration details separately.

About NEO212

NEO212 is an investigational oral conjugate of temozolomide and NEO100. It is being studied for CNS cancers, including recurrent glioblastoma. Preclinical studies support further evaluation of its potential activity and delivery characteristics; clinical efficacy and safety have not been established. NEO212 is being developed under an FDA investigational new drug application.

About NeOnc Technologies Holdings, Inc.

NeOnc Technologies Holdings, Inc. is a clinical-stage biopharmaceutical company developing therapies for central nervous system cancers. Its investigational programs include intranasal NEO100 and oral NEO212. NEO212 has completed Phase 1 dose escalation and is advancing toward Phase 2 development. NeOnc exclusively licenses a worldwide portfolio of issued patents and pending applications from the University of Southern California related to NEO100, NEO212 and other drug candidates and delivery approaches. For more information, visit https://neonc.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the planned NEO212 study and its ability to support accelerated approval and verify clinical benefit; the timing and results of interim and final analyses; the potential for earlier patient access and marketing approval; protocol finalization and study initiation; issuance and receipt of the FDA's official meeting minutes; the anticipated investor webinar and its timing; and the Company's clinical development programs and the clinical potential of NEO212. These statements reflect current expectations and involve risks and uncertainties. NEO212 is investigational and has not been approved by any regulatory authority. Agreement on a study design or potential regulatory pathway does not constitute marketing approval or guarantee that a future application will be accepted or approved. The Company's account of the meeting reflects its understanding pending receipt of the FDA's official meeting minutes; those minutes may clarify or differ from that understanding. Additional clinical, nonclinical, dose-optimization or manufacturing work may be required; study designs and regulatory requirements may change; future studies may not demonstrate adequate safety or efficacy; and clinical development remains subject to applicable clinical, regulatory and institutional requirements. Accelerated approval, if granted, would be subject to requirements to verify clinical benefit, and failure to verify benefit could result in withdrawal of approval. Issuance of meeting minutes and the anticipated investor webinar may be delayed, and the webinar may not occur. The Company will require substantial additional capital to fund its operations, which may not be available on acceptable terms or at all. Actual results may differ materially. Readers should consider the risk factors described in the Company's most recent filings with the Securities and Exchange Commission. These statements speak only as of the date of this release. The Company undertakes no obligation to update forward-looking statements except as required by law.

"NEO100" and "NEO212" are registered trademarks of NeOnc Technologies Holdings, Inc.

Contacts

Company Contact
info@neonc.com

Investor Contact
Jon Nugent
Jon Nugent Communications
jon@jonnugent.com
205-566-3026