The 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): December 13, 2023

BLACK DIAMOND THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39200**	**81-4254660**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

One Main Street, 14th Floor **Cambridge, Massachusetts**	**02141**
(Address of Principal Executive Offices)	(Zip Code)

(617) 252-0848
(Registrant's telephone number, including area code)

Not Applicable
(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 to 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, $0.0001 par value per share	BDTX	The Nasdaq Global Select 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 7.01. Regulation FD Disclosure.

On December 13, 2023, Black Diamond Therapeutics, Inc. (the "Company") issued a press release titled "Black Diamond Announces Topline Results from Phase 1 Dose Escalation Trial of BDTX-1535 in Patients with Recurrent GBM." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and 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 they be deemed incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On December 13, 2023, the Company announced topline results from the dose escalation portion of the Phase 1 clinical trial of BDTX-1535 in patients with recurrent glioblastoma ("GBM") who expressed epidermal growth factor receptor ("EGFR") alterations at the time of their initial diagnosis.

Phase 1 Dose Escalation Clinical Trial Topline Results in Patients with Recurrent GBM

Clinical data as of November 2023 reflect 27 patients with recurrent GBM who received a range of doses spanning 15 mg to 400 mg once daily ("QD") in the dose escalation cohort. No new safety signals were observed, and adverse events were consistent with the EGFR tyrosine kinase inhibitor class of drugs, including primarily Grade 1 and 2 diarrhea and rash. Patients with non-small cell lung cancer dosed at 100 mg QD or greater demonstrated confirmed partial responses in lung lesions and central nervous system metastases.

Key enrollment and inclusion factors:

- Of the 27 patients with recurrent GBM, 22 were started at or escalated to a dose of 100 mg QD or greater and reached at least one post baseline tumor assessment.
- Patients were heavily pretreated, with a median of two prior lines of therapy (range of one to four). All patients except one had received prior temozolomide. Other prior treatments included chemotherapy, bevacizumab, checkpoint inhibitors or investigational agents.
- Patients were required to have EGFR alterations at the time of diagnosis, but EGFR status was not known at time of treatment with BDTX-1535 as biopsies are not commonly performed for recurrent disease.

Key results:

- Of the 22 patients evaluable for efficacy, three patients were on therapy longer than ten months, one patient longer than six months, and five patients longer than four months. Historical progression-free survival in this population is in the range of two to four months.
- The patient on therapy the longest remains on BDTX-1535 at 100 mg QD for over fifteen months with prolonged disease stabilization. This patient had previously progressed after three months of temozolomide treatment.
- Of the 19 patients with measurable disease by Response Assessment in Neuro-Oncology criteria, one patient achieved a confirmed partial response and eight patients experienced stable disease. The patient with the confirmed partial response stayed on treatment for longer than four months at 200 mg QD.

The Company plans to submit results from the dose escalation GBM cohort for presentation at a medical meeting in the second quarter of 2024.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward looking statements. Such statements include, but are not limited to, the continued development and advancement of BDTX-1535, including the Phase 1 clinical trial and the expected timing for presentation of the full BDTX-1535 dose escalation data in GBM, and the potential of BDTX-1535 to benefit patients with GBM in an earlier line of treatment. In some cases, you can identify forward-looking statements by terminology such as "believe," "estimate," "intend," "may," "plan," "potentially," "will," "expect," "enable," "likely" or the negative of these terms or other similar expressions. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include those risks and uncertainties set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the United States Securities and Exchange Commission and in its subsequent filings filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Black Diamond Therapeutics, Inc., dated December 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

BLACK DIAMOND THERAPEUTICS, INC.

Date: December 13, 2023

By: /s/ Brent Hatzis-Schoch
Name: Brent Hatzis-Schoch
Title: Chief Operating Officer and General Counsel

Exhibit 99.1

Black Diamond Therapeutics Announces Topline Results from Phase 1 Dose Escalation Trial of BDTX-1535 in Patients with Recurrent GBM

Initial results show promising clinical activity in heavily pretreated patients

22 patients evaluable for efficacy: 3 patients on therapy longer than 10 months, 1 patient longer than 6 months, and 5 patients longer than 4 months

19 patients with measurable disease by RANO criteria: 1 patient with confirmed partial response and 8 patients with stable disease

BDTX-1535 generally well tolerated, consistent with prior disclosures and no new safety signals observed

"Window of opportunity" trial enrolling patients to assess PK in brain tissue

CAMBRIDGE, Mass., December 13, 2023 (GLOBE NEWSWIRE) – Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with genetically defined cancers, today announced topline results from the dose escalation portion of the Phase 1 clinical trial of BDTX-1535 in patients with recurrent glioblastoma (GBM) who expressed epidermal growth factor receptor (EGFR) alterations at the time of their initial diagnosis. BDTX-1535, a fourth-generation, brain-penetrant, covalent EGFR inhibitor, is under investigation in a Phase 1 clinical trial for the treatment of patients with non-small cell lung cancer (NSCLC) or GBM.

