Black Diamond Therapeutics Reports Second Quarter 2026 Financial Results and Provides Corporate Update

August 05, 2026

- *Presented positive Phase 2 results for silevertinib in frontline patients with non-classical EGFRm NSCLC at the 2026 ASCO Annual Meeting, including that no patients developed de novo brain metastases and that patients with baseline brain metastases achieved a CNS objective response rate of 86%*
- *The results position silevertinib as a potential best-in-class brain-penetrant EGFR inhibitor; an update on the Phase 2 trial and FDA feedback on a pivotal development path for silevertinib in frontline patients with non-classical EGFRm NSCLC are anticipated in Q4 2026*
- *Cash, cash equivalents, and investments of $110.5 million as of June 30, 2026, expected to be sufficient to fund operations into 2H of 2028*

CAMBRIDGE, Mass., Aug. 05, 2026 (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, including silevertinib, a potential best-in-class brain-penetrant epidermal growth factor receptor (EGFR) inhibitor, today reported financial results for the second quarter ended June 30, 2026, and provided a corporate update.

“Silevertinib continued to demonstrate robust clinical activity and durable responses in frontline patients with non-classical EGFR-mutant NSCLC, as presented at ASCO in May,” said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We are particularly encouraged that no patients developed de novo brain metastases and that the CNS ORR was 86% in patients with baseline brain metastases. Approximately 80% of all patients with non-classical EGFR mutations progress in the brain, and approximately 40% of patients with non-classical EGFR-mutant NSCLC present with brain metastases at diagnosis, underscoring silevertinib’s potential to address this significant unmet medical need. We look forward to engaging with the FDA and providing an update on the pivotal development path for silevertinib in frontline NSCLC in the fourth quarter.”

Recent Developments & Upcoming Milestones:

- On May 30, 2026, at the American Society of Clinical Oncology (ASCO) Annual Meeting, data were presented from the Phase 2 trial of silevertinib dosed at 200 mg once daily (QD) in 43 frontline NSCLC patients harboring a broad spectrum of EGFR non-classical mutations, including compound and P-Loop and C-Helix Compressing (PACC) mutations. As of an April 11, 2026 data cutoff date, results were as follows:
  - Objective Response Rate (ORR by RECIST 1.1), CNS ORR (ORR by RANO-BM), and Disease Control Rate (DCR) were 60%, 86% and 91%, respectively
  - Variant allele frequency reduction observed in all evaluable patients across 25 unique EGFR non-classical mutations, including PACC
  - Median duration of response had not been reached (95% CI: 7.0, NE)
  - Preliminary median progression-free survival of 15.2 months (95% CI: 10.8, NE)
  - No patients developed de novo brain metastases
  - 23 of 43 patients (53%) remained on therapy, with the longest at 23.5 months
  - No new safety signals were observed. The rate of treatment-related adverse events greater than or equal to Grade 3 was reduced to 28% following dose reduction, and patients maintained or deepened clinical responses after dose reduction.
  - Safety, pharmacokinetics, pharmacodynamics and efficacy data support a 150 mg QD dose for pivotal development
- The Company plans to provide an update on the Phase 2 trial of silevertinib in frontline patients with non-classical EGFR-mutant (EGFRm) NSCLC in the fourth quarter of 2026.
- The Company is seeking U.S. Food and Drug Administration (FDA) feedback on a pivotal development path for silevertinib in frontline patients with non-classical EGFRm NSCLC, and expects to provide an update in the fourth quarter of 2026.
- The Phase 2 trial of silevertinib in combination with temozolomide in newly diagnosed EGFRvIII+ glioblastoma (GBM) is enrolling patients in the safety lead-in portion of the study. The Company remains on track to initiate the randomized portion of the study in the fourth quarter of 2026.

Financial Highlights

- **Cash Position:** Black Diamond ended the second quarter of 2026 with approximately $110.5 million in cash, cash

equivalents, and investments compared to $128.7 million as of December 31, 2025. Net cash used in operations was $8.0 million for the second quarter of 2026 compared to net cash used in operations of $9.2 million for the second quarter of 2025.

