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): November 8, 2021

BLACK DIAMOND THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39200**	**81-4254660**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

One Main Street, 10th Floor
Cambridge, MA 02142
(Address of principal executive offices, including 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:

Title of each class	Trade Symbol(s)	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 ☒

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2021, Black Diamond Therapeutics, Inc. announced its financial results for the third quarter ended September 30, 2021. 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 in this 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 No.	Description
99.1	Press Release issued by Black Diamond Therapeutics, Inc., dated November 8, 2021.
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: November 8, 2021

By: /s/ Thomas Leggett
Thomas Leggett
Chief Financial Officer and Principal Financial Officer

Black Diamond Therapeutics Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- *Black Diamond continues preparation for initiation of the Phase 2 portion of MasterKey-01 study of BDTX-189 this year*
- *Pre-clinical data from BDTX-1535, BRAF, and FGFR programs presented at AACR-NCI-EORTC (ANE) International Conference*
- *Strategic partnership established with OpenEye to accelerate drug discovery efforts through cloud-based molecular dynamics technology*
- *Cash, cash equivalents, and investments of $235.0 million as of September 30, 2021, expected to be sufficient to fund operations into the second half of 2023*

CAMBRIDGE, Mass. and NEW YORK, *November 8, 2021* (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, 2021 and provided a corporate update.

“Black Diamond’s approach remains deeply rooted in our proprietary Mutation-Allostery-Pharmacology (MAP) drug discovery engine, which leverages population-level genetic sequencing that allows for the identification of novel oncogenic mutations. We are well-positioned to advance differentiated MasterKey programs across a range of oncogenic targets for patient populations with unmet need,” said David Epstein, Ph.D., President and Chief Executive Officer of Black Diamond Therapeutics. “We are excited by the continued development and advancement of our pipeline of MasterKey inhibitor programs, including the BDTX-189 MasterKey-01 study, our BDTX-1535 program with an IND filing anticipated by the first half of 2022, and our BRAF and fibroblast growth factor receptor (FGFR) programs.”

Recent Developments

BDTX-189:

- Black Diamond remains on track with preparations for initiating the Phase 2 portion of the MasterKey-01 Phase 1/2 study of BDTX-189 by the end of 2021. The Company completed the Phase 1 dose-escalation portion of the study and has selected the recommended Phase 2 dose for BDTX-189.

BDTX-1535:

- Black Diamond continues to advance BDTX-1535 through IND-enabling studies and expects to file an IND application by the first half of 2022.
- In October 2021, Black Diamond presented preclinical data for BDTX-1535 at the ANE International Conference:

- In cell-based assays, BDTX-1535 achieved potent and selective inhibition of a range of EGFR mutations expressed in glioblastoma (GBM) and non-small cell lung cancer (NSCLC), including canonical, non-canonical, and drug-resistance mutations, such as EGFR-C797S that can arise following treatment with osimertinib.
- BDTX-1535 demonstrated a favorable brain-penetrant pharmacokinetic (PK) profile in mouse, rat, and dog models.
- In a range of tumor models, including intercranial GBM models and lung cancer drug resistance models expressing the targeted EGFR mutations, BDTX-1535 showed dose-dependent tumor growth inhibition and achieved complete regression without notable impact on body weight.

Early-Stage Pipeline:

