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): January 7, 2026

BridgeBio Oncology Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-41955	39-3690783
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

256 E. Grand Avenue, Suite 104
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

(650) 405-4770
(Telephone number, including area code, of agent for service)

(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:

☐ 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 Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	BBOT	The Nasdaq Global Market

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 January 7, 2026, BridgeBio Oncology Therapeutics, Inc. (the "Company") issued a press release titled "*BBOT Announces New Clinical Data Advancing Its Portfolio of Three Innovative and Differentiated RAS and PI3Kα Pipeline Programs*." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated January 7, 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 thereunto duly authorized.

BRIDGEBIO ONCOLOGY THERAPEUTICS, INC.

Date: January 7, 2026

By: /s/ Eli Wallace
Name: Eli Wallace
Title: Chief Executive Officer

BBOT Announces New Clinical Data Advancing Its Portfolio of Three Innovative and Differentiated RAS and PI3Ka Pipeline Programs

- BBO-8520 monotherapy in patients with *KRAS^{G12C}* non-small cell lung cancer (NSCLC) showed a 65% objective response rate (ORR) and a 66% 6-month progression-free survival (PFS), with 83% of patients eligible for 6-month follow-up remaining on treatment for ≥6 months, alongside a potentially differentiated safety profile. Encouraging early efficacy signals were seen in patients with *KRAS^{G12C}* and *STK11* and/or *KEAP1* co-mutants, where all five initial patients achieved partial response.
- BBO-8520 in combination with pembrolizumab, at active dose levels, demonstrated promising efficacy data and a distinct, differentiated safety profile. A favorable liver safety profile was observed compared with pembrolizumab monotherapy.
- BBO-11818 monotherapy demonstrated a partial response (PR) in pancreatic cancer and anti-tumor activity was observed across dose levels and tumor types with tumor reductions at higher dose levels with a generally favorable, differentiated safety profile in dose escalation.
- BBO-10203 demonstrated a potentially differentiated safety profile without any observed events of hyperglycemia and without any enrollment restrictions on baseline HbA1c and glucose levels; combination studies with standard-of-care (SOC) treatments in colorectal cancer (CRC) and breast cancer (BC) have been initiated; internal combination studies with BBO-8520 and BBO-11818 are anticipated to open this year.
- Company webcast to be held today at 8:30 a.m. Eastern Time (ET).

SOUTH SAN FRANCISCO, Calif., January 7, 2026 — BridgeBio Oncology Therapeutics, Inc. (“BBOT”) (Nasdaq: BBOT), a clinical-stage biopharmaceutical company focused on RAS-pathway malignancies, today announced positive preliminary safety and antitumor data across its three orally bioavailable, differentiated small molecule RAS and PI3Ka programs. The data updates include BBO-8520, a direct inhibitor targeting both the ON and OFF states of KRAS^{G12C}; BBO-11818, a panKRAS inhibitor targeting mutant KRAS in both the ON and OFF states, and BBO-10203, a RAS-PI3Ka breaker with a novel mechanism of action designed to inhibit the physical interaction between RAS and PI3Ka.

“Today’s data underscore the strength of our differentiated precision oncology portfolio targeting RAS and PI3Ka,” said Eli Wallace, PhD, Chief Executive Officer of BBOT. “By focusing on ON biology and leveraging strong chemistry, we are developing highly selective therapies designed to be better tolerated and, as a result, deliver greater anti-tumor activity. We are pleased to see our strategy now being validated clinically. Our differentiated product candidates can be combined both with one another—such as our selective KRAS ON/OFF inhibitors and our potentially first-in-class RAS:PI3Ka breaker—and with standard-of-care therapies, positioning BBOT to enable powerful dual-pathway targeting and improve outcomes for patients with aggressive cancers.”

"BBO-8520 continues to demonstrate a favorable benefit-risk profile, with encouraging efficacy data, a generally tolerable safety profile, and a potentially differentiated liver toxicity profile, both as monotherapy and in combination with pembrolizumab," said Yong (Ben) Ben, MD, Chief Medical and Development Officer of BBOT. "Similarly, BBO-11818 has also demonstrated favorable tolerability and early signs of efficacy. Notably this data announcement includes the first publicly disclosed monotherapy panKRAS inhibitor response in a patient with pretreated pancreatic ductal adenocarcinoma (PDAC)."