- **Research and Development Expenses:** Research and development (R&D) expenses were $7.4 million for the second quarter of 2026, compared to $9.3 million for the same period in 2025. The decrease in R&D expenses was primarily due to the progression of our Phase 2 trial for silevertinib in NSCLC, partially offset by increased spend related to the start-up activities for the Phase 2 trial for silevertinib in GBM.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $4.7 million for the second quarter of 2026, compared to $4.1 million for the same period in 2025. The increase in G&A expenses was primarily due to an increase in IP-related costs.
- **Net Loss:** Net loss for the second quarter of 2026 was $9.9 million, as compared to a net loss of $10.6 million for the same period in 2025.

Financial Guidance

- Black Diamond ended the second quarter of 2026 with approximately $110.5 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 half of 2028.

About Silevertinib

Silevertinib is an investigational oral, covalent, brain-penetrant fourth-generation tyrosine kinase inhibitor (TKI) that selectively targets classical and more than 50 non-classical EGFR mutations in NSCLC. It is also designed to potently inhibit key EGFR alterations seen in GBM, including EGFRvIII, while avoiding the paradoxical EGFR activation reported with reversible TKIs. To date, over 200 patients with EGFRm NSCLC or EGFR-altered GBM have been treated with silevertinib.

In addition to the ongoing Phase 2 trial of silevertinib in patients with non-classical EGFRm NSCLC, the Company also initiated a randomized Phase 2 trial of silevertinib in patients with newly diagnosed EGFRvIII-positive GBM (NCT07326566) in May 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 silevertinib, an investigational 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 continued development and advancement of silevertinib, including the ongoing Phase 2 clinical trials, the timing of clinical updates for silevertinib in patients with NSCLC and in patients with GBM, and the anticipated timing of initiation of the randomized portion of the Phase 2 clinical trial in GBM, the Company's planned interactions with the FDA, including expectations regarding anticipated feedback from the FDA on a pivotal development path for silevertinib in frontline patients with non-classical EGFRm NSCLC and the timing thereof, the selection of a dose for pivotal development, the potential of silevertinib to address the unmet medical need for newly diagnosed GBM patients and newly diagnosed NSCLC patients with non-classical EGFR mutations and benefit patients with NSCLC across multiple lines of therapy, the potential future development plans for silevertinib in NSCLC and GBM, the competitive landscape and market for silevertinib or any of the Company's other current or future product candidates, including statements relating to the estimated percentage of newly diagnosed NSCLC patients with non-classical EGFR mutations and the potential addressable patient population, 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the United States Securities and Exchange Commission (the "SEC") and in its subsequent filings with the SEC. 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)

	June 30, 2026	December 31, 2025
Cash, cash equivalents, and investments	$ 110,506	$ 128,652
Total assets	$ 125,029	$ 143,010
Accumulated deficit	$ (483,681)	$ (464,740)
Total stockholders' equity	$ 96,091	$ 112,211

Black Diamond Therapeutics, Inc.

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ —	$ 70,000
Operating expenses:				
Research and development	$ 7,393	$ 9,319	$ 14,396	$ 19,825
General and administrative	4,664	4,101	8,920	9,065
Total operating expenses	12,057	13,420	23,316	28,890
Income (loss) from operations	(12,057)	(13,420)	(23,316)	41,110
Other income (expense):				
Interest income	922	1,118	1,945	1,713
Other income (expense)	1,230	1,741	2,430	3,158
Total other income (expense), net	2,152	2,859	4,375	4,871
Net income (loss)	$ (9,905)	$ (10,561)	$ (18,941)	$ 45,981
Net income (loss) per share - basic	$ (0.17)	$ (0.19)	$ (0.33)	$ 0.81
Net income (loss) per share - diluted	$ (0.17)	$ (0.19)	$ (0.33)	$ 0.80
Weighted average common shares outstanding - basic	57,367,283	56,803,450	57,300,718	56,734,010
Weighted average common shares outstanding - diluted	57,367,283	56,803,450	57,300,718	57,474,118

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