- Black Diamond continues to progress its early-stage pipeline programs designed to target cancers driven by mutations in BRAF and FGFR. The Company anticipates IND filings for both programs in 2022.
- In October 2021, Black Diamond presented pre-clinical data for both the BRAF and FGFR programs at the ANE International Conference:
  - **BRAF**:
    - The presentation described preclinical data for a lead compound from Black Diamond's BRAF program, which is designed for potency and selectivity against a spectrum of non-canonical Class II/III mutations, in addition to Class I mutations (V600E).
    - In cell-based assays, the lead compound demonstrated potent inhibition of a spectrum of Class I/II/III BRAF mutations.
    - In contrast to current-generation BRAF inhibitors, such as encorafenib and vemurafenib, treatment of cells harboring wild type BRAF (WT-BRAF) with the Black Diamond compound was not observed to lead to an increase in protein kinase RNA-like endoplasmic reticulum kinase (pERK), a signal of paradoxical activation.
    - In a BRAF-KIAA1549 fusion allograft tumor model, the lead compound exhibited dose-dependent inhibition of pERK and anti-tumor efficacy.
  - **FGFR**:
    - The presentation was illustrative of the Black Diamond approach, centered on a four-pronged optimization strategy with the goal of delivering an inhibitor that has broad coverage of FGFR2 and FGFR3 oncogenes, while sparing inhibition of FGFR1 and retaining activity against resistance mutations.
    - In cell-based assays, FGFR program compounds demonstrated potent and selective inhibition of a spectrum of FGFR2/3 oncogenic mutations, while sparing FGFR1. Additionally, FGFR program compounds demonstrated improved potency against resistance mutations.
    - In an in vivo study conducted in a UM-UC-14 (FGFR3-S249C) mouse model, FGFR program compounds demonstrated anti-tumor activity. Additionally, in mouse and rat models, FGFR program compounds did not promote hyperphosphatemia.

Corporate:

- In September 2021, Black Diamond entered into a strategic partnership with OpenEye Scientific to incorporate OpenEye's Orion® molecular design platform into Black Diamond's proprietary Mutation-Allostery-Pharmacology (MAP) drug discovery engine to help advance MasterKey inhibitor cancer therapies. OpenEye's Orion Software-as-a-Service platform enables Black Diamond to perform rapid simulations and analysis of protein motion.

Financial Highlights

- Black Diamond ended the third quarter of 2021 with $235.0 million in cash, cash equivalents, and investments compared to $315.1 million as of December 31, 2020. Net cash used in operations was $26.5 million for the third quarter of 2021 compared to $11.5 million for the third quarter of 2020.
- Research and development (R&D) expenses were $27.6 million for the third quarter of 2021 compared to $12.9 million for the third quarter of 2020. The increase in R&D expenses was primarily related to an increase in headcount and increased spend across preclinical and clinical development.
- General and administrative (G&A) expenses were $7.7 million for the third quarter of 2021 compared to $5.6 million for the third quarter of 2020. The increase in G&A expenses was primarily due to an increase in personnel and other corporate-related costs.

About Black Diamond Therapeutics, Inc.

Black Diamond Therapeutics is a precision oncology medicine company pioneering the discovery of MasterKey therapies. Black Diamond targets undrugged mutations in patients with genetically defined cancers. Black Diamond is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. The Company's proprietary technology platform and drug discovery engine, the Mutation-Allostery-Pharmacology (MAP) platform, is designed to allow Black Diamond to analyze population-level genetic sequencing data to identify oncogenic mutations that promote cancer across tumor types, group these mutations into families, and develop a single small molecule therapy that targets a specific family of mutations, termed a MasterKey therapy. 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 of BDTX-189 and the timing for initiating the Phase 2 portion of the ongoing clinical trial of BDTX-189, the continued development and advancement of BDTX-1535 in IND-enabling studies, including expectations for filing an IND, and the development of the BRAF and FGFR programs, including timing for filing INDs in each program, 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 ongoing COVID-19 pandemic will have on the Company’s clinical trials and pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in its 2020 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission and 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)

	September 30, 2021	December 31, 2020
Cash, cash equivalents, and investments	$ 235,008	$ 315,067
Total assets	$ 274,126	$ 329,670
Accumulated deficit	$ (217,953)	$ (118,224)
Total stockholders' equity	$ 218,948	$ 307,758

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 27,626	$ 12,929	$ 77,165	$ 30,453
General and administrative	7,738	5,551	23,627	15,934
Total operating expenses	35,364	18,480	100,792	46,387
Loss from operations	(35,364)	(18,480)	(100,792)	(46,387)
Other income (expense):				
Interest expense	—	—	—	(1)
Interest income	776	1,162	2,876	2,787
Other (expense) income	(489)	(594)	(1,813)	(1,027)
Total other income (expense), net	287	568	1,063	1,759
Net loss	$ (35,077)	$ (17,912)	$ (99,729)	$ (44,628)
Net loss per share, basic and diluted	$ (0.97)	$ (0.50)	$ (2.76)	$ (1.42)
Weighted average common shares outstanding, basic and diluted	36,219,137	35,927,485	36,175,249	31,860,716

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