

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED September 30, 2022
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _ TO _
COMMISSION FILE NUMBER 001-38501

BLACK DIAMOND THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	81-4254660
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Main Street, 14th Floor Cambridge, Massachusetts	02142
(Address of principal executive offices)	(Zip Code)
(617) 252-0848	
(Registrant's telephone number, including area code)	
Not Applicable	
(Former name, former address and former fiscal year, if changed since last report)	

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001	BDTX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 31, 2022, the registrant had 36,366,206 shares of common stock, \$0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Quarterly Report”), contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “could”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the progress, timing and success of preclinical studies and our clinical trials of BDTX-1535, BDTX-4933 and any other product candidates, including the availability, timing and announcement of data and results of such studies and trials;
- the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and Investigational New Drug, or IND, applications and other regulatory submissions;
- the continued development and advancement of our FGFR program and the timing for nominating a development candidate;
- our ability to obtain and maintain regulatory approval for BDTX-1535 and BDTX-4933 or any of our other current or future product candidates that we may identify or develop;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to identify future product candidates for treatment of additional disease indications;
- our ability to develop our current product candidates for the treatment of various cancers;
- the rate and degree of market acceptance and clinical utility for any current or future product candidates we may develop;
- the effects of competition with respect to BDTX-1535, BDTX-4933 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- the implementation of our strategic plans for our business, any product candidates we may develop and our Mutation-Allosteric-Pharmacology (“MAP”) drug discovery engine;
- our ability to successfully develop companion diagnostics for use with our current or future product candidates;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates and MAP drug discovery engine;
- our ability to obtain additional funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved, and to further expand our MAP drug discovery engine;
- the period over which we expect our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our future financial performance and our ability to effectively manage our anticipated growth;
- our estimates regarding the market opportunities for our product candidates, including our competitive position and the success of competing therapies that are or may become available;

- our need for and ability to attract and retain key scientific, management and other personnel and to identify, hire and retain additional qualified professionals;
- the potential for our business development efforts to maximize the value of our platform and product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- our ability to establish or maintain collaborations or strategic relationships and the ability and willingness of our third-party strategic collaborators to undertake research and development activities relating to our current or future product candidates;
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”);
- our ability to maintain an effective system of internal controls;
- the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our common stock and our ability to access capital markets; and
- the ultimate impact of the ongoing coronavirus, or COVID-19 pandemic, or any other health epidemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our clinical trials, our research programs, healthcare systems or the global economy as a whole.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, “Risk Factors” and elsewhere in our most recent Annual Report on Form 10-K for the year ended December 31, 2021 (the “Annual Report”) and in other Securities and Exchange Commission (the “SEC”) filings. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Some of these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic, including as a result of the emergence of new variants or subvariants, and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

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This Quarterly Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to this Quarterly Report. In this Quarterly Report, the terms “Black Diamond Therapeutics,” “Black Diamond,” the “Company,” “we,” “us,” “our,” and similar designations refer to Black Diamond Therapeutics, Inc. and, where appropriate, our subsidiaries.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

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We have applied for various trademarks that we use in connection with the operation of our business. This Quarterly Report may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Quarterly Report is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Quarterly Report may appear without the ®, ™ or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner of these trademarks, service marks and trade names will not assert, to the fullest extent under applicable law, its rights.

From time to time, we may use our website or our LinkedIn profile at www.linkedin.com/company/black-diamond-therapeutics to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.blackdiamondtherapeutics.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this Quarterly Report.

Part I - FINANCIAL INFORMATION**Item I. Condensed Consolidated Financial Statements (Unaudited)**

Black Diamond Therapeutics, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of	
	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,960	\$ 65,799
Investments	90,221	143,987
Prepaid expenses and other current assets	6,797	5,917
Total current assets	150,978	215,703
Property and equipment, net	2,731	3,035
Restricted cash	1,168	1,223
Right-of-use assets	25,539	27,705
Other non-current assets	—	16
Total assets	<u>\$ 180,416</u>	<u>\$ 247,682</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,760	\$ 4,107
Accrued expenses and other current liabilities	15,383	19,535
Total current liabilities	21,143	23,642
Non-current operating lease liabilities	26,042	28,140
Total liabilities	47,185	51,782
Commitments and contingencies (Note 10)	—	—
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock; \$0.0001 par value; 500,000,000 shares authorized at September 30, 2022 and December 31, 2021; 36,366,206 shares issued and outstanding at September 30, 2022 and 36,234,624 shares issued and outstanding at December 31, 2021	5	5
Additional paid-in capital	449,625	440,129
Accumulated other comprehensive loss	(2,488)	(414)
Accumulated deficit	(313,911)	(243,820)
Total stockholders' equity	133,231	195,900
Total liabilities and stockholders' equity	<u>\$ 180,416</u>	<u>\$ 247,682</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (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
Comprehensive loss:				
Net loss	\$ (21,654)	\$ (35,077)	\$ (70,091)	\$ (99,729)
Other comprehensive income:				
Change in unrealized loss on investments	(202)	(68)	(2,074)	(471)
Comprehensive loss	\$ (21,856)	\$ (35,145)	\$ (72,165)	\$ (100,200)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (70,091)	\$ (99,729)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	9,291	10,661
Depreciation expense	382	82
Amortization of premium on investments	456	1,814
Noncash rent expense	2,049	1,331
Other non-cash items	—	(15)
Loss on disposal of property and equipment	8	3
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	(880)	(2,163)
Other non-current assets	16	7
Accounts payable	1,653	2,263
Accrued expenses and other current liabilities	(3,929)	10,692
Non-current operating lease liabilities	(2,098)	(1,048)
Net cash used in operating activities	<u>(63,143)</u>	<u>(76,102)</u>
Cash flows from investing activities:		
Purchases of equipment	(192)	(2,377)
Proceeds from sales and maturities of investments	87,690	134,331
Purchases of investments	(36,454)	(44,583)
Net cash provided by investing activities	<u>51,044</u>	<u>87,371</u>
Cash flows from financing activities:		
Proceeds from exercise of common stock options and ESPP	205	729
Net cash provided by financing activities	<u>205</u>	<u>729</u>
Net (decrease) increase in cash and cash equivalents	(11,894)	11,998
Cash, cash equivalents and restricted cash, beginning of period	67,022	35,828
Cash, cash equivalents and restricted cash, end of period	<u>\$ 55,128</u>	<u>\$ 47,826</u>
Cash and cash equivalents, end of period	\$ 53,960	\$ 46,603
Restricted cash, end of period	1,168	1,223
Cash, cash equivalents and restricted cash, end of period	<u>\$ 55,128</u>	<u>\$ 47,826</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of equipment included in accounts payable and accrued expenses	\$ —	\$ 216
Right-of-use assets obtained in exchange for operating lease obligation	\$ (117)	\$ 21,484
Right-of-use asset derecognized upon early lease termination	\$ —	\$ 476