"These initial results in patients with recurrent GBM are encouraging, as there are no approved therapies available for those who progress following initial treatment, and there is strong rationale for a brain penetrant, covalent EGFR inhibitor such as BDTX-1535 to have a meaningful impact in earlier lines of therapy," said Patrick Wen, M.D., Director of The Center for Neuro-Oncology at Dana-Farber Cancer Institute.

Clinical data as of November 2023 reflect 27 patients with recurrent GBM who received a range of doses spanning 15mg to 400mg once daily (QD) in the dose escalation cohort. Combined pharmacokinetic (PK) and safety data from these 27 patients with GBM and 27 patients with NSCLC were previously presented on October 14, 2023 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. No new safety signals were observed; adverse events were consistent with the EGFR tyrosine kinase inhibitor (TKIs) class of drugs, including primarily Grade 1 and 2 diarrhea and rash. Patients with NSCLC dosed at 100mg QD or greater demonstrated confirmed partial responses in lung lesions and CNS metastases.

Key enrollment and inclusion factors

- Of the 27 patients with recurrent GBM, 22 were started at or escalated to a dose of 100mg QD or greater and reached at least one post baseline tumor assessment.
- Patients were heavily pretreated, with a median of 2 prior lines of therapy (range 1-4). All patients except one had received prior temozolomide. Other prior treatments included chemotherapy, bevacizumab, checkpoint inhibitors or investigational agents.
- Patients were required to have EGFR alterations at the time of diagnosis, but EGFR status was not known at time of treatment with BDTX-1535 as biopsies are not commonly performed for recurrent disease.

Key results

- Of the *22* patients evaluable for efficacy, 3 patients were on therapy longer than 10 months, 1 patient longer than 6 months, and 5 patients longer than 4 months. Historical progression-free survival (PFS) in this population is in the range of 2-4 months.
- The patient on therapy the longest remains on BDTX-1535 at 100mg QD for over 15 months with prolonged disease stabilization. This patient had previously progressed after 3 months of temozolomide treatment.
- Of the 19 patients with measurable disease by Response Assessment in Neuro-Oncology (RANO) criteria, 1 patient achieved a confirmed partial response (PR) and 8 patients experienced stable disease (SD). The patient with the PR stayed on treatment for longer than 4 months at 200 mg QD.

Black Diamond plans to submit results from the dose escalation GBM cohort for presentation at a medical meeting in the second quarter of 2024. Enrollment is ongoing in a "window of opportunity" clinical trial of BDTX-1535 in second-line patients with high-grade glioma. The trial (NCT06072586) is sponsored by the Ivy Brain Tumor Center in Phoenix, Arizona and is enrolling patients prior to a planned resection in order to assess PK and pharmacodynamics (PD) in brain tissue. Patients achieving adequate drug levels in the gadolinium non-enhancing regions of the tumor will continue with treatment following surgery. The trial will enroll up to 22 patients, and clinical data is expected in the second quarter of 2024.

"We believe the 'window of opportunity' trial of BDTX-1535 will provide valuable information on both drug levels in the brain and clinical activity in second-line patients, and will inform potential next steps in our development program," said Sergey Yurasov, M.D., Ph.D., Chief Medical Officer of Black Diamond Therapeutics. "More than half of all newly diagnosed GBM patients express an altered form of EGFR, and preclinical data demonstrate BDTX-1535 potently inhibits this spectrum of alterations. Therefore, BDTX-1535 may be optimally suited to benefit first-line patients."

About BDTX-1535

BDTX-1535 is an oral, brain-penetrant MasterKey inhibitor of oncogenic epidermal growth factor receptor (EGFR) mutation in non-small cell lung cancer (NSCLC), including families of non-classical driver mutations (e.g., L747P, L718Q), acquired resistance C797S mutation, and complex mutations. BDTX-1535 is a fourth generation TKI that potently inhibits, based on preclinical data, more than 50 oncogenic EGFR mutations expressed across a diverse group of patients with NSCLC in multiple lines of therapy. Based on preclinical data, BDTX-1535 also inhibits EGFR extracellular domain mutations and alterations commonly expressed in glioblastoma (GBM) and avoids paradoxical activation observed with earlier generation reversible TKIs. Dose escalation of BDTX-1535 in patients with GBM is complete and dose expansion is currently ongoing in patients with NSCLC (NCT05256290).

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage oncology company focused on the development of MasterKey therapies that address families of oncogenic mutations in clinically validated targets. The Company's MasterKey therapies are designed to address broad genetically defined patient populations, overcome resistance, minimize wild-type mediated toxicities, and be brain-penetrant to treat CNS disease. The Company is advancing two clinical stage programs: BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR mutant NSCLC and GBM, and BDTX-4933, a brain penetrant RAF MasterKey inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors. For more information, please visit www.blackdiamondtherapeutics.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the continued development and advancement of BDTX-1535, including the Phase 1 clinical trial, the expected timing for clinical updates on data from the "window of opportunity" clinical trial of BDTX-1535 in recurrent GBM patients and presentation of the full BDTX-1535 dose escalation data in GBM, and the potential of BDTX-1535 to benefit patients with GBM in an earlier line of treatment. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the United States Securities and Exchange Commission and in its subsequent filings filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contacts

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