Dr. Ben continued, "Across all BBO-10203 cohorts, the safety profile appears differentiated relative to previously reported data with other PI3Ka kinase inhibitors and demonstrated no hyperglycemia of any grade, even without any restrictions on HbA1c status and glucose level at baseline. We have identified a recommended go-forward dose of 500 mg and have initiated combination cohorts, which represent the primary development opportunity for this asset."

"Patients with *KRAS^{G12C}* mutant NSCLC face a clear unmet need, as durable and well-tolerated treatment options remain limited," said Ben Solomon, MBBS, FRACP, PhD, medical oncologist at the Peter MacCallum Cancer Centre in Melbourne, Australia, and an ONKORAS-101 principal investigator. "With immunotherapy widely used, safety and tolerability in combination are critical. The BBO-8520 monotherapy and combination data are compelling, demonstrating meaningful anti-tumor activity with a safety profile well suited for combination therapy. These results highlight BBO-8520's potential to become an important front-line combination partner with pembrolizumab."

BBO-8520 (Direct KRAS^{G12C} ON/OFF)

ONKORAS-101 (NCT06343402) is an open-label, multi-center Phase 1a/1b study designed to evaluate the safety, tolerability, preliminary antitumor activity, and pharmacokinetics of BBO-8520 as a single agent and in combination with pembrolizumab in patients with *KRAS^{G12C}* mutant NSCLC. Patients have been enrolled across doses ranging from 100 mg to 700 mg once daily (QD).

BBO-8520 Key Findings

- As of November 15, 2025, a 65% (11/17) objective response rate (ORR) was observed in NSCLC patients with a *KRAS^{G12C}* mutation across all dose levels, including 10 partial responses (PRs) and one complete response (CR). Responses appear durable with a 6-month progression-free survival (PFS) of 66% and with 83% of patients remaining on study for ≥6 months.
- In this interim readout, BBO-8520 demonstrated a generally well-tolerated and manageable monotherapy safety profile with a meaningfully differentiated liver toxicity profile.
    - No dose-limiting toxicities (DLTs); no grade ≥4 treatment-related adverse events (TRAEs); no treatment-related serious adverse events (TRSAEs). Nausea, vomiting, and diarrhea were the most common TRAEs.

- BBO-8520 was generally well tolerated in combination with pembrolizumab from 200 mg to 500 mg. A favorable liver safety profile was observed compared to pembrolizumab monotherapy.
- Each efficacy evaluable patient treated with BBO-8520 in combination with pembrolizumab (n=8) experienced a tumor reduction regardless of PD-L1 status, and 3 out of 3 front-line patients and 2 out of 5 patients previously treated with $KRAS^{G12C}$ inhibitor(s) achieved partial response.
- Encouraging early efficacy signals were seen in patients with *$KRAS^{G12C}$* and *STK11* and/or *KEAP1* co-mutants, where all five initial patients achieved PR.

BBO-8520 Upcoming Catalysts

- BBOT plans to provide additional data updates, including additional pembrolizumab combination efficacy and safety data, in the second half of 2026.
- Combination studies with BBO-10203 are expected to open later in 2026.

BBO-11818 (Direct panKRAS ON/OFF)

KONQUER-101 (NCT06917079) is evaluating the safety and preliminary antitumor activity of BBO-11818, a panKRAS inhibitor, in heavily pretreated subjects with locally advanced unresectable or metastatic *KRAS* mutant solid tumors. Patients have been enrolled across dose levels ranging from 50 mg to 800 mg on a twice daily schedule (BID). Monotherapy dose escalation is ongoing and monotherapy expansions and combination cohorts are planned.

BBO-11818 Key Findings

- As of December 10, 2025, BBO-11818 demonstrated encouraging early anti-tumor activity across dose levels and tumor types including a PR in a patient with pancreatic ductal adenocarcinoma (PDAC) with a 44% tumor reduction as well as tumor reductions at higher dose levels.
- BBO-11818 monotherapy treatment (n=13) appeared generally tolerable with no DLTs. TRAEs were largely gastrointestinal-related.
- BBO-11818 demonstrated approximately dose-proportional exposure with 600 mg BID covering *G12D* and *G12V* mutant alleles.

BBO-11818 Upcoming Catalysts

- BBOT plans to provide additional data updates, including additional monotherapy and combination efficacy and safety data, in the second half of 2026.
- Combination studies with BBO-10203 are expected to open later in 2026.