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Par Value				
BALANCE - December 31, 2020	36,078,383	\$ 5	\$ 425,363	\$ 614	\$ (118,224)	\$ 307,758
Exercise of common stock options	62,607	—	481	—	—	481
Vesting of restricted stock units	4,998	—	—	—	—	—
Stock-based compensation	1,224	—	3,094	—	—	3,094
Unrealized loss on investments	—	—	—	(279)	—	(279)
Net loss	—	—	—	—	(30,301)	(30,301)
BALANCE - March 31, 2021	36,147,212	5	428,938	335	(148,525)	280,753
Exercise of common stock options	48,014	—	184	—	—	184
Vesting of restricted stock units	8,331	—	—	—	—	—
Stock-based compensation	2,269	—	4,558	—	—	4,558
Unrealized loss on investments	—	—	—	(124)	—	(124)
Net loss	—	—	—	—	(34,351)	(34,351)
BALANCE - June 30, 2021	36,205,826	5	433,680	211	(182,876)	251,020
Vesting of restricted stock units	13,673	—	—	—	—	—
Issuance of common stock related to ESPP	6,162	—	64	—	—	64
Stock-based compensation	3,195	—	3,009	—	—	3,009
Unrealized loss on investments	—	—	—	(68)	—	(68)
Net loss	—	—	—	—	(35,077)	(35,077)
BALANCE - September 30, 2021	<u>\$36,228,856</u>	<u>\$ 5</u>	<u>\$ 436,753</u>	<u>\$ 143</u>	<u>\$ (217,953)</u>	<u>\$ 218,948</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Par Value				
BALANCE - December 31, 2021	36,234,624	\$ 5	\$ 440,129	\$ (414)	\$ (243,820)	\$ 195,900
Exercise of common stock options	3,565	—	11	—	—	11
Vesting of restricted stock units	5,000	—	—	—	—	—
Issuance of common stock related to ESPP	31,341	—	142	—	—	142
Stock-based compensation	13,038	—	3,375	—	—	3,375
Unrealized loss on investments	—	—	—	(1,361)	—	(1,361)
Net loss	—	—	—	—	(25,507)	(25,507)
BALANCE - March 31, 2022	36,287,568	5	443,657	(1,775)	(269,327)	172,560
Vesting of restricted stock units	3,333	—	—	—	—	—
Stock-based compensation	24,836	—	3,252	—	—	3,252
Unrealized loss on investments	—	—	—	(511)	—	(511)
Net loss	—	—	—	—	(22,930)	(22,930)
BALANCE - June 30, 2022	36,315,737	5	446,909	(2,286)	(292,257)	152,371
Exercise of common stock options	1,408	—	5	—	—	5
Vesting of restricted stock units	7,227	—	—	—	—	—
Issuance of common stock related to ESPP	22,321	—	47	—	—	47
Stock-based compensation	19,513	—	2,664	—	—	2,664
Unrealized loss on investments	—	—	—	(202)	—	(202)
Net loss	—	—	—	—	(21,654)	(21,654)
BALANCE - September 30, 2022	36,366,206	\$ 5	\$ 449,625	\$ (2,488)	\$ (313,911)	\$ 133,231

