

**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, 2023
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 (State or other jurisdiction of incorporation or organization) One Main Street, 14th Floor Cambridge, Massachusetts (Address of principal executive offices)	81-4254660 (I.R.S. Employer Identification No.) 02142 (Zip Code)
(617) 252-0848 (Registrant's telephone number, including area code)	
Not Applicable (Former name, 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 30, 2023, the registrant had 51,635,184 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 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 trials;
- the scope, timing, progress and results of our clinical trials, development efforts and regulatory submissions;
- our ability to obtain and maintain regulatory approval for BDTX-1535 and BDTX-4933 or any of our future product candidates that we may identify or develop;
- the effects of competition with respect to BDTX-1535, BDTX-4933 or any of our future product candidates, as well as innovations by current and future competitors in our industry;
- our evaluation of strategic alternatives for BDTX-4876 and one other preclinical program, including our ability to execute and realize the anticipated benefits of any strategic alternatives we may pursue;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- 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 implementation of our strategic plans for our business, any product candidates we may develop and our Mutation-Allostery-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;
- 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; and
- 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.

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, 2022 (the Annual Report) and in other Securities and Exchange Commission (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 global health crises, 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.

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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 57,978	\$ 34,315
Investments	86,278	88,492
Prepaid expenses and other current assets	2,793	4,899
Total current assets	147,049	127,706
Property and equipment, net	1,816	2,587
Restricted cash	819	1,168
Right-of-use assets	22,698	24,794
Total assets	\$ 172,382	\$ 156,255
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 694	\$ 1,877
Accrued expenses and other current liabilities	14,372	13,384
Total current liabilities	15,066	15,261
Non-current operating lease liabilities	22,999	25,299
Total liabilities	38,065	40,560
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock; \$0.0001 par value; 500,000,000 shares authorized at September 30, 2023 and December 31, 2022; 51,635,184 shares issued and outstanding at September 30, 2023 and 36,434,297 shares issued and outstanding at December 31, 2022	7	5
Additional paid-in capital	532,697	452,503
Accumulated other comprehensive loss	(364)	(1,824)
Accumulated deficit	(398,023)	(334,989)
Total stockholders' equity	134,317	115,695
Total liabilities and stockholders' equity	\$ 172,382	\$ 156,255

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 16,154	\$ 15,847	\$ 44,061	\$ 49,828
General and administrative	7,858	6,277	21,544	21,148
Total operating expenses	24,012	22,124	65,605	70,976
Loss from operations	(24,012)	(22,124)	(65,605)	(70,976)
Other income (expense):				
Interest income	439	562	1,600	1,354
Other (expense) income	566	(92)	971	(469)
Total other income (expense), net	1,005	470	2,571	885
Net loss	\$ (23,007)	\$ (21,654)	\$ (63,034)	\$ (70,091)
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.60)	\$ (1.54)	\$ (1.93)
Weighted average common shares outstanding, basic and diluted	50,943,155	36,346,181	41,367,347	36,304,050
Comprehensive loss:				
Net loss	\$ (23,007)	\$ (21,654)	\$ (63,034)	\$ (70,091)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments, net	297	(202)	1,460	(2,074)
Comprehensive loss	\$ (22,710)	\$ (21,856)	\$ (61,574)	\$ (72,165)

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,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (63,034)	\$ (70,091)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,068	9,291
Depreciation expense	351	382
(Accretion) amortization on investments	(361)	456
Noncash rent expense	2,096	2,049
Loss on disposal of equipment	358	8
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	2,106	(880)
Other non-current assets	—	16
Accounts payable	(1,033)	1,653
Accrued expenses and other current liabilities	988	(3,929)
Non-current operating lease liabilities	(2,300)	(2,098)
Net cash used in operating activities	<u>(52,761)</u>	<u>(63,143)</u>
Cash flows from investing activities:		
Purchases of equipment	(33)	(192)
Proceeds from sale of equipment	95	—
Proceeds from sales and maturities of investments	50,136	87,690
Purchases of investments	(46,101)	(36,454)
Net cash provided by investing activities	<u>4,097</u>	<u>51,044</u>
Cash flows from financing activities:		
Proceeds from exercise of common stock options and ESPP	128	205
Proceeds from issuance of common stock, net of issuance costs	71,850	—
Net cash provided by financing activities	<u>71,978</u>	<u>205</u>
Net increase (decrease) in cash and cash equivalents	23,314	(11,894)
Cash, cash equivalents and restricted cash, beginning of period	35,483	67,022
Cash, cash equivalents and restricted cash, end of period	<u>\$ 58,797</u>	<u>\$ 55,128</u>
Cash and cash equivalents, end of period	\$ 57,978	\$ 53,960
Restricted cash, end of period	819	1,168
Cash, cash equivalents and restricted cash, end of period	<u>\$ 58,797</u>	<u>\$ 55,128</u>
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease obligation	\$ —	\$ (117)