BBO-10203 (RAS:PI3K*a *Breaker)

BREAKER-101 (NCT06625775) is a multicenter, open-label, Phase 1a/1b study evaluating the safety, tolerability, pharmacokinetics (PK), and preliminary antitumor activity of BBO-10203 as monotherapy and in combination with trastuzumab, fulvestrant ± ribociclib, or FOLFOX + bevacizumab in patients with locally advanced or metastatic HER2+ breast cancer (BC), HR+/HER2- BC, *KRAS* mutant colorectal cancer (CRC), and *KRAS* mutant NSCLC.

In the monotherapy portion of the study, 24 patients, most of whom were heavily pretreated CRC patients, were enrolled across dose levels from 150 mg to 750 mg QD. Based on safety, PK and target engagement, the 500 mg QD dose has been selected as the recommended dose for expansion, and combination studies with standard-of-care treatments in CRC and BC have been initiated.

BBO-10203 Key Findings

- As of December 10, 2025, the BBO-10203 safety profile has demonstrated the potential to be highly differentiated compared to previously reported data on other PI3Ka-targeting agents.
  - No DLTs.
  - No grade ≥3 TRAEs except for one incidence of asymptomatic hypokalemia (lab abnormality); no dose reductions; no TRSAEs.
  - Without restrictions on baseline enrollment HbA1c status or glucose levels, no hyperglycemia of any grade was observed, consistent with preclinical findings.
- BBO-10203 achieved target systemic exposure and rapid full target engagement.
- Clinical benefit was observed in patients with CRC (>80% 3L+) and HR+ BC who were previously heavily treated and tumor reductions were observed in some patients.

BBO-10203 Upcoming Catalysts

- BBOT plans to provide additional data updates, which will include combination data in HER2+ BC, HR+/HER2- *PIK3CA* mutant BC and *KRAS* mutant CRC, in the second half of 2026.
- Combination studies with BBO-8520 and BBO-11818 are expected to open later in 2026.

Company Webcast

BBOT will host a company webcast on Wednesday, January 7, 2026, at 8:30 am Eastern Time to discuss the data updates for BBO-8520, BBO-11818, and BBO-10203. To participate in the live webcast, participants may register in advance here. A live webcast of the call will be available on the Investors section of BBOT's website at https://investors.bbotx.com/news-events/events. Following the live webcast, a replay will be available on the company's website for at least 90 days**.**

About BBOT

BBOT is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small molecule therapeutics targeting RAS and PI3Ka malignancies. BBOT has the goal of improving outcomes for patients with cancers driven by the two most prevalent oncogenes in human tumors. For more information, please visit **www.bbotx.com** and follow us on **LinkedIn**.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements in this press release that are not historical facts may be deemed forward-looking statements, which generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements, including express or implied statements relating to the clinical and therapeutic potential of our product candidates, including as monotherapy or in combination with other therapeutics, our plans to continue and expand our clinical trials, our anticipated data readouts, and the timing of these events, are based on the information currently available to us and various assumptions we have made, whether or not identified in this press release, and are the current expectations of BBOT’s management and are not predictions of actual performance. Many actual events and circumstances are beyond the control of BBOT. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; initial and interim data from BBOT’s clinical trials not being indicative of final data; the design and success of ongoing and planned clinical trials; adverse events that may be encountered in BBOT’s clinical trials; risks related to the approval of BBOT’s product candidates and the timing of expected regulatory and business milestones, including the progress of enrollment in clinical trials and availability of data from ongoing and planned clinical trials; the impact of competitive products; risks relating to BBOT’s ability to obtain sufficient supply of materials; and those factors discussed in documents BBOT has filed or will file with the U.S. Securities and Exchange Commission.

In addition, forward-looking statements reflect BBOT's expectations, plans, or forecasts of future events and views as of the date of this press release and are qualified in their entirety by reference to the cautionary statements herein. BBOT anticipates that subsequent events and developments will cause BBOT's assessments to change. These forward-looking statements should not be relied upon as any guarantee, assurance, prediction or definitive statement of fact or probability or as representing BBOT's assessments as of any date subsequent to the date of this press release. Neither BBOT, nor its affiliates undertake any obligation to update these forward-looking statements, except as required by law.

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