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Black Diamond Therapeutics, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(Amounts in thousands, except share and per share amounts)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Black Diamond Therapeutics, Inc. (the “Company”) is a clinical-stage precision oncology medicine company pioneering the discovery and development of MasterKey therapies. The Company was originally organized as a limited liability company in December 2014 under the name ASET Therapeutics LLC. In September 2016, the Company was converted to a corporation under the laws of the State of Delaware under the name ASET Therapeutics, Inc. The Company changed its name to Black Diamond Therapeutics, Inc. in January 2018. Since its inception, the Company has devoted substantially all of its efforts to raising capital, obtaining financing, and incurring research and development costs related to the development of its Mutation-Allostery-Pharmacology computational and drug discovery engine.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any products, if approved, will be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnological companies. In addition, the Company is dependent upon the services of its employees, consultants and service providers. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On February 1, 2021, the Company filed a shelf registration statement on Form S-3 ASR (the “Shelf”), with the Securities and Exchange Commission (the “SEC”), which covers the offering, issuance and sale of the Company’s common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Company simultaneously entered into an Open Market Sale AgreementSM with Jefferies LLC, as sales agent, to provide for the issuance and sale by the Company of up to \$150 million of its common stock from time to time through Jefferies as its sales agent (the “ATM Program”). The Shelf became automatically effective upon filing on February 1, 2021. As of September 30, 2022, no sales have been made pursuant to the ATM Program.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Historically, the Company has funded its operations primarily with proceeds from the sale of preferred and common stock. The Company expects to continue to generate operating losses for the foreseeable future.

As of November 8, 2022, the issuance date of the condensed consolidated financial statements, the Company expects that its cash, cash equivalents and investments will be sufficient to fund its currently planned operations for at least the next 12 months from the filing date of these unaudited interim condensed consolidated financial statements.

The Company may seek additional funding through private or public equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The ongoing COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, and other public health safety measures.

The Company has been closely monitoring the impact of the ongoing COVID-19 pandemic on all aspects of the Company's business, including how it has impacted and may continue to impact the Company's operations and the operations of its suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, the Company has taken steps to minimize the current environment's impact on its business and strategy, including devising contingency plans and securing additional resources from third party service providers. Furthermore, for the safety of the Company's employees and families, the Company has introduced enhanced safety measures for scientists to be present in its labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. Certain of the Company's third party service providers have also experienced shutdowns or other business disruptions.

The extent to which COVID-19 ultimately impacts the Company's business, results of operations or financial condition will depend on future developments, which, despite progress in vaccination efforts, remain highly uncertain and cannot be predicted with confidence, such as the duration of the ongoing COVID-19 pandemic, new strains of the virus, including any future variants or subvariants that may emerge, which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines, new information that may emerge concerning the severity of COVID-19, and any additional preventative and protective actions taken to contain the pandemic or treat its impact, among others. The Company does not yet know the full extent of potential delays or impacts on the Company's business, clinical trials, research programs, healthcare systems or the global economy and cannot presently predict the scope and severity of any potential business shutdowns or disruptions but if the Company or any of the third parties with whom it engages were to experience prolonged business shutdowns or other disruptions, the Company's ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on the Company's business, results of operations and financial condition. The estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following is a summary of significant accounting policies followed in the preparation of these condensed consolidated financial statements.

Principles of consolidation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries, Black Diamond Therapeutics (Canada), Inc. and Black Diamond Therapeutics Security Corporation, after elimination of all significant intercompany accounts and transactions.

Unaudited interim financial information

The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this Quarterly Report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report. In the opinion of the Company's management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results for the interim periods presented have been included.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

The full extent to which the ongoing COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered the impact of COVID-19 on estimates within its financial statements and there may be changes to those estimates in future periods. As of the date of issuance of these condensed consolidated financial statements, the Company has not experienced material business disruptions or incurred impairment losses in the carrying value of its assets as a result of the pandemic and is not aware of any specific related event or circumstance that would require it to update its estimates.

Recently issued accounting pronouncements

The Company believes that no recently issued accounting standards will have a material impact on its condensed consolidated financial statements, or apply to its operations.

3. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair value measurements at September 30, 2022 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 51,898	\$ —	\$ —	\$ 51,898
Investments:				
Commercial paper	—	4,998	—	4,998
Corporate bonds	—	46,438	—	46,438
U.S. Government agencies	—	38,785	—	38,785
Total	\$ 51,898	\$ 90,221	\$ —	\$ 142,119

	Fair value measurements at December 31, 2021 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 63,730	\$ —	\$ —	\$ 63,730
Investments:				
Corporate bonds	—	104,066	—	104,066
U.S. Government agencies	—	39,921	—	39,921
Total	\$ 63,730	\$ 143,987	\$ —	\$ 207,717

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

There were no transfers in or out of Level 3 categories in the periods presented.

4. INVESTMENTS

As of September 30, 2022, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 4,999	\$ —	\$ (1)	\$ 4,998
Corporate bonds	47,581	—	(1,143)	46,438
U.S. Government agencies	40,129	—	(1,344)	38,785
Total	\$ 92,709	\$ —	\$ (2,488)	\$ 90,221

As of December 31, 2021, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate bonds	\$ 104,261	\$ 47	\$ (242)	\$ 104,066
U.S. Government agencies	40,140	—	(219)	39,921
Total	\$ 144,401	\$ 47	\$ (461)	\$ 143,987

As of September 30, 2022, all marketable securities held by the Company had remaining contractual maturities of one year or less, except for U.S. government agencies, corporate bonds and commercial paper with a fair value of \$44,587 that had maturities of one to three years.

As of December 31, 2021, all marketable securities held by the Company had remaining contractual maturities of one year or less, except for U.S. government agencies and corporate bonds with a fair value of \$86,187 that had maturities of one to three years.

As of September 30, 2022, the marketable securities in a loss position had a maturity of less than one year, except for U.S. government agencies, corporate bonds and commercial paper with a fair value of \$44,587, that had maturities of one to three years. As of December 31, 2021, the marketable securities in a loss position had a maturity of less than one year, except for U.S. government agencies and corporate bonds, with a fair value of \$86,187, that had maturities of one to three years.

