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

August 06, 2024

- *Initial Phase 2 data of BDTX-1535 in 2L/3L patients with EGFRm NSCLC on track for later in Q3 2024*
- *On track to announce initial Phase 2 data of BDTX-1535 in 1L patients with non-classical EGFRm NSCLC in Q1 2025, and initial Phase 1 data of BDTX-4933 in KRASm NSCLC in Q4 2024*
- *Upcoming poster presentation at 2024 ESMO Congress in September, titled "Real World Evidence of Treatment Practices and Therapeutic Outcomes for Newly Diagnosed NSCLC Patients with Non-classical EGFR Mutations Demonstrates High Unmet Medical Need"*
- *Cash, cash equivalents, and investments of $123.0 million as of June 30, 2024, expected to be sufficient to fund operations into Q4 of 2025*

CAMBRIDGE, Mass., Aug. 06, 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 second quarter ended June 30, 2024, and provided a corporate update.

"We continue to execute on enrollment of patients with EGFR mutant NSCLC into second/third-line and first-line Phase 2 cohorts, and remain on track to announce initial results later in the third quarter of this year and in the first quarter of 2025, respectively", said Mark Velleca, M.D., Ph.D., Chief Executive Officer of Black Diamond Therapeutics. "We also look forward to sharing analyses of real world data at the 2024 ESMO Congress in September 2024 on treatment practices and therapeutic outcomes for newly diagnosed NSCLC patients with non-classical EGFR mutations that demonstrate a significant unmet medical need."

Recent Developments & Upcoming Milestones:

BDTX-1535:

- In April 2024, Black Diamond described real world evidence of the evolving EGFR mutation landscape in patients with non-small cell lung cancer (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 analyses revealed a spectrum of previously underappreciated 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 epidermal growth factor receptor mutation positive (EGFRm) NSCLC patients.
- In June 2024, Black Diamond presented additional data from the Phase 1 dose escalation trial of BDTX-1535 in patients with relapsed/recurrent glioblastoma (GBM), and initial intratumoral pharmacokinetic data 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), at the American Society of Clinical Oncology (ASCO) Annual Meeting. Safety and tolerability data in the Phase 1 trial were consistent with BDTX-1535 clinical data in patients with NSCLC previously presented in October 2023 at the European Organization for Research and Treatment of Cancer-National Cancer Institute-American Association for Cancer Research (AACR-NCI-EORTC) International Conference on Molecular Targets and Cancer Therapeutics. Among 19 efficacy evaluable patients, several experienced stable disease with promising durability. Results from the investigator-sponsored trial demonstrated that BDTX-1535 penetrates the blood brain barrier with clinically meaningful unbound drug concentration in gadolinium non-enhancing regions of the brain and inhibition of corresponding pharmacodynamic markers. Eight out of nine patients exceeded the pre-specified threshold for drug concentration in the brain tumor tissue and continued on study.
- Black Diamond anticipates the following upcoming key milestones for BDTX-1535:
    - 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 later in Q3 2024.
    - Disclosure of initial Phase 2 data in 1L EGFRm NSCLC patients with non-classical mutations remains on track for Q1 2025 (NCT05256290).
    - An abstract has been accepted for presentation at the 2024 European Society for Medical Oncology (ESMO) Congress titled "Real World Evidence of Treatment Practices and Therapeutic Outcomes for Newly Diagnosed NSCLC Patients with Non-classical EGFR Mutations Demonstrates High Unmet Medical Need", which will detail an analysis of Guardant Inform data on treatment outcomes for newly diagnosed NSCLC patients with tumors expressing non-classical mutations.

BDTX-4933:

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

Corporate

- Chief Business Officer & Chief Financial Officer, Fang Ni, Pharm.D, will participate in a panel discussion at the Wedbush PacGrow Healthcare Conference taking place August 13-14, 2024, in New York, NY.

Financial Highlights

- **Cash Position:** Black Diamond ended the second quarter of 2024 with approximately $123.0 million in cash, cash equivalents, and investments compared to $131.4 million as of December 31, 2023. Net cash used in operations was $14.7 million for the second quarter of 2024 compared to $14.4 million for the second quarter of 2023.
- **Research and Development Expenses:** Research and development (R&D) expenses were $12.6 million for the second quarter of 2024, compared to $13.2 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 $9.6 million for the second quarter of 2024, compared to $6.9 million for the same period in 2023. The increase in G&A expenses was primarily due to an increase in consulting and other professional fees.
- **Net Loss:** Net loss for the second quarter of 2024 was $19.9 million, as compared to $19.2 million for the same period in 2023.

Financial Guidance

- Black Diamond ended the second quarter of 2024 with approximately $123.0 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 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 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 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 relapsed/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 future development plans for BDTX-1535 in NSCLC and GBM, the estimates regarding the market opportunities for the Company's product candidates, 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)

June 30, 2024	December 31, 2023

	(in thousands)	
Cash, cash equivalents, and investments	$ 122,971	$ 131,400
Total assets	$ 149,986	$ 158,567
Accumulated deficit	$ (455,565)	$ (417,431)
Total stockholders' equity	$ 111,021	$ 116,736

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 12,556	$ 13,154	$ 26,101	$ 27,907
General and administrative	9,574	6,878	16,275	13,686
Total operating expenses	22,130	20,032	42,376	41,593
Loss from operations	(22,130)	(20,032)	(42,376)	(41,593)
Other income (expense):				
Interest income	464	539	1,101	1,161
Other income (expense)	1,757	341	3,141	405
Total other income (expense), net	2,221	880	4,242	1,566
Net loss	$ (19,909)	$ (19,152)	$ (38,134)	$ (40,027)
Net loss per share, basic and diluted	$ (0.36)	$ (0.52)	$ (0.71)	$ (1.09)
Weighted average common shares outstanding, basic and diluted	55,155,220	36,516,114	53,482,034	36,500,085

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