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
	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 gain (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 gain (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 gain (loss) on investments	—	—	—	(202)	—	(202)
Net loss	—	—	—	—	(21,654)	(21,654)
BALANCE - September 30, 2022	<u>\$36,366,206</u>	<u>\$ 5</u>	<u>\$ 449,625</u>	<u>\$ (2,488)</u>	<u>\$ (313,911)</u>	<u>\$ 133,231</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, 2022	36,434,297	\$ 5	\$ 452,503	\$ (1,824)	\$ (334,989)	\$ 115,695
Vesting of restricted stock units	23,575	—	—	—	—	—
Surrender of shares for taxes	(3,903)	—	—	—	—	—
Issuance of common stock related to ESPP	33,202	—	51	—	—	51
Stock-based compensation	24,776	—	2,671	—	—	2,671
Unrealized gain (loss) on investments	—	—	—	648	—	648
Net loss	—	—	—	—	(20,875)	(20,875)
BALANCE - March 31, 2023	36,511,947	5	455,225	(1,176)	(355,864)	98,190
Vesting of restricted stock units	1,875	—	—	—	—	—
Stock-based compensation	19,703	—	2,646	—	—	2,646
Unrealized gain (loss) on investments	—	—	—	515	—	515
Net loss	—	—	—	—	(19,152)	(19,152)
BALANCE - June 30, 2023	36,533,525	5	457,871	(661)	(375,016)	82,199
Issuance of common stock, net of issuance costs	15,000,000	2	71,998	—	—	72,000
Exercise of common stock options	5,370	—	20	—	—	20
Vesting of restricted stock units	63,547	—	—	—	—	—
Surrender of shares for taxes	(14,554)	—	—	—	—	—
Issuance of common stock related to ESPP	35,803	—	57	—	—	57
Stock-based compensation	11,493	—	2,751	—	—	2,751
Unrealized gain (loss) on investments	—	—	—	297	—	297
Net loss	—	—	—	—	(23,007)	(23,007)
BALANCE - September 30, 2023	51,635,184	\$ 7	\$ 532,697	\$ (364)	\$ (398,023)	\$ 134,317

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 oncology company focused on the development of MasterKey therapies that target families of oncogenic mutations in clinically validated targets. 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 and advancement of its product candidates identified by its Mutation-Allostery-Pharmacology (MAP) drug discovery engine.

The Company is subject to risks and uncertainties common to clinical-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 November 14, 2022, the Company filed a shelf registration statement on Form S-3 (the Shelf Registration Statement), 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 up to a maximum offering price of \$500 million. The Company simultaneously entered into an Open Market Sale AgreementSM with Jefferies LLC (Jefferies), 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 (the ATM Program). The Shelf Registration Statement became effective on November 22, 2022. As of September 30, 2023, no sales have been made pursuant to the ATM Program.

On July 5, 2023, the Company completed an underwritten public offering (the Follow-on Offering) of 15,000,000 shares of the Company's common stock at a price to the public of \$5.00 per share. The aggregate net proceeds from the Follow-on Offering totaled approximately \$71.9 million, after deducting underwriting discounts and commissions, as well as other offering expenses.

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 stock and common stock. The Company expects to continue to generate operating losses for the foreseeable future.

As of November 6, 2023, 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.

The Company will 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, or reduce headcount and general and administrative costs, 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.

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 Company continues to monitor the impact of global economic developments, political unrest, high inflation, disruptions in capital markets, changes in international trade relationships and military conflicts, and health crises, on all aspects of its business, and has considered the impact of these factors on estimates within its financial statements. The extent to which future developments may impact the Company's business, results of operations or financial condition are uncertain and cannot be predicted with confidence and there may be changes to 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 these factors and is not aware of any specific related event or circumstance that would require it to update its estimates.