As of September 30, 2022, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were temporary. In determining whether the decline in fair value of these securities was temporary, the Company evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis. There have been no impairments of the Company's assets measured and carried at fair value during the nine months ended September 30, 2022 and the year ended December 31, 2021.

5. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Laboratory equipment	\$ 792	\$ 682
Furniture and fixtures	17	17
Computer and office equipment	120	120
Leasehold improvements	2,512	2,437
Construction in process	—	148
Property and equipment	3,441	3,404
Less: accumulated depreciation	(710)	(369)
Total Property and Equipment, net	<u>\$ 2,731</u>	<u>\$ 3,035</u>

Depreciation expense for the nine months ended September 30, 2022 and 2021 was \$382 and \$82, respectively.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Contracted research services	\$ 7,755	\$ 12,192
Payroll and related expenses	3,890	5,088
Professional and consulting fees	963	1,935
Current portion of operating lease liability	2,775	320
Total accrued expenses and other current liabilities	<u>\$ 15,383</u>	<u>\$ 19,535</u>

7. STOCK-BASED COMPENSATION

2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the “2020 Plan”) was approved by the Company’s board of directors on December 5, 2019, and the Company’s stockholders on January 14, 2020 and became effective on the date immediately prior to the date on which the registration statement for the Company’s initial public offering (“IPO”) was declared effective. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company’s officers, employees, directors and consultants. The 2020 Plan provides for an annual increase, to be added on the first day of each fiscal year, by up to 4% of the Company’s outstanding shares of common stock as of the last day of the prior year. On January 1, 2022, 1,449,384 shares of common stock, representing 4% of the Company’s outstanding shares of common stock as of December 31, 2021, were added to the 2020 Plan.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the “2020 ESPP”) was approved by the Company’s board of directors on December 5, 2019, and the Company’s stockholders on January 14, 2020, and became effective on the date immediately prior to the date on which the registration statement for the Company’s IPO was declared effective. The 2020 ESPP provides for an annual increase, to be added on the first day of each fiscal year, by up to 1% of the number of shares of the Company’s common stock outstanding on the immediately preceding December 31. The number of authorized shares reserved for issuance under the 2020 ESPP was increased by 326,364 shares effective as of January 1, 2022.

Stock-based compensation expense

The Company recorded stock-based compensation expense in the following award type categories included within the condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	\$ 2,481	\$ 2,783	\$ 8,674	\$ 9,793
Restricted stock units	108	134	418	694
Employee Stock Purchase Plan and Other	75	92	199	174
	<u>\$ 2,664</u>	<u>\$ 3,009</u>	<u>\$ 9,291</u>	<u>\$ 10,661</u>

For the nine months ended September 30, 2022, the Company issued 57,387 shares of common stock out of its 2020 Plan under its policy where non-employee directors may elect to receive their compensation in the form of common stock in lieu of cash.

The Company recorded stock-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 1,201	\$ 732	\$ 4,255	\$ 4,586
General and administrative	1,463	2,277	5,036	6,075
	<u>\$ 2,664</u>	<u>\$ 3,009</u>	<u>\$ 9,291</u>	<u>\$ 10,661</u>

Options

The following table summarizes the stock option activity under the Company's equity awards plans:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Intrinsic Value (in thousands)
Outstanding December 31, 2021	4,903,839	\$ 17.38	7.6	\$ 847
Granted	1,882,450	\$ 3.33		
Exercised	(4,973)	\$ 3.20		
Cancelled or forfeited	(1,042,595)	\$ 16.16		
Outstanding September 30, 2022	5,738,721	\$ 13.00	7.8	\$ 27
Options vested or expected to vest at September 30, 2022	5,738,721	\$ 13.00	7.8	\$ 27
Options exercisable at September 30, 2022	2,650,851	\$ 15.78	6.6	\$ 27

For the nine months ended September 30, 2022, total unrecognized compensation cost related to the unvested stock-options was \$19,145, which is expected to be recognized over a weighted average period of 2.1 years.

Restricted stock units

The fair values of restricted stock units are based on the market value of the Company's stock on the date of the grant. Under terms of the time-based restricted stock agreements covering the common stock, shares of restricted common stock are subject to a vesting schedule. The following table summarizes time-based restricted stock activity since January 1, 2022:

	Number of shares	Weighted average grant date fair value
Unvested restricted common stock as of December 31, 2021	30,667	\$ 29.53
Granted	185,795	\$ 2.32
Vested	(15,560)	\$ 29.13
Cancelled or forfeited	(31,023)	\$ 4.28
Unvested restricted common stock as of September 30, 2022	169,879	\$ 4.42

The total fair value of time-based restricted stock units vested during the nine months ended September 30, 2022 was \$453.

For the nine months ended September 30, 2022, total unrecognized compensation cost related to the time-based unvested restricted stock units was \$515, which is expected to be recognized over a weighted average period of 1.2 years.

For the three months ended September 30, 2022, the Company granted no performance restricted stock units to its employees related to the achievement of certain clinical development and/or financing milestones and had 18,900 performance restricted stock units forfeited. As of September 30, 2022, the Company had 248,225 performance restricted stock units outstanding.

