Black Diamond Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 08, 2022

- *Presented new data at the 34th EORTC-NCI-AACR Symposium highlighting robust preclinical anti-tumor activity of BDTX-1535 and BDTX-4933 across multiple families of oncogenic mutations while sparing wild type; both MasterKey therapies demonstrate key attributes of next generation small molecule inhibitors*
- *On track to provide a clinical update on BDTX-1535 in 2023 and to file an IND for BDTX-4933 in the first half of 2023*
- *Strengthened clinical development leadership with appointment of Melanie Morrison as Senior Vice President, Development Operations, who brings over two decades of experience in oncology drug development*
- *Cash, cash equivalents and investments of approximately $144.2 million as of September 30, 2022; expected to be sufficient to fund operations into the third quarter of 2024*

CAMBRIDGE, Mass. and NEW YORK,, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

"We continue to focus on advancement of our lead programs while leveraging our Mutation-Allostery-Pharmacology (MAP) Drug Discovery Engine for discovery of new MasterKey therapies. Our differentiated approach to precision cancer medicine research has the potential to address substantial unmet need of patients with genetically defined cancers. Our recent preclinical posters at the EORTC-NCI-AACR Symposium further demonstrate our unique approach to developing groundbreaking therapeutics that can target families of oncogenic mutations by employing protein conformation-based drug design. We are gearing up for several upcoming clinical and preclinical milestones in the year ahead, most importantly our first clinical update on the BDTX-1535 program in patients with resistant EGFR mutations in NSCLC and patients with GBM harboring EGFR alterations expected in 2023. We also look forward to submitting an IND for BDTX-4933, our brain penetrant BRAF MasterKey inhibitor, in the first half of 2023," said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "With a proprietary drug discovery engine, intelligent trial design and a growing pipeline of novel MasterKey therapies, we believe Black Diamond is well-positioned to execute across our near- and long-term goals."

Recent Developments

BDTX-1535:

- BDTX-1535 is designed to be a potent, selective, irreversible (covalent) and brain-penetrant MasterKey inhibitor of epidermal growth factor receptor (EGFR) mutations expressed in glioblastoma multiforme (GBM) and resistance mutations in non-small cell lung cancer (NSCLC), including de novo resistance and acquired resistance to third generation EGFR inhibitors. BDTX-1535 is currently being evaluated in a Phase 1 Study in GBM patients with EGFR alterations and NSCLC patients with EGFR resistance mutations and was designed using Black Diamond's proprietary MAP Drug Discovery Engine to target the common, activated conformations used by oncogenic EGFR to drive tumor cell growth in GBM and NSCLC.
- In October 2022, Black Diamond presented two posters at the 34th European Organisation for Research and Treatment of Cancer—National Cancer Institute—American Association for Cancer Research (EORTC-NCI-AACR) Symposium in Barcelona, Spain, with new preclinical data:
    - Showcasing BDTX-1535's preclinical exposure and anti-tumor activity across patient derived xenograft (PDX) and allograft models of both NSCLC and GBM;
    - Demonstrating that multiple EGFR extracellular domain alterations, which can form active covalent homodimers and result in paradoxical EGFR activation by reversible inhibitors, are blocked by the irreversible CNS penetrant inhibitor BDTX-1535;
    - Outlining features of BDTX-1535 that are believed to be essential for an effective EGFR blockade in GBM, including highly potent targeting of the family of oncogenic EGFR alterations in GBM while sparing inhibition of wild type (WT) EGFR, high CNS penetrance, and an avoidance of paradoxical activation through irreversible inhibition of oncogenic EGFR;
    - Describing the significant unmet clinical need of NSCLC patients with acquired and intrinsic resistance EGFR mutations against 3rd generation EGFR tyrosine kinase inhibitors (TKIs) which is potentially addressed by BDTX-1535 targeting activated conformations of EGFR caused by these alterations; and
    - Highlighting that BDTX-1535 is designed using Black Diamond's proprietary MAP Drug Discovery Engine to target common activated EGFR conformations in NSCLC which result from multiple classical, intrinsic, and acquired oncogenic alterations including C797S, L718Q, G724S, and S768I mutations.

- The Company remains on track to provide a clinical update on BDTX-1535 in 2023.

BDTX-4933:

- BDTX-4933 is designed to be a highly potent brain-penetrant BRAF MasterKey inhibitor against Class I, II, and III BRAF mutations, together with MAPK pathway alterations that promote activated RAF conformations, with the ability to avoid paradoxical activation. BDTX-4933 was designed using Black Diamond's proprietary MAP Drug Discovery Engine and is currently in Investigational New Drug (IND) enabling studies.
- In October 2022, Black Diamond presented a poster at the 34th EORTC-NCI-AACR Symposium highlighting preclinical data showing BDTX-4933 to be a CNS penetrant BRAF MasterKey inhibitor active against tumors that are driven by a Class I/II/III BRAF mutation, as well as by other oncogenic MAPK pathway alterations that promote constitutive RAF dimer activation. BDTX-4933 demonstrated potent, on-target inhibition of the RAF-MEK-ERK signaling pathway and anti-tumor activity in multiple preclinical models, including intracranial tumor models.
- Black Diamond expects to submit an IND application for BDTX-4933 with the U.S. Food and Drug Administration (FDA) in the first half of 2023.

