Black Diamond Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

March 17, 2022

- *IND allowed by U.S. FDA and Phase 1 study of BDTX-1535 initiated for the treatment of GBM and NSCLC including those with CNS metastases*
- *Preclinical data demonstrating the potential of MasterKey programs BDTX-1535, CNS-BRAF (BDTX-4933), and FGFR presented at AACR-NCI-EORTC (ANE) International Conference*
- *Appointed Elizabeth Montgomery as Chief People Officer, who brings nearly two decades of global human resources leadership experience in life sciences*
- *Cash, cash equivalents, and investments of $209.8 million as of December 31, 2021, expected to be sufficient to fund operations into 2024*

CAMBRIDGE, Mass. and NEW YORK, March 17, 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

“At Black Diamond, we are on a mission to expand the reach of precision cancer medicines and are pleased with the work we have accomplished in 2021 as demonstrated by the breadth of our MasterKey inhibitor pipeline,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “In the year ahead, our priorities are to execute on the Phase 1 trial of BDTX-1535 and continue to advance our pipeline using our proprietary MAP drug discovery engine as we focus on our early stage programs, including CNS-BRAF (BDTX-4933). We believe our differentiated MasterKey therapies and novel approach to targeting oncogenic mutations can bring meaningful clinical benefit to patients not adequately served by today’s approved therapies.”

Recent Developments

BDTX-1535:

- In March 2022, Black Diamond initiated the Phase 1 study of BDTX-1535 for the treatment of glioblastoma multiforme (GBM) and non-small cell lung cancer (NSCLC) including those with central nervous system (CNS) metastases, following the U.S. Food and Drug Administration (FDA)’s allowance of the investigational new drug (IND) application for the study in January 2022.
- In October 2021, the Company presented preclinical data at the ANE International Conference on Molecular Targets and Cancer Therapeutics, showing that in cell-based assays, BDTX-1535 achieved potent and selective inhibition of a range of EGFR mutations expressed in NSCLC and demonstrated a favorable brain-penetrant pharmacokinetic (PK) profile in animal models. Additionally, BDTX-1535 showed dose-dependent tumor growth inhibition and complete regression in an allograft mouse model harboring EGFR C797S acquired resistance mutation.
- The Company expects to provide a clinical update on the Phase 1 study of BDTX-1535 in the second half of 2023.

BDTX-189:

- The Company is actively enrolling patients in the safety expansion cohort of the Phase 1 study of BDTX-189 in order to inform the future development of the program.
- The Company expects to provide further guidance on the BDTX-189 program in 2022.

CNS-BRAF Program (BDTX-4933):

- Black Diamond is developing a CNS-penetrant BRAF inhibitor against a family of Class I, II, III canonical and non-canonical mutations. The Company's CNS-BRAF development candidate, BDTX-4933, is designed to be highly selective and potent, with the ability to avoid paradoxical activation.
- In October 2021, the Company presented preclinical data at the ANE International Conference for a lead compound from the BRAF program, demonstrating potent inhibition of a family of Class II/III BRAF mutations shown in cell-based assays.
- Black Diamond initiated IND-enabling studies for this program in the first quarter of 2022.

MAP Drug Discovery Engine:

- Black Diamond is continuing to develop its Mutation-Allostery-Pharmacology (MAP) Drug Discovery Engine, predicting and validating novel oncogenic mutant families from population level tumor genomics, and exploring opportunities beyond oncology and small molecules to bring therapies to underserved patients.
- In October 2021, Black Diamond shared multiple preclinical data presentations from its pipeline programs at the ANE International Conference including BDTX-1535, CNS-BRAF (BDTX-4933) and FGFR program compounds. The data showcased the potential breadth of coverage of oncogenic mutations across each program's therapeutic area in animal models. Collectively, the presentations support the promise of the MAP Drug Discovery Engine's algorithmic approach to targeting oncogenic mutations.

Corporate:

- In February 2022, Black Diamond appointed Elizabeth Montgomery as its Chief People Officer, who joined the Company with nearly two decades of expertise and experience in developing strong corporate culture at a number of life sciences organizations.

Financial Highlights

- **Cash Position:** Black Diamond ended 2021 with approximately $209.8 million in cash, cash equivalents, and investments compared to $315.1 million as of December 31, 2020. Net cash used in operations was $100.1 million for the year ended December 31, 2021 compared to $52.1 million for the year ended December 31, 2020.
- **Research and Development Expenses:** Research and development (R&D) expenses were $19.7 million for the fourth quarter of 2021, compared to $17.8 million for the same period in 2020. Research and development expenses were $96.8 million for the year ended December 31, 2021, compared to $48.2 million for the year ended December 31, 2020. The increase in R&D expenses was primarily due to an increase in headcount and increased spend across preclinical and clinical development.
- **General and Administrative Expenses:** General and administrative (G&A) expenses were $6.4 million for the fourth quarter of 2021, compared to $5.4 million for the same period in 2020, and $30.0 million for the year ended December 31, 2021, compared to $21.4 million for the year ended December 31, 2020. The increase in G&A expenses was primarily due to an increase in personnel and other corporate-related costs.
- **Net Loss:** Net loss for the fourth quarter of 2021 was $25.9 million, as compared to $22.6 million for the same period in 2020. Net loss for the year ended December 31, 2021 was $125.6 million compared to $67.3 million for the year ended December 31, 2020.

Financial Guidance

- Black Diamond ended 2021 with approximately $209.8 million in cash, cash equivalents and investments, which the Company believes is sufficient to fund its anticipated operating expenses and capital expenditure requirements into 2024.

About Black Diamond Therapeutics

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, the continued development of the BRAF program, including the timing for initiating IND-enabling studies, the continued development of the FGFR program, including plans for nominating a development candidate, the continuation of the BDTX-189 safety expansion cohort and the resulting data, 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: the success, cost, and timing of the Company's product candidate development activities and planned IND-enabling studies and clinical trials, the Company's ability to execute on its strategy, regulatory developments in the United States, the Company's ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and preclinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in its Annual Report on Form 10-K for the year ended December 31, 2020, filed with the United States Securities and Exchange Commission and in its other 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)

	December 31,	
	2021	2020
	(in thousands)	
Cash, cash equivalents, and investments	$ 209,786	$ 315,067
Total assets	$ 247,682	$ 329,670
Accumulated deficit	$ (243,820)	$ (118,224)
Total stockholders' equity (deficit)	$ 195,900	$ 307,758

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 19,664	$ 17,756	$ 96,829	$ 48,209
General and administrative	6,416	5,427	30,043	21,361
Total operating expenses	26,080	23,183	126,872	69,570
Loss from operations	(26,080)	(23,183)	(126,872)	(69,570)
Other income (expense):				
Interest expense	—	—	—	(1)
Interest income	588	1,254	3,464	4,041
Other income (expense)	(375)	(697)	(2,188)	(1,724)
Total other income (expense), net	213	557	1,276	2,316
Net loss	$ (25,867)	$ (22,626)	$ (125,596)	$ (67,254)
Net loss per share, basic and diluted	$ (0.71)	$ (0.63)	$ (3.47)	$ (2.05)
Weighted average common shares outstanding, basic and diluted	36,229,809	36,023,503	36,189,002	32,907,100

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