Recognition of stock-based compensation expense associated with performance restricted stock units commences when the performance conditions are considered probable of achievement, using management's best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

As of September 30, 2022, for performance-based restricted stock units that were outstanding, the achievement of the milestones that had not been met was considered not probable, and therefore no expense has been recognized related to these awards in the nine months ended September 30, 2022.

Employee stock purchase plan

The 2020 ESPP enables eligible employees to purchase shares of the Company's common stock at the end of each six-month offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Eligible employees generally included all employees. Offering periods begin on the first trading day of January and July of each year and end on the last trading day in June and December of each year, except for the first offering period which began on the first trading day in March and ended on the last trading day in June. Share purchases are funded through payroll deductions of up to 10% of an employee's eligible compensation for each payroll period, up to \$25 each calendar year.

During the nine months ended September 30, 2022 and 2021, there were 53,662 and 6,162 shares, respectively, issued under the 2020 ESPP.

8. NET LOSS PER SHARE

Net loss per share

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	\$ (21,654)	\$ (35,077)	\$ (70,091)	\$ (99,729)
Weighted average common shares outstanding, basic and diluted	36,346,181	36,219,137	36,304,050	36,175,249
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.97)	\$ (1.93)	\$ (2.76)

The Company's potentially dilutive securities, which include options, unvested restricted stock and warrants to purchase common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2022	2021
Options to purchase common stock	5,738,721	4,926,476
Unvested restricted stock	169,879	30,667
Shares issuable under employee stock purchase plan	48,805	24,806
Warrants to purchase common stock	10,757	10,757
	5,968,162	4,992,706

9. LEASES

The Company has historically entered into lease arrangements for its facilities. As of September 30, 2022, the Company had two operating leases with required future minimum payments. The Company determined the classification of these leases to be operating leases and recorded right-of-use assets and lease liabilities as of the effective dates. The Company's leases generally do not include termination or purchase options.

Operating leases

In July 2020, the Company entered into a seven-year agreement with an option to extend for five additional years to lease two floors totaling approximately 25,578 square feet of office space for its principal office, which is located in Cambridge, MA. The lease on the first floor commenced on August 1, 2020 and the lease on the second floor commenced March 9, 2021. The Company recognized the respective lease balances on the condensed consolidated balance sheets when the lease of each floor commenced. Under the terms of the lease, the Company was required to issue a \$1,168 letter of credit as security for the lease.

The Company previously leased an office space in Cambridge, MA under a lease that commenced in February 2019 for approximately 2,357 square feet of office space, which was set to expire on April 30, 2022, subject to an option to extend the lease for three additional years. Effective June 15, 2021, the lease was terminated, and the remaining right-of-use asset and lease liability were derecognized. A gain of \$5 was recognized for the termination of the lease.

In December 2020, the Company entered into an eleven-year agreement to lease approximately 18,120 square feet of office and laboratory space in New York, NY. The Company has an option to extend the lease for five additional years. The lease commenced August 26, 2021 and the related lease balance was recognized on the condensed consolidated balance sheet.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating lease for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Lease Cost				
Operating lease cost	\$ 1,057	\$ 900	\$ 3,173	\$ 1,975
Short-term lease cost	38	287	78	862
Variable lease cost	241	136	717	212
Total lease cost	\$ 1,336	\$ 1,323	\$ 3,968	\$ 3,049

Other Operating Lease Information	September 30, 2022	September 30, 2021
Gain on lease termination	\$ —	\$ 5
Cash paid for amounts included in the measurement of lease liability	\$ 1,884	\$ 1,860
Weighted-average remaining lease term	8.1	8.9
Weighted-average discount rate	5.3 %	5.3 %

The variable lease costs for the three and nine months ended September 30, 2022 and 2021 include common area maintenance and other operating charges. As the Company's leases do not provide an implicit rate, the Company utilized its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Future minimum lease payments under the Company's operating leases as of September 30, 2022 were as follows:

	As of September 30, 2022
2022 (excluding the nine months ended September 30, 2022)	\$ 1,051
2023	4,244
2024	4,359
2025	4,477
2026	4,599
Thereafter	16,973
Total lease payments	35,703
Less: interest	(6,886)
Total lease liability	\$ 28,817

10. COMMITMENTS AND CONTINGENCIES

The Company enters into contracts in the normal course of business with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of service providers, up to the date of cancellation.

License agreements

The Company is a party to license agreements, which include contingent payments. These payments will become payable if and when certain development, regulatory and commercial milestones are achieved. As of September 30, 2022, the satisfaction and timing of the contingent payments is uncertain and not reasonably estimable.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2022 or December 31, 2021.

Legal proceedings

The Company is not currently party to and is not aware of any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

11. BENEFIT PLANS

The Company has a tax-qualified 401(k) and Profit Sharing defined contribution plan (the “401(k) Plan”). Under the 401(k) Plan, the Company provides an employer safe harbor matching contribution equal to 100% of a participant’s eligible contributions of up to 6% of eligible compensation, subject to limits established by the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the “Code”). All matching contributions are fully vested when made. During the three and nine months ended September 30, 2022 and 2021, the Company contributed \$154, \$911, \$207 and \$772, respectively, to the 401(k) Plan.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2021, as well as Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 17, 2022. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in our Annual Report on Form 10-K and in other SEC filings.

