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 5, 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 November 5, 2024, Black Diamond Therapeutics, Inc. announced its financial results for the three and nine months ended September 30, 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 November 5, 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: November 5, 2024

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

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

- *Announced encouraging initial Phase 2 data of BDTX-1535 in patients with recurrent EGFRm NSCLC with a broad spectrum of classical, non-classical, and C797S resistance mutations in September 2024*
- *Presented real-world treatment practices and patient outcomes in newly diagnosed NSCLC patients with non-classical EGFR mutations at the 2024 ESMO Congress*
- *Clinical updates of BDTX-1535 in EGFRm NSCLC and regulatory feedback expected in Q1 2025*
- *Cash, cash equivalents, and investments of $112.7 million as of September 30, 2024; expected to be sufficient to fund operations into Q2 of 2026*

CAMBRIDGE, MA, *November 5, 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 third quarter ended September 30, 2024, and provided a corporate update.

"We are focused on the advancement of BDTX-1535 for the treatment of patients with EGFRm NSCLC and look forward to providing clinical updates on our Phase 2 trial for both newly diagnosed patients and patients with relapsed/refractory EGFRm NSCLC in the first quarter of 2025," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "We also look forward to sharing feedback on a registrational path in relapsed/refractory EGFRm NSCLC following a meeting planned with the FDA in the first quarter of 2025."

Recent Developments & Upcoming Milestones:

BDTX-1535:

- In September 2024, Black Diamond announced initial Phase 2 data demonstrating encouraging clinical responses and durability of BDTX-1535 in patients with relapsed/refractory epidermal growth factor receptor (EGFR) mutant (EGFRm) non-small cell lung cancer (NSCLC). The 200 mg daily dose of BDTX-1535 was selected for pivotal development, showing robust EGFRm target coverage and a favorable tolerability profile with no new safety signals observed. A preliminary overall response rate (ORR) of 42% was seen in 19 patients with known osimertinib resistance EGFR mutations (either C797S or PACC "P-loop αC-helix compressing" mutations). Encouraging durability was noted with a duration of response (DOR) of approximately eight months or more in the first three patients who achieved a partial response (PR), while 14 of the 19 patients remained on treatment.
- In September 2024, Black Diamond presented a poster analyzing real-world treatment outcomes for newly diagnosed NSCLC patients with non-classical EGFR mutations (NCMs) at the 2024 European Society for Medical Oncology (ESMO) Congress. The analyses revealed the presence of a broad spectrum of NCMs, including PACC mutations, and allowed association with real-world treatment practices and therapeutic outcomes. Findings further demonstrated that current treatment practices for patients with NCMs are heterogenous: 36% of patients received osimertinib or afatinib and 60% of patients received chemotherapy and/or immunotherapy.

- In October 2024, the Ivy Brain Tumor Center, which is sponsoring a "window of opportunity" (also known as Phase 0/1 "Trigger") trial of BDTX-1535 in patients with recurrent high-grade glioma (HGG), presented updated study results demonstrating that BDTX-1535 effectively penetrates rarely accessible regions of glioblastoma and suppresses EGFR signaling in patient tumors at the 19th Meeting of the European Association of Neuro-Oncology. These encouraging data provide rationale for the program's expansion into newly diagnosed glioblastoma patients with EGFR aberrations.
- In the first quarter of 2025, Black Diamond expects to disclose initial Phase 2 data in first-line EGFRm NSCLC patients with non-classical mutations as well as updated Phase 2 results in the recurrent EGFRm NSCLC setting (NCT05256290) together with an update on a potential registrational path for the recurrent setting.

Corporate

- In October 2024, Black Diamond announced a corporate restructuring plan to prioritize its resources on advancing and optimizing development plans for its lead program BDTX-1535, strengthen operational efficiencies and extend the Company's expected cash runway into the second quarter of 2026. As part of the restructuring, Black Diamond also deprioritized its Phase 1 RAS/RAF inhibitor, BDTX-4933, and is actively seeking partnerships for the program.

Financial Highlights

- **Cash Position:** Black Diamond ended the third quarter of 2024 with approximately $112.7 million in cash, cash equivalents, and investments compared to $131.4 million as of December 31, 2023. Net cash used in operations was $11.3 million for the third quarter of 2024 compared to $18.4 million for the third quarter of 2023.
- **Research and Development Expenses:** Research and development (R&D) expenses were $12.9 million for the third quarter of 2024, compared to $16.2 million for the same period in 2023. The decrease in R&D expenses was primarily due to workforce efficiencies and reduced spending on early discovery projects.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $5.2 million for the third quarter of 2024, compared to $7.9 million for the same period in 2023. The decrease in G&A expenses was primarily due to a decrease in consulting and other professional fees.
- **Net Loss:** Net loss for the third quarter of 2024 was $15.6 million, as compared to $23.0 million for the same period in 2023.

Financial Guidance

- Black Diamond ended the third quarter of 2024 with approximately $112.7 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 second quarter of 2026.

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 central nervous system disease. The Company is advancing a Phase 2 NSCLC trial of BDTX-1535, a brain-penetrant fourth-generation EGFR MasterKey inhibitor targeting EGFR-mutant NSCLC and GBM. For more information, please visit www.blackdiamondtherapeutics.com.

From time to time, we may use our website or our LinkedIn profile at www.linkedin.com/company/black-diamond-therapeutics to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.blackdiamondtherapeutics.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this press release.

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 unmet medical need for newly diagnosed NSCLC patients with non-classical EGFR mutations and benefit patients with NSCLC across multiple lines of therapy, the continued development and advancement of BDTX-1535, including the ongoing clinical trials and the timing of clinical updates for BDTX-1535 in patients with NSCLC, the expected timing for regulatory feedback and the disclosure of potential registrational pathways for BDTX-1535 in NSCLC, potential partnership opportunities for BDTX-4933, the expected cost savings from the corporate restructuring plan, the potential future development plans for BDTX-1535 in NSCLC and GBM, and the Company’s expected cash runway. Any forward-looking statements in this press release 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)

	September 30, 2024	December 31, 2023
	(in thousands)	
Cash, cash equivalents, and investments	$ 112,682	$ 131,400
Total assets	$ 137,896	$ 158,567
Accumulated deficit	$ (471,122)	$ (417,431)
Total stockholders' equity	$ 97,426	$ 116,736

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 12,914	$ 16,154	$ 39,015	$ 44,061
General and administrative	5,216	7,858	21,491	21,544
Total operating expenses	18,130	24,012	60,506	65,605
Loss from operations	(18,130)	(24,012)	(60,506)	(65,605)
Other income (expense):				
Interest income	516	439	1,617	1,600
Other income (expense)	2,057	566	5,198	971
Total other income (expense), net	2,573	1,005	6,815	2,571
Net loss	$ (15,557)	$ (23,007)	$ (53,691)	$ (63,034)
Net loss per share, basic and diluted	$ (0.28)	$ (0.45)	$ (0.99)	$ (1.54)
Weighted average common shares outstanding, basic and diluted	56,507,956	50,943,155	54,498,037	41,367,347

Contact

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