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, 2023 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 10,930	\$ —	\$ —	\$ 10,930
Investments:				
Commercial paper	—	34,375	—	34,375
Corporate bonds	—	33,751	—	33,751
U.S. Government agencies	—	18,152	—	18,152
Total	<u>\$ 10,930</u>	<u>\$ 86,278</u>	<u>\$ —</u>	<u>\$ 97,208</u>

	Fair value measurements at December 31, 2022 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 32,278	\$ —	\$ —	\$ 32,278
Investments:				
Commercial paper	—	3,747	—	3,747
Corporate bonds	—	45,643	—	45,643
U.S. Government agencies	—	39,102	—	39,102
Total	<u>\$ 32,278</u>	<u>\$ 88,492</u>	<u>\$ —</u>	<u>\$ 120,770</u>

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, 2023, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 34,421	\$ —	\$ (46)	\$ 34,375
Corporate bonds	33,936	—	(185)	33,751
U.S. Government agencies	18,285	—	(133)	18,152
Total	\$ 86,642	\$ —	\$ (364)	\$ 86,278

As of December 31, 2022, investments were comprised of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 3,748	\$ —	\$ (1)	\$ 3,747
Corporate bonds	46,443	—	(800)	45,643
U.S. Government agencies	40,125	—	(1,023)	39,102
Total	\$ 90,316	\$ —	\$ (1,824)	\$ 88,492

As of September 30, 2023, all marketable securities held by the Company had remaining contractual maturities of one year or less. As of September 30, 2023, all marketable securities held by the Company were in a loss position.

As of December 31, 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 \$13,687 that had maturities of one to three years. As of December 31, 2022, all marketable securities held by the Company were in a loss position.

As of September 30, 2023, the Company reviewed its investment portfolio to assess the unrealized losses on its available-for-sale investments. 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. The Company also determined no portion of the unrealized losses relate to a credit loss. There have been no impairments of the Company's assets measured and carried at fair value during the nine months ended September 30, 2023 and the year ended December 31, 2022.

5. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	September 30, 2023	December 31, 2022
Laboratory equipment	\$ —	\$ 770
Furniture and fixtures	17	17
Computer and office equipment	25	38
Leasehold improvements	2,512	2,512
Property and equipment	2,554	3,337
Less: accumulated depreciation	(738)	(750)
Total Property and Equipment, net	\$ 1,816	\$ 2,587

Depreciation expense for the nine months ended September 30, 2023 and 2022 was \$351 and \$382, respectively.

6. EQUITY METHOD INVESTMENT

In December 2022, the Company received 9,000,000 shares of common stock in a newly formed antibody-focused precision oncology company, Launchpad Therapeutics, Inc. (Launchpad), in exchange for contributing early discovery-stage antibody programs and granting Launchpad a license to use its MAP drug discovery engine to discover, develop and commercialize large molecule therapeutics. As of the transaction date and as of September 30, 2023, the Company has a 39.1% voting interest in Launchpad and one seat on Launchpad's Board of Directors which provide the Company with significant influence over Launchpad. The remaining voting interest in Launchpad is held by Versant Ventures and New Enterprise Associates (NEA), who are shareholders of the Company.

The Company accounted for the transaction under the equity method and recorded the carrying value of the Company's investment in Launchpad common shares of \$2,250 in equity method investments in the consolidated balance sheets. The contributed in process research and development (IPR&D) had zero basis on the Company's books prior to the transaction, therefore the Company recognized a gain on sale of IPR&D of \$2,232 in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. The Company also recognized a loss from investments in equity method investee of \$1,540 in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2022, associated with the Company's proportionate share of Launchpad's losses. The assets contributed by the Company were principally IPR&D and were not deemed a business by Launchpad, therefore the Company determined its remaining basis difference of \$710 was substantially related to IPR&D and immediately expensed it. As of December 31, 2022, the carrying value of the investment in Launchpad was reduced to zero. Since the Company has no obligation to provide financing support to Launchpad, the Company is not required to record further losses exceeding the carrying value of the investment. The Company also determined that its investment in Launchpad is not material or significant to its operations or financial position. As of September 30, 2023, the carrying value of the investment in Launchpad was zero.

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Contracted research services	\$ 5,641	\$ 4,713
Payroll and related expenses	4,539	4,648
Professional and consulting fees	1,149	1,182
Current portion of operating lease liability	3,043	2,841
Total accrued expenses and other current liabilities	\$ 14,372	\$ 13,384

8. 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, 2023, 1,457,371 shares of common stock, representing 4% of the Company's outstanding shares of common stock as of December 31, 2022, 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, 2023.