Overview

We are a clinical-stage precision oncology medicine company pioneering the discovery and development of MasterKey therapies. We target undrugged oncogenic driver mutations in patients with genetically defined cancers. The foundation of our company is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. Our proprietary technology platform, which we refer to as our Mutation-Allostery-Pharmacology, or MAP, drug discovery engine, is designed to allow us to analyze population-level genetic sequencing data to discover oncogenic mutations that promote cancer across tumor types. Our goal is to identify families of mutations that can be inhibited with MasterKey therapies thereby providing precision oncology to greater numbers of patients with genetically defined tumors.

We have designed our product candidates to potently and selectively inhibit families of oncogenic mutations which occur across a range of tumor types. BDTX-1535, currently in the dose escalation portion of the ongoing Phase I clinical trial, was designed to inhibit oncogenic mutations in the ErbB-1 epidermal growth factor receptor (EGFR), while sparing normal, or wild type, EGFR (WT-EGFR) activity. The brain penetration properties of BDTX-1535 support the potential treatment of glioblastoma (GBM) and non-small cell lung cancer (NSCLC) patients with or without brain disease. BDTX-4933, currently in IND-enabling studies, was designed to inhibit Class I, II and III canonical and non-canonical mutations. In addition to being a highly selective and potent inhibitor, BDTX-4933 avoids paradoxical activation and is brain penetrant for the treatment of patients with or without brain disease. We are also leveraging our MAP drug discovery engine to identify other families of oncogenic mutations in validated oncogenes, which has the potential to expand the reach of MasterKey therapies. In April 2022, we announced the discontinuation of the development of BDTX-189 to focus on progressing our pipeline through important upcoming milestones for BDTX-1535 and BDTX-4933 as well as discovery efforts.

Since our inception in 2014, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights while conducting research and development activities for our programs. We do not have any products approved for sale and have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product. We have not yet successfully completed any pivotal clinical trials, obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

To date, we have funded our operations with proceeds from the sale of preferred stock and common stock. Since inception, we have incurred significant operating losses. Our net losses were \$70.1 million and \$99.7 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of \$313.9 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- advance clinical studies for BDTX-1535 and continue preclinical studies for BDTX-4933 and our other product candidates;
- continue to identify additional product candidates from our proprietary MAP drug discovery engine;
- obtain, maintain, expand and protect our intellectual property portfolio;
- attract and retain key clinical, scientific, management and commercial personnel;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any; and
- acquire or in-license additional product candidates.

As of September 30, 2022, we had cash, cash equivalents and investments of approximately \$144.2 million, which we believe will fund our operating expenses and capital expenditure requirements into the third quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and capital resources.” To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

COVID-19 considerations

The ongoing COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, and other public health safety measures.

The Company has been closely monitoring the impact of the ongoing COVID-19 pandemic on all aspects of the Company’s business, including how it has impacted and may continue to impact the Company’s operations and the operations of its suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, the Company has taken steps to minimize the current environment’s impact on its business and strategy, including devising contingency plans and securing additional resources from third party service providers. Furthermore, for the safety of the Company’s employees and families, the Company has introduced enhanced safety measures for scientists to be present in its labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. Certain of the Company’s third party service providers have also experienced shutdowns or other business disruptions.

The extent to which COVID-19 ultimately impacts the Company’s business, results of operations or financial condition will depend on future developments, which, despite progress in vaccination efforts, remain highly uncertain and cannot be predicted with confidence, such as the duration of the ongoing COVID-19 pandemic, new strains of the virus, including any future variants or subvariants that may emerge, which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines, new information that may emerge concerning the severity of COVID-19, and any additional preventative and protective actions taken to contain the pandemic or treat its impact, among others. The Company does not yet know the full extent of potential delays or impacts on the Company’s business, clinical trials, research programs, healthcare systems or the global economy and cannot presently predict the scope and severity of any potential business shutdowns or disruptions but if the Company or any of the third parties with whom it engages were to experience prolonged business shutdowns or other disruptions, the Company’s ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on the Company’s business, results of operations and financial condition. The estimates of the impact on the Company’s business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

Additionally, inflation generally affects the Company by increasing its employee-related costs and clinical trial expenses, as well as other operating expenses. The Company's financial condition and results of operations may also be impacted by other factors it may not be able to control, such as global supply chain disruptions, global trade disputes or political instability. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

Components of our results of operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and contract manufacturing organizations, or CMOs, that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under license, acquisition and option agreements. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we continue our clinical trials for BDTX-1535, as well as conduct other preclinical and clinical development, including submitting regulatory filings for other product candidates.

We expect our discovery research efforts and our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above current year levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with IND-enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the U.S. Food and Drug Administration, or the FDA, and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and administrative expenses

General and administrative expenses consist primarily of salaries and benefits, travel and stock-based compensation expense for personnel in executive, business development, finance, human resources, legal, information technology, pre-commercial and support personnel functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates and prepare for potential commercialization activities. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Other income (expense)

Other income (expense) consists primarily of interest income earned on our cash equivalents and investment balances, and realized and unrealized foreign currency transaction gains and losses.

