UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 9, 2022

BLACK DIAMOND THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

One Main Street, 14th Floor Cambridge, Massachusetts (Address of principal executive offices) 001-39200 (Commission File Number) 81-4254660 (I.R.S. Employer Identification No.) 02142 (Zip Code)

(617) 252-0848 (Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	
Title of each class	<u>Symbol(s)</u>	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	BDTX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company \boxtimes

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2022, Black Diamond Therapeutics, Inc. announced its financial results for the second quarter ended June 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits Exhibit	X.
No.	Description
<u>99.1</u>	Press Release issued by Black Diamond Therapeutics, Inc., dated August 9, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Black Diamond Therapeutics, Inc.

Date: August 9, 2022

By: /s/ Brent Hatzis-Schoch

Brent Hatzis-Schoch Chief Operating Officer and General Counsel



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

- Strengthened leadership team with appointment of Sergey Yurasov, M.D., Ph.D., as Chief Medical Officer
- Advanced MasterKey therapy pipeline with first patient dosed in Phase 1 global study of BDTX-1535, and continued INDenabling studies of BDTX-4933
- Cash, cash equivalents and investments of approximately \$160.9 million as of June 30, 2022; expected to be sufficient to fund operations into the third quarter of 2024

CAMBRIDGE, Mass. and NEW YORK, *August 9, 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 second quarter ended June 30, 2022 and provided a corporate update.

"Black Diamond is well positioned for strong clinical and discovery execution with clear scientific and operational strategies laid out across our business. We are excited to have our newly appointed Chief Medical Officer, Dr. Sergey Yurasov, on board as we continue to progress our Phase 1 global study of BDTX-1535, with the goal of sharing a clinical update in 2023," said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. "Our precision medicine approach to cancer treatment centers on our proprietary ability to identify drug families of oncogenic mutations. Our recent publication in the American Association for Cancer Research (AACR)'s journal demonstrates this by revealing previously overlooked oncogenic mutations in HER2. This is a clear example of our Mutation-Allostery-Pharmacology (MAP) discovery engine at work, supporting the value of oncogenicity prediction, biological validation, protein conformation-based drug design and MasterKey inhibitor development against mutation families. There remains an unmet need for patients with genetically defined cancers and we believe that these key facets of our scientific approach have the potential to bolster the current precision cancer medicine landscape."

Recent Developments

BDTX-1535:

- BDTX-1535 is designed to be a potent, selective, irreversible 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.
- In April 2022, the first patient was dosed in the Phase 1 study of BDTX-1535 and the Company expects to provide a clinical update on BDTX-1535 in 2023.

BDTX-4933:

- BDTX-4933 is designed to be a brain-penetrant BRAF inhibitor against families of Class I, II, and III canonical and noncanonical mutations being developed for the treatment of patients with or without brain tumors. BDTX-4933 is also designed to be highly selective and potent, with the ability to avoid paradoxical activation.
- Black Diamond expects to submit an investigational new drug (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 Discovery Engine:

- In May 2022, Black Diamond announced the publication of new computational and functional analyses, identifying 22 new oncogenic human epidermal growth factor receptor 2 (HER2) allosteric mutations that support the Mutation-Allostery-Pharmacology (MAP) discovery engine's capabilities. The paper, titled, "Computational and Functional Analyses of HER2 Mutations Revealing Allosteric Activation Mechanisms and Altered Pharmacologic Effects" by Ishiyama et al. was published online by the American Association for Cancer Research (AACR)'s Cancer Research Journal.
- 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 June 2022, Black Diamond appointed Sergey Yurasov, M.D., Ph.D., as its Chief Medical Officer, bringing over 25 years of oncology drug development experience and regulatory expertise. Dr. Yurasov joined Black Diamond from Nuvation Bio, where he served as Chief Medical Officer and spearheaded multiple clinical development programs for oncology indications and small molecule programs.

Financial Highlights

- **Cash Position:** Black Diamond ended the second quarter of 2022 with approximately \$160.9 million in cash, cash equivalents, and investments compared to \$209.8 million as of December 31, 2021. Net cash used in operations was \$18.1 million for the second quarter of 2022 compared to \$25.2 million for the second quarter of 2021.
- **Research and Development Expenses:** Research and development (R&D) expenses were \$16.2 million for the second quarter of 2022 compared to \$26.7 million for the second 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 \$7.0 million for the second quarter of 2022, compared to \$8.0 million for the second quarter of 2021.
- Net Loss: Net loss for the second quarter of 2022 was \$22.9 million, as compared to \$34.4 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 clinical-stage 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 and the timing for filing an Investigational New Drug, or IND, application for BDTX-4933, 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)

	June 30, 2022	December 31, 2021		
Cash, cash equivalents, and investments	\$ 160,890	\$	209,786	
Total assets	\$ 198,834	\$	247,682	
Accumulated deficit	\$ (292,257)	\$	(243,820)	
Total stockholders' equity	\$ 152,371	\$	195,900	

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

(in thousands, except share and per share addy								
	Three Months Ended June 30,		Six Months Ended June 30,					
		2022		2021		2022		2021
Operating expenses:								
Research and development	\$	16,195	\$	26,719	\$	33,981	\$	49,539
General and administrative		6,978		7,996		14,871		15,889
Total operating expenses		23,173		34,715		48,852		65,428
Loss from operations		(23,173)		(34,715)		(48,852)		(65,428)
Other income (expense):								
Interest income		386		948		792		2,100
Other (expense) income		(143)		(584)		(377)		(1,324)
Total other income (expense), net		243		364		415		776
Net loss	\$	(22,930)	\$	(34,351)	\$	(48,437)	\$	(64,652)
Net loss per share, basic and diluted	\$	(0.63)	\$	(0.95)	\$	(1.33)	\$	(1.79)
Weighted average common shares outstanding, basic and diluted		36,293,856		36,182,541		36,282,636		36,152,942

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