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,	
	2023	2022	2023	2022
Stock options	\$ 2,595	\$ 2,481	\$ 7,525	\$ 8,674
Restricted stock units	58	108	250	418
Employee Stock Purchase Plan and Other	98	75	293	199
	<u>\$ 2,751</u>	<u>\$ 2,664</u>	<u>\$ 8,068</u>	<u>\$ 9,291</u>

For the nine months ended September 30, 2023, the Company issued 55,972 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,	
	2023	2022	2023	2022
Research and development	\$ 767	\$ 1,201	\$ 2,549	\$ 4,255
General and administrative	1,984	1,463	5,519	5,036
	<u>\$ 2,751</u>	<u>\$ 2,664</u>	<u>\$ 8,068</u>	<u>\$ 9,291</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, 2022	5,359,400	\$ 12.40	7.8	\$ 76
Granted	4,327,850	\$ 2.92		
Exercised	(5,370)	\$ 3.79		
Cancelled or forfeited	(1,269,121)	\$ 7.39		
Expired	(68,124)	\$ 28.26		
Outstanding September 30, 2023	8,344,635	\$ 8.12	8.2	\$ 1,244
Options vested or expected to vest at September 30, 2023	8,344,635	\$ 8.12	8.2	\$ 1,244
Options exercisable at September 30, 2023	3,689,107	\$ 13.12	6.8	\$ 243

For the nine months ended September 30, 2023, total unrecognized compensation cost related to the unvested stock-options was \$11,148, which is expected to be recognized over a weighted average period of 2.7 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, 2023:

	Number of shares	Weighted average grant date fair value
Unvested restricted common stock as of December 31, 2022	101,397	\$ 5.92
Vested	(61,522)	\$ 8.26
Cancelled or forfeited	(17,201)	\$ 2.14
Unvested restricted common stock as of September 30, 2023	22,674	\$ 2.53

The total fair value of time-based restricted stock units vested during the nine months ended September 30, 2023 was \$505.

For the nine months ended September 30, 2023, total unrecognized compensation cost related to the time-based unvested restricted stock units was \$43, which is expected to be recognized over a weighted average period of 0.6 years.

The Company had 239,475 performance restricted stock units outstanding at the year ended December 31, 2022. For the nine months ended September 30, 2023, the Company granted no performance restricted stock units to its employees, released 27,475 performance restricted stock units due to the achievement of certain clinical development and/or financing milestones, had 193,000 performance restricted stock units expire, and had no performance restricted stock units forfeited. As of September 30, 2023, the Company had 19,000 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, 2023, no milestones for outstanding performance-based restricted stock units were considered probable.

As of September 30, 2023, two milestones for outstanding performance restricted stock units were achieved. For the nine months ended September 30, 2023, the Company recognized stock-based compensation expense related to these milestones of \$52. The milestones that had not been met were considered not probable, and therefore no expense had been recognized related to these awards in the nine months ended September 30, 2023.

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, 2023 and 2022, there were 69,005 and 53,662 shares, respectively, issued under the 2020 ESPP.

9. NET LOSS PER SHARE

Net loss per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (23,007)	\$ (21,654)	\$ (63,034)	\$ (70,091)
Weighted average common shares outstanding, basic and diluted	50,943,155	36,346,181	41,367,347	36,304,050
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.60)	\$ (1.54)	\$ (1.93)

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,	
	2023	2022
Options to purchase common stock	8,344,635	5,738,721
Unvested restricted stock	22,674	169,879
Shares issuable under employee stock purchase plan	28,780	48,805
Unvested performance restricted stock units	19,000	248,225
Warrants to purchase common stock	10,757	10,757
	8,425,846	6,216,387

10. LEASES

The Company has historically entered into lease arrangements for its facilities. As of September 30, 2023, 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, which was reduced to \$779 in August 2023 pursuant to the terms of the lease agreement. Additionally, on December 12, 2022, the Company entered into a sublease for one floor of its Cambridge, Massachusetts office space. The sublease terminates on August 31, 2028, which is also the date on which the Company's lease terminates.