Discovery-Stage Pipeline and MAP Drug Discovery Engine:

- Black Diamond continues to leverage its MAP drug discovery engine to advance its discovery-stage pipeline and anticipates progressing its fibroblast growth factor receptor (FGFR) program towards development candidate nomination in 2022, in addition to disclosing a development candidate against a new target in 2023.

Corporate:

- In October 2022, Black Diamond appointed Melanie Morrison as Senior Vice President, Development Operations, who joined the Company with over two decades of experience in clinical operations, program management, product leadership and other key development functions and in driving corporate transitions from early to late-stage development at several biopharmaceutical companies. Prior to joining Black Diamond, Ms. Morrison served as Senior Vice President, Clinical Operations and Program Management at Nuvation Bio Inc.

Financial Highlights

- **Cash Position:** Black Diamond ended the third quarter of 2022 with approximately $144.2 million in cash, cash equivalents, and investments compared to $209.8 million as of December 31, 2021. Net cash used in operations was $16.5 million for the third quarter of 2022 compared to $26.5 million for the third quarter of 2021.
- **Research and Development Expenses:** Research and development (R&D) expenses were $15.8 million for the third quarter of 2022 compared to $27.6 million for the third quarter of 2021. The decrease in R&D expenses was primarily due to reduced activities on the BDTX-189 program and reduced spending on early discovery projects.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $6.3 million for the third quarter of 2022, compared to $7.7 million for the third quarter of 2021. The decrease in G&A expenses was primarily due to a decrease in personnel and other corporate-related costs.
- **Net Loss:** Net loss for the third quarter of 2022 was $21.7 million, as compared to $35.1 million for the same period in 2021.

Financial Guidance

Following the Company's pipeline prioritization and workforce realignment announcement in April 2022, Black Diamond has extended its cash runway, which is expected to be sufficient to fund its anticipated operating expenses and expenditure requirements into the third quarter of 2024.

About Black Diamond Therapeutics, Inc.

Black Diamond Therapeutics is a precision oncology medicine company pioneering the development of novel MasterKey therapies. Black Diamond is addressing the significant unmet need for novel precision oncology therapies for patients with genetically defined cancers who have limited treatment options. Black Diamond is built upon a deep understanding of cancer genetics, onco-protein function, and drug discovery. The Company's proprietary Mutation-Allostery-Pharmacology, or MAP Drug Discovery Engine is designed to allow Black Diamond to analyze population-level genetic sequencing tumor data to predict and validate oncogenic mutations that promote cancer across tumor types as MasterKey mutations. Black Diamond discovers and develops selective MasterKey therapies against these families of oncogenic mutations. Black Diamond was founded by David M. Epstein, Ph.D., and Elizabeth Buck, Ph.D. 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 continued development and advancement of BDTX-1535 and BDTX-4933, including the ongoing Phase 1 clinical trial and the expected timing for data updates for BDTX-1535, the timing for completion of IND-enabling studies for BDTX-4933 and the timing for filing an Investigational New Drug, or IND, application for BDTX-4933, the timing and potential achievement of upcoming clinical and preclinical milestones for each program, the continued

development of the FGFR program, including plans for nominating a development candidate, in addition to plans to disclose an additional development candidate against a new target, the continued development of the MAP Drug Discovery Engine 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, 2021, 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, 2022	December 31, 2021
Cash, cash equivalents, and investments	$ 144,181	$ 209,786
Total assets	$ 180,416	$ 247,682
Accumulated deficit	$ (313,911)	$ (243,820)
Total stockholders' equity	$ 133,231	$ 195,900

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 15,847	$ 27,626	$ 49,828	$ 77,165
General and administrative	6,277	7,738	21,148	23,627
Total operating expenses	22,124	35,364	70,976	100,792
Loss from operations	(22,124)	(35,364)	(70,976)	(100,792)
Other income (expense):				
Interest income	562	776	1,354	2,876
Other (expense) income	(92)	(489)	(469)	(1,813)
Total other income (expense), net	470	287	885	1,063
Net loss	$ (21,654)	$ (35,077)	$ (70,091)	$ (99,729)
Net loss per share, basic and diluted	$ (0.60)	$ (0.97)	$ (1.93)	$ (2.76)
Weighted average common shares outstanding, basic and diluted	36,346,181	36,219,137	36,304,050	36,175,249

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