Black Diamond Therapeutics Reports Second Quarter 2025 Financial Results and Provides Corporate Update

August 07, 2025

- *Enrollment completed for the Phase 2 trial of silevertinib (BDTX-1535) in 1L patients with non-classical EGFRm NSCLC (n=43); ORR and preliminary DOR data on track for Q4 2025*
- *Exploring partnership opportunities to advance pivotal development of silevertinib in NSCLC and GBM*
- *Plan to meet with FDA regarding 1L NSCLC development path in 1H 2026, when PFS data becomes available*
- *Cash, cash equivalents, and investments of $142.8 million as of June 30, 2025; expected to be sufficient to fund operations into Q4 of 2027*

CAMBRIDGE, Mass., Aug. 07, 2025 (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 second quarter ended June 30, 2025, and provided a corporate update.

“With enrollment completed in our silevertinib Phase 2 trial for the treatment of newly diagnosed patients with EGFRm NSCLC, we look forward to sharing a clinical update in the fourth quarter of 2025,” said Mark Velleca, M.D., Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “Given the evolving competitive and regulatory landscape, we are also exploring partnership opportunities to advance silevertinib into pivotal development and bring this potential best-in-class treatment to patients as quickly as possible.”

Recent Developments & Upcoming Milestones:

Silevertinib (BDTX-1535):

- In July 2025, Black Diamond completed enrollment (n=43) in the Phase 2 trial of silevertinib in frontline non-small cell lung cancer (NSCLC) patients with non-classical EGFR mutations.
- In the fourth quarter of 2025, Black Diamond expects to disclose objective response rate (ORR) and preliminary duration of response (DOR) data from all patients (n=43) in the Phase 2 trial of silevertinib in frontline NSCLC with non-classical EGFR mutations.
- Black Diamond is exploring partnership opportunities in NSCLC and glioblastoma (GBM) to advance silevertinib into pivotal development.
- The Company plans to solicit U.S. Food and Drug Administration (FDA) feedback on a potential registrational path in frontline EGFRm NSCLC in 1H 2026, when progression free survival (PFS) data from the ongoing Phase 2 trial becomes available.

Financial Highlights

- **Cash Position:** Black Diamond ended the second quarter of 2025 with approximately $142.8 million in cash, cash equivalents, and investments compared to $98.6 million as of December 31, 2024. Net cash used in operations was $9.2 million for the second quarter of 2025 compared to net cash used in operations of $14.7 million for the second quarter of 2024.
- **Research and Development Expenses:** Research and development (R&D) expenses were $9.3 million for the second quarter of 2025, compared to $12.6 million for the same period in 2024. The decrease in R&D expenses was primarily due to workforce efficiencies and outlicensing of BDTX-4933 to increase focus on the development of silevertinib.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $4.1 million for the second quarter of 2025, compared to $9.6 million for the same period in 2024. The decrease in G&A expenses was primarily due to the restructuring announced in October 2024.
- **Net Income/Loss:** Net loss for the second quarter of 2025 was $10.6 million, as compared to a net loss of $19.9 million for the same period in 2024.

Financial Guidance

- Black Diamond ended the second quarter of 2025 with approximately $142.8 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 fourth quarter of 2027.

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 silevertinib, 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 continued development and advancement of silevertinib, including the ongoing Phase 2 clinical trial and the timing of clinical updates for silevertinib in patients with NSCLC and in patients with GBM, enrollment in the investigator sponsored Phase 0/1 clinical trial of silevertinib of newly diagnosed GBM patients with EGFR alterations, the expected timing for regulatory feedback and the disclosure of a potential registrational pathway for silevertinib in NSCLC, the potential of silevertinib 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 potential future development plans for silevertinib in NSCLC and GBM, a potential partnership for silevertinib, 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, 2024, 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)

	June 30, 2025	December 31, 2024
	(in thousands)	
Cash, cash equivalents, and investments	$ 142,829	$ 98,575
Total assets	$ 166,385	$ 122,640
Accumulated deficit	$ (441,126)	$ (487,107)
Total stockholders' equity	$ 132,610	$ 83,285

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Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
License revenue	$ —	$ —	$ 70,000	$ —
Operating expenses:				
Research and development	$ 9,319	$ 12,556	$ 19,825	$ 26,101
General and administrative	4,101	9,574	9,065	16,275
Total operating expenses	13,420	22,130	28,890	42,376
Income (loss) from operations	(13,420)	(22,130)	41,110	(42,376)

Other income (expense):				
Interest income	1,118	464	1,713	1,101
Other income (expense)	1,741	1,757	3,158	3,141
Total other income (expense), net	2,859	2,221	4,871	4,242
Net income (loss)	$ (10,561)	$ (19,909)	$ 45,981	$ (38,134)
Net income (loss) per share - basic	$ (0.19)	$ (0.36)	$ 0.81	$ (0.71)
Net income (loss) per share - diluted	$ (0.19)	$ (0.36)	$ 0.80	$ (0.71)
Weighted average common shares outstanding - basic	56,803,450	55,155,220	56,734,010	53,482,034
Weighted average common shares outstanding - diluted	56,803,450	55,155,220	57,474,118	53,482,034

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