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, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Lease Cost				
Operating lease cost	\$ 1,054	\$ 1,057	\$ 3,162	\$ 3,173
Short-term lease cost	24	38	52	78
Variable lease cost	246	241	628	717
Sublease income	(334)	—	(804)	—
Total lease cost	\$ 990	\$ 1,336	\$ 3,038	\$ 3,968

Other Operating Lease Information	September 30, 2023	September 30, 2022
Cash paid for amounts included in the measurement of lease liability	\$ 3,164	\$ 1,884
Weighted-average remaining lease term	7.1	8.1
Weighted-average discount rate	5.3 %	5.3 %

The variable lease costs for the three and nine months ended September 30, 2023 and 2022 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, 2023 were as follows:

	As of September 30, 2023
2023 (excluding the nine months ended September 30, 2023)	\$ 1,080
2024	4,359
2025	4,477
2026	4,599
2027	4,724
Thereafter	12,250
Total lease payments	31,489
Less: interest	(5,447)
Total lease liability	\$ 26,042

11. 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, 2023, 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, 2023 or December 31, 2022.

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.

12. 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, 2023 and 2022, the Company contributed \$143, \$686, \$154 and \$911, 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, 2022, 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, 2022, which was filed with the SEC on March 9, 2023. 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 oncology company focused on the development of MasterKey therapies that target families of oncogenic mutations in clinically validated targets. The foundation of our company is built upon a deep understanding of cancer genetics, onco-protein structure and function, and medicinal chemistry. Our MasterKey therapies are designed to address a broad spectrum of genetically defined tumors, overcome resistance, minimize wild-type mediated toxicities, and be brain-penetrant to treat central nervous system (CNS) disease. We are advancing two clinical-stage programs: BDTX-1535, a brain-penetrant, fourth-generation EGFR MasterKey inhibitor, targeting epidermal growth factor receptor (EGFR) mutant non-small cell lung cancer (NSCLC) and glioblastoma multiforme (GBM), and BDTX-4933, a brain-penetrant, RAF MasterKey inhibitor targeting KRAS, NRAS and BRAF alterations in solid tumors.

Our lead product candidate, BDTX-1535, is being studied in a Phase 1 clinical trial, currently in dose expansion for patients with NSCLC and dose escalation for patients with GBM. BDTX-1535 is an oral, brain-penetrant MasterKey inhibitor of oncogenic EGFR mutation in NSCLC, including families of non-classical (formerly referred to as “intrinsic”) driver mutations (e.g., L747P, L718Q), the acquired resistance C797S mutation, and complex mutations. BDTX-1535 is a fourth-generation tyrosine kinase inhibitor (TKI) that potently inhibits, based on preclinical data, greater than fifty oncogenic EGFR mutations and alterations expressed across a diverse group of patients with NSCLC in multiple lines of therapy, while sparing wild type EGFR activity. Based on preclinical data, BDTX-1535 also inhibits EGFR extracellular domain mutations and alterations commonly expressed in GBM and avoids paradoxical activation observed with earlier generation reversible TKIs.

In September 2023, we announced the dosing of the first patients in the BDTX-1535 Phase 1 clinical trial expansion cohorts to assess overall response rate (ORR) by RECIST 1.1 and durability of response (DOR) in patients with NSCLC with the EGFR acquired resistance C797S mutation after progression on a third generation EGFR TKI and non-classical (intrinsic) driver mutations after progression on an EGFR TKI. We expect to share initial results from this portion of the trial in 2024.

In October 2023, we presented new clinical data at a medical conference from the dose escalation portion of the Phase 1 clinical trial of BDTX-1535 in patients with NSCLC. Data shared at the conference were from 27 patients with advanced/metastatic NSCLC who received a range of doses spanning 25mg to 400mg once daily.

Durable clinical responses were observed at a starting dose of 100mg or above in patients with NSCLC who had multiple lines of prior therapy. Five of the 13 patients with either non-classical (intrinsic) driver, the acquired resistance C797S mutation or complex mutations, who had measurable disease at study start and underwent post-baseline tumor assessment, had a confirmed partial response (PR) by RECIST 1.1. Evidence of reduction in brain metastases was observed, including a patient with more than three prior therapies. Results showed that three responders continue on therapy for greater than six months (two confirmed PRs, one unconfirmed PR) and that one patient with confirmed PR continued on therapy for six months. Two additional patients with stable disease were shown to continue on therapy for greater than 12 months. Eradication of targeted variant alleles and significant circulating tumor DNA reductions were also observed for all NSCLC EGFR mutation subtypes in patients treated with BDTX-1535 across dose levels.

