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 9, 2024

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, MA 02142
(Address of principal executive offices, including 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 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	Trade 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 2.02. Results of Operations and Financial Condition.

On May 9, 2024, Black Diamond Therapeutics, Inc. announced its financial results for the three months ended March 31, 2024. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) 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 issued by Black Diamond Therapeutics, Inc., dated May 9, 2024.

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: May 9, 2024

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

Black Diamond Therapeutics Reports First Quarter 2024 Financial Results and Provides Corporate Update

- *Initial Phase 2 data of BDTX-1535 in 2L/3L EGFRm NSCLC patients on track for Q3 2024*
- *Enrollment ongoing in Phase 2 trial of BDTX-1535 in 1L patients with non-classical EGFRm NSCLC; initial data expected Q1 2025*
- *Presented real world evidence on the evolving EGFR mutation landscape in NSCLC, and the potential of BDTX-1535 across multiple lines of therapy at the 2024 AACR annual meeting*
- *Poster presentations upcoming June 1st at 2024 ASCO Annual Meeting on BDTX-1535 in GBM patients: Phase 1 dose-escalation data and initial "window of opportunity" trial results*
- *Cash, cash equivalents, and investments of $115.2 million as of March 31, 2024, expected to be sufficient to fund operations into Q3 of 2025*

CAMBRIDGE, MA, *May 9, 2024* (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 cancer, today reported financial results for the first quarter ended March 31, 2024, and provided a corporate update.

"We reached an important inflection in BDTX-1535 development this past quarter, as we initiated dosing of patients with non-classical EGFR mutant NSCLC in the first-line setting, and are on track to release initial results from the ongoing Phase 2 second/third-line cohorts in the third quarter of this year ", said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "Our recent AACR presentation on the evolving EGFR mutation landscape highlights the major unmet need in EGFR mutant NSCLC, and the differentiated BDTX-1535 profile as the potential first- and best-in-class fourth-generation oral TKI in clinical development addressing the full spectrum of classical, non-classical, and C797S resistance mutations in NSCLC."

Recent Developments & Upcoming Milestones:

BDTX-1535:

- Following receipt of End of Phase 1 feedback from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023, Black Diamond initiated dosing of a Phase 2 first-line cohort in patients with non-classical epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC) during the first quarter of 2024. (NCT05256290)
- In April 2024, Black Diamond described real world evidence of the evolving EGFR mutation landscape in patients with NSCLC and the potential of BDTX-1535 to address a broader range of mutations compared to existing therapies at the 2024 American Association for Cancer Research (AACR) annual meeting. The oral presentation titled "BDTX-1535 – A MasterKey EGFR Inhibitor Targeting Classical, Non-Classical and the C797S Resistance Mutation to Address the Evolved Landscape of EGFR Mutant NSCLC," evaluated more than 235,000 sequenced cases of NSCLC sourced from Guardant Health (GuardantINFORM™) and Foundation Medicine (FoundationInsights™). The analyses revealed a broad spectrum of non-classical mutations, as well as an increased prevalence of the acquired resistance mutation, C797S. These non-classical EGFR mutations were present in 20-30% of newly diagnosed EGFRm NSCLC patients.

- Black Diamond anticipates the following upcoming key milestones for BDTX-1535:
  - Poster presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2024, of Phase 1 dose escalation data in patients with relapsed/recurrent GBM, and initial intratumoral pharmacokinetic results from a "window of opportunity" (also known as a Phase 0/1 "Trigger") trial sponsored by the Ivy Brain Tumor Center, in patients with recurrent high-grade glioma (HGG).
  - Disclosure of initial Phase 2 data in 2L/3L EGFRm NSCLC patients with non-classical mutations or the acquired resistance C797S mutation remains on track for Q3 2024.

BDTX-4933:

- Enrollment of patients with BRAF and select RAS/MAPK mutation-positive cancers, with an emphasis on patients with KRAS mutant NSCLC is ongoing in a Phase 1 dose escalation trial of BDTX-4933, a brain-penetrant oral inhibitor of oncogenic alterations in KRAS, NRAS and BRAF (NCT05786924). An update from this trial is anticipated in Q4 2024.

Corporate

- In April 2024, the Company announced changes to its Board of Directors. Industry veterans Shannon Campbell and Prakash Raman, Ph.D., have been appointed to the Company's Board of Directors. In addition, Wendy Dixon, Ph.D., and Alex Mayweg, Ph.D., have stepped down as members of the Board of Directors.

Financial Highlights

- **Cash Position:** Black Diamond ended the first quarter of 2024 with approximately $115.2 million in cash, cash equivalents, and investments compared to $131.4 million as of December 31, 2023. Net cash used in operations was $21.2 million for the first quarter of 2024 compared to $20.0 million for the first quarter of 2023.
- **Research and Development Expenses:** Research and development (R&D) expenses were $13.5 million for the first quarter of 2024, compared to $14.8 million for the same period in 2023. The decrease in R&D expenses was primarily due to reduced spending on early discovery projects.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $6.7 million for the first quarter of 2024, compared to $6.8 million for the same period in 2023. The decrease in G&A expenses was primarily due to a decrease in personnel related costs and legal and other professional fees.
- **Net Loss:** Net loss for the first quarter of 2024 was $18.2 million, as compared to $20.9 million for the same period in 2023.

Financial Guidance

- Black Diamond ended the first quarter of 2024 with approximately $115.2 million in cash, cash equivalents and investments which the Company believes is sufficient to fund its anticipated operating expenses and capital expenditure requirements into the third quarter of 2025.

About Black Diamond Therapeutics

Black Diamond Therapeutics is a clinical-stage oncology company developing MasterKey therapies that target families of oncogenic mutations in patients with cancer. The Company's MasterKey therapies are designed to address a broad spectrum of genetically defined tumors, 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 potential of BDTX-1535 to address the full spectrum of EGFR mutations in NSCLC, the continued development and advancement of BDTX-1535 and BDTX-4933, including the ongoing clinical trials and the timing of clinical updates for BDTX-1535 in patients with NSCLC and in patients with recurrent GBM, and for Phase 1 clinical trial results for BDTX-4933, the expected timing for additional updates on data from the “window of opportunity” clinical trial of BDTX-1535 in patients with recurrent HGG, the potential of BDTX-1535 to benefit patients with NSCLC across multiple lines of therapy, potential future development plans for BDTX-1535 in NSCLC and GBM, including in treatment naïve and recurrent settings, and the Company’s expected cash runway. 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, 2023, 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.

Black Diamond Therapeutics, Inc.

Condensed Consolidated Balance Sheet Data (Unaudited)

(in thousands)

	March 31, 2024	December 31, 2023
	(in thousands)	
Cash, cash equivalents, and investments	$ 115,199	$ 131,400
Total assets	$ 142,521	$ 158,567
Accumulated deficit	$ (435,656)	$ (417,431)
Total stockholders' equity	$ 104,306	$ 116,736

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 13,545	$ 14,753
General and administrative	6,701	6,808
Total operating expenses	20,246	21,561
Loss from operations	(20,246)	(21,561)
Other income (expense):		
Interest income	637	622
Other income (expense)	1,384	64
Total other income (expense), net	2,021	686
Net loss	$ (18,225)	$ (20,875)
Net loss per share, basic and diluted	$ (0.35)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	51,808,849	36,483,878

Contact

For Investors:
Mario Corso, Head of Investor Relations, Black Diamond Therapeutics
mcorso@bdtx.com

For Media:
media@bdtx.com

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