Results of operations

Comparison of the three months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change
	2022	2021	
	(in thousands)		
Operating expenses:			
Research and development	\$ 15,847	\$ 27,626	\$ (11,779)
General and administrative	6,277	7,738	(1,461)
Total operating expenses	22,124	35,364	(13,240)
Loss from operations	(22,124)	(35,364)	13,240
Other income (expense):			
Interest income	562	776	(214)
Other (expense) income	(92)	(489)	397
Total other income (expense), net	470	287	183
Net loss	\$ (21,654)	\$ (35,077)	\$ 13,423

Research and development

Research and development expenses were \$15.8 million for the three months ended September 30, 2022, compared to \$27.6 million for the three months ended September 30, 2021. The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change
	2022	2021	
	(in thousands)		
BDTX-189 research and development expenses	\$ 1,572	\$ 7,105	\$ (5,533)
BDTX-1535 research and development expenses	2,578	2,425	153
Other research programs and platform development expenses	5,193	9,608	(4,415)
Personnel expenses	5,136	6,055	(919)
Allocated facility expenses	997	1,070	(73)
Other expenses	371	1,363	(992)
	\$ 15,847	\$ 27,626	\$ (11,779)

The decrease of \$11.8 million for the three months ended September 30, 2022 was primarily due to a decrease of \$5.5 million in spend relating to BDTX-189 associated with reduced trial activities stemming from the discontinuation of the development of BDTX-189 to focus on upcoming milestones for our pipeline programs, BDTX-1535 and BDTX-4933. In addition, we decreased spend relating to other research programs and platform development by \$4.4 million for the three months ended September 30, 2022 due to reduced spending on early discovery projects, compared to the three months ended September 30, 2021.

General and administrative

General and administrative expenses were \$6.3 million for the three months ended September 30, 2022 compared to \$7.7 million for the three months ended September 30, 2021. This was primarily a result of a decrease in personnel-related costs, legal and other professional fees.

Other income (expense)

Other income was \$0.5 million for the three months ended September 30, 2022, compared to \$0.3 million for the three months ended September 30, 2021. The increase was primarily attributable to amortization of premium on investments decreasing at a higher rate in 2022 compared to 2021 and interest income decreasing due to market conditions.

Comparison of the nine months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change
	2022	2021	
(in thousands)			
Operating expenses:			
Research and development	\$ 49,828	\$ 77,165	\$ (27,337)
General and administrative	21,148	23,627	(2,479)
Total operating expenses	70,976	100,792	(29,816)
Loss from operations	(70,976)	(100,792)	29,816
Other income (expense):			
Interest income	1,354	2,876	(1,522)
Other (expense) income	(469)	(1,813)	1,344
Total other income (expense), net	885	1,063	(178)
Net loss	\$ (70,091)	\$ (99,729)	\$ 29,638

Research and development

Research and development expenses were \$49.8 million for the nine months ended September 30, 2022, compared to \$77.2 million for the nine months ended September 30, 2021. The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change
	2022	2021	
(in thousands)			
BDTX-189 research and development expenses	\$ 6,616	\$ 22,592	\$ (15,976)
BDTX-1535 research and development expenses	5,055	4,872	183
Other research programs and platform development expenses	15,915	26,837	(10,922)
Personnel expenses	18,041	18,765	(724)
Allocated facility expenses	3,002	2,418	584
Other expenses	1,199	1,681	(482)
	\$ 49,828	\$ 77,165	\$ (27,337)

The decrease of \$27.3 million in the nine months ended September 30, 2022 was primarily due to a decrease of \$16.0 million in spend relating to BDTX-189 associated with reduced trial activities stemming from the discontinuation of the development of BDTX-189 to focus on upcoming milestones for our pipeline programs, BDTX-1535 and BDTX-4933. In addition, we decreased spend relating to other research programs and platform development by \$10.9 million for the nine months ended September 30, 2022 due to reduced spending on early discovery projects, compared to the nine months ended September 30, 2021. Facility costs increased \$0.6 million for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021 due to the signing of a new lease.

General and administrative

General and administrative expenses were \$21.1 million for the nine months ended September 30, 2022, compared to \$23.6 million for the nine months ended September 30, 2021. This was primarily a result of a decrease in personnel-related costs, legal and other professional fees.

Other income (expense)

Other income was \$0.9 million for the nine months ended September 30, 2022, compared to \$1.1 million for the nine months ended September 30, 2021. The decrease was primarily attributable to amortization of premium on investments decreasing at a higher rate in 2022 compared to 2021 and interest income decreasing due to market conditions.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from any product sales or any other sources and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations to date primarily with proceeds from the sale of preferred stock.

On February 3, 2020, we completed an IPO of 12,174,263 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,587,947 additional shares of common stock, for aggregate gross proceeds of \$231.3 million. We received \$212.1 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. Through September 30, 2022, we had received net cash proceeds of \$200.6 million from previous sales of our preferred stock and as of September 30, 2022, we had cash, cash equivalents and investments of \$144.2 million.

On February 1, 2021, we filed a shelf registration statement on Form S-3 ASR, or the Shelf, with the SEC, which covers the offering, issuance and sale of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into an Open Market Sale AgreementSM, or the Sales Agreement, with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to \$150 million of our common stock, or the Shares, from time to time through Jefferies as our sales agent, or the ATM Program. The Shelf became automatically effective upon filing on February 1, 2021. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. We may sell the Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any Shares under the Sales Agreement. We or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. As of September 30, 2022, no sales have been made pursuant to the ATM Program.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Cash used in operating activities	\$ (63,143)	\$ (76,102)
Cash provided by investing activities	51,044	87,371
Cash provided by financing activities	205	729
Net (decrease) increase in cash and cash equivalents	\$ (11,894)	\$ 11,998

Operating activities

During the nine months ended September 30, 2022, we used cash in operating activities of \$63.1 million, primarily resulting from our net loss of \$70.1 million, partially offset by the non-cash charge related to stock compensation expense of \$9.3 million.