A favorable emerging safety profile was demonstrated and no unexpected safety signals were identified, with the majority of adverse events at doses of 100mg and 200mg being mild or moderate. No dose limiting toxicities were observed at 200mg or below.

We expect to provide an update on the Phase 1 dose escalation data in the cohort of patients with GBM in the fourth quarter of 2023. In October 2023, enrollment began in a Phase 0/1 “window of opportunity” clinical trial of BDTX-1535 in patients with recurrent high-grade glioma. The trial is sponsored by the Ivy Brain Tumor Center in Phoenix, Arizona and is enrolling patients prior to a planned resection. Patients achieving adequate drug levels in the gadolinium non-enhancing regions of the tumor will continue with treatment following surgery.

Our second product candidate, BDTX-4933, is an oral, brain-penetrant RAF MasterKey inhibitor, which is designed to address oncogenic alterations in KRAS, NRAS and BRAF, while also avoiding paradoxical activation. In preclinical studies, BDTX-4933 has demonstrated a potential best-in-class profile, showing potent target engagement, inhibition of MAPK signaling and strong anti-tumor activity/tumor regression across patient-derived tumor xenograft models driven by either KRAS, NRAS or BRAF mutations and alterations. BDTX-4933 also exhibits high CNS exposure leading to dose-dependent tumor growth inhibition and a survival benefit in an intracranial tumor model with oncogenic BRAF mutation. A Phase 1 clinical trial for BDTX-4933 was initiated in the second quarter of 2023 in patients with BRAF and select RAS/MAPK mutation-positive cancers, with an emphasis on patients with KRAS mutant NSCLC. The trial is currently in dose escalation.

In October 2023, we presented preclinical data for BDTX-4933 at a medical conference, which showed that BDTX-4933 potently and selectively inhibited the proliferation of tumor cells expressing a range of KRAS, NRAS and BRAF mutations, suggesting clear differentiation compared to other RAF inhibitors. BDTX-4933 demonstrated strong anti-tumor activity and regression across preclinical models expressing several MAPK pathway mutations, including KRAS G12D, KRAS G12V, and KRAS G13C mutant NSCLC models. BDTX-4933 exhibited high CNS exposure with dose-dependent tumor growth inhibition and survival benefit in an intracranial xenograft BRAF tumor model.

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 \$63.0 million and \$70.1 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$398.0 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 trials for BDTX-1535 and BDTX-4933;
- 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 a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates, and reduce headcount and general and administrative costs.

Because of the numerous risks and uncertainties associated with product development, 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. Even if we are able to generate product sales, we may not become profitable. 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 reduce or terminate our operations.

Additionally, we continue to actively monitor macroeconomic conditions and market volatility resulting from global economic developments, political unrest, high inflation, disruptions in capital markets, changes in international trade relationships and military conflicts, and health crises. While we believe such factors have had no significant impact on our business or financial results during the periods presented, future developments and potential impacts on our business are uncertain and cannot be predicted with confidence.

As of September 30, 2023, we had cash, cash equivalents and investments of approximately \$144.3 million, which we believe will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2025. 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.

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, preclinical studies, and clinical trials as well as under agreements with 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 the conduct of preclinical studies, clinical trials, and our drug discovery efforts, including acquiring and manufacturing materials, manufacturing validation batches, fees to investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development support 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.

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 and BDTX-4933. 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 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 clinical trials and other development activities;
- 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 (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 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 continued 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, sublease income, realized and unrealized foreign currency transaction gains and losses, and gain (loss) on sale of IP related to equity method investment.

Equity in (losses) of unconsolidated entity

Equity in (losses) of unconsolidated entity consists of our share of equity method investee losses on the basis of our equity ownership percentage and IPR&D charges resulting from basis differences.