During the nine months ended September 30, 2021, we used cash in operating activities of \$76.1 million, primarily resulting from our net loss of \$99.7 million, partially offset by the non-cash charge related to stock compensation expense of \$10.7 million and an increase in prepaid expenses and other current assets.

Changes in accounts payable and accrued expenses in all periods were generally due to growth in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Investing activities

During the nine months ended September 30, 2022, we had cash provided by investing activities of \$51.0 million primarily from the sales and maturities of investments.

During the nine months ended September 30, 2021, we had cash provided by investing activities of \$87.4 million primarily from the sales and maturities of investments.

Financing activities

During the nine months ended September 30, 2022, we had cash provided by financing activities of \$0.2 million, consisting of proceeds from exercise of stock options and participation in the employee stock purchase plan.

During the nine months ended September 30, 2021, we had cash provided by financing activities of \$0.7 million consisting of proceeds from exercise of stock options.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance BDTX-1535 through clinical trials and continue preclinical studies for BDTX-4933 and our other product candidates;
- advance preclinical development of our early stage programs, including our FGFR program, including plans for nominating a development candidate;

- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel; and
- obtain, maintain, expand and protect our intellectual property portfolio.

As of September 30, 2022, we had cash, cash equivalents and investments of \$144.2 million, which we believe will fund our operating expenses and capital expenditure requirements into the third quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the ability to receive additional non-dilutive funding;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the costs of operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, as we can generate substantial product revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties or through other sources of financing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. However, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. Similarly, adverse macroeconomic conditions and market volatility resulting from global economic developments, political unrest, high inflation, the ongoing COVID-19 pandemic or other factors could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms or at all. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all.

To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, your the ownership interest of our stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the your rights as a of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. In addition, debt financing may involve significant cash payment obligations and specific financial ratios that may restrict our ability to operate our business would result in fixed payment obligations.

If we raise additional funds through collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain capital through arrangements with collaborators on terms unfavorable to us or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

Contractual obligations and commitments

The following summarizes our contractual obligations as of September 30, 2022:

	Payments Due by Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
	(in thousands)				
Property leases - commenced	\$ 4,215	\$ 8,777	\$ 9,260	\$ 13,451	\$ 35,703
Total	\$ 4,215	\$ 8,777	\$ 9,260	\$ 13,451	\$ 35,703

Property leases – commenced

The amounts reported for property leases represent future minimum lease payments under non-cancelable operating leases in effect as of September 30, 2022. The minimum lease payments do not include common area maintenance charges or real estate taxes.

Other contractual obligations

The contractual obligations table does not include any potential future milestone payments or royalty payments we may be required to make under our existing license agreements due to the uncertainty of the occurrence of the events requiring payment under those agreements.

Critical accounting policies and significant judgments and use of estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Use of Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 17, 2022. During the nine months ended September 30, 2022, there were no material changes to our critical accounting policies from those previously disclosed.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not “opt out” of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The information required with respect to this item can be found under “Legal Proceedings” in Note 10 to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q and is incorporated by reference into this Item 1. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business, the resolution of which we do not anticipate would have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

Our business faces significant risks and uncertainties. Certain important factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to carefully consider the discussion of risk factors in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021, which could materially affect our business, financial condition or future results, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the Securities and Exchange Commission, or the SEC. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business, prospects, financial condition and results of operations. Certain statements in this Quarterly Report are forward-looking statements. Please also see the section entitled “Special Note Regarding Forward-Looking Statements.”

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from IPO of Common Stock

On February 3, 2020, we completed the IPO of our common stock pursuant to which we issued and sold 12,174,263 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,587,947 additional shares of common stock, at a public offering price of \$19.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-235789), which was declared effective by the SEC on January 29, 2020. J.P. Morgan Securities LLC, Jefferies LLC, Cowen and Company, LLC and Canaccord Genuity LLC acted as joint book-running managers of the offering and as representatives of the underwriters.

We received aggregate gross proceeds from our IPO of \$231.3 million, or aggregate net proceeds of \$212.1 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on January 30, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit No.	Exhibit Index
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

*	Filed herewith.
+	This certification will 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 liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Black Diamond Therapeutics, Inc.

Date: November 8, 2022

By: /s/ David M. Epstein

David M. Epstein
President and Chief Executive Officer
(Principal Executive Officer)

Black Diamond Therapeutics, Inc.

Date: November 8, 2022

By: /s/ Fang Ni

Fang Ni
Chief Business and Interim Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, David M. Epstein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of Black Diamond Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2022

By: /s/ David M. Epstein

David M. Epstein
President, Chief Executive Officer
and Director
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Fang Ni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of Black Diamond Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2022

By: /s/ Fang Ni
Fang Ni
Chief Business and Interim Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, David M. Epstein, the Principal Executive Officer, and Fang Ni, the Principal Financial Officer, of Black Diamond Therapeutics, Inc. (the “Company”), hereby certify, that, to their knowledge:

- (1) the Quarterly Report on Form 10-Q for the period ended September 30, 2022 (the “Report”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2022

By: /s/ David M. Epstein
David M. Epstein
President, Chief Executive Officer
and Director
(Principal Executive Officer)

Date: November 8, 2022

By: /s/ Fang Ni
Fang Ni
Chief Business and Interim Financial Officer
(Principal Financial Officer)