Results of operations

Comparison of the three months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Change
	2023	2022	
(in thousands)			
Operating expenses:			
Research and development	\$ 16,154	\$ 15,847	\$ 307
General and administrative	7,858	6,277	1,581
Total operating expenses	24,012	22,124	1,888
Loss from operations	(24,012)	(22,124)	(1,888)
Other income (expense):			
Interest income	439	562	(123)
Other (expense) income	566	(92)	658
Total other income (expense), net	1,005	470	535
Net loss	\$ (23,007)	\$ (21,654)	\$ (1,353)

Research and development

Research and development expenses were \$16.2 million for the three months ended September 30, 2023, compared to \$15.8 million for the three months ended September 30, 2022. The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Change
	2023	2022	
(in thousands)			
BDTX-1535 research and development expenses	\$ 5,988	\$ 2,578	\$ 3,410
BDTX-4933 research and development expenses	1,618	1,334	284
BDTX-189 research and development expenses	—	1,572	(1,572)
Other research programs and platform development expenses	2,080	3,859	(1,779)
Personnel expenses	4,773	5,136	(363)
Allocated facility expenses	926	997	(71)
Other expenses	769	371	398
	\$ 16,154	\$ 15,847	\$ 307

The increase of \$0.3 million for the three months ended September 30, 2023 was primarily due to an increase of \$3.4 million related to the progression of our clinical trial for BDTX-1535, offset by decreased spend relating to other research programs and platform development of \$1.8 million due to reduced spending on early discovery projects as we deepen our focus on our clinical-stage assets, compared to the three months ended September 30, 2022. In addition, BDTX-189 expenses decreased \$1.6 million due to the discontinuation of the development of BDTX-189 to focus on the development of BDTX-1535 and BDTX-4933.

General and administrative

General and administrative expenses were \$7.9 million for the three months ended September 30, 2023 compared to \$6.3 million for the three months ended September 30, 2022. This was primarily a result of an increase in costs related to the transition of our former President and Chief Executive Officer in September 2023, along with other legal and other professional fees.

Other income (expense)

Other income was \$1.0 million for the three months ended September 30, 2023, compared to \$0.5 million for the three months ended September 30, 2022. The increase was primarily attributable to amortization of premium on investments decreasing at a higher rate in 2023 compared to 2022, and sublease income in 2023.

Comparison of the nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Change
	2023	2022	
(in thousands)			
Operating expenses:			
Research and development	\$ 44,061	\$ 49,828	\$ (5,767)
General and administrative	21,544	21,148	396
Total operating expenses	65,605	70,976	(5,371)
Loss from operations	(65,605)	(70,976)	5,371
Other income (expense):			
Interest income	1,600	1,354	246
Other (expense) income	971	(469)	1,440
Total other income (expense), net	2,571	885	1,686
Net loss	\$ (63,034)	\$ (70,091)	\$ 7,057

Research and development

Research and development expenses were \$44.1 million for the nine months ended September 30, 2023, compared to \$49.8 million for the nine months ended September 30, 2022. The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Change
	2023	2022	
(in thousands)			
BDTX-1535 research and development expenses	\$ 13,149	\$ 5,055	\$ 8,094
BDTX-4933 research and development expenses	5,015	1,538	3,477
BDTX-189 research and development expenses	—	6,616	(6,616)
Other research programs and platform development expenses	6,973	14,377	(7,404)
Personnel expenses	14,552	18,041	(3,489)
Allocated facility expenses	2,725	3,002	(277)
Other expenses	1,647	1,199	448
	\$ 44,061	\$ 49,828	\$ (5,767)

The decrease of \$5.8 million for the nine months ended September 30, 2023 was primarily due to a decrease of \$6.6 million in BDTX-189 expenses due to the discontinuation of the development of BDTX-189 to focus on the development of BDTX-1535 and BDTX-4933, compared to the nine months ended September 30, 2022. Additionally, there was a net increase of \$11.6 million related to the progression of our clinical trials for BDTX-1535 and BDTX-4933, offset by decreased spend relating to other research programs and platform development of \$7.4 million due to reduced spending on early discovery projects as we deepen our focus on our clinical-stage assets. Personnel expenses decreased \$3.5 million as a result of the realignment of our workforce in April 2022 to focus on the development of BDTX-1535 and BDTX-4933.

General and administrative

General and administrative expenses were \$21.5 million for the nine months ended September 30, 2023 compared to \$21.1 million for the nine months ended September 30, 2022. This was primarily a result of an increase in costs related to the transition of our former President and Chief Executive Officer in September 2023, along with other legal and other professional fees.

Other income (expense)

Other income was \$2.6 million for the nine months ended September 30, 2023, compared to \$0.9 million for the nine months ended September 30, 2022. The increase was primarily attributable to amortization of premium on investments decreasing at a higher rate in 2023 compared to 2022, sublease income in 2023 and interest income increasing 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 common and 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, 2023, we had received net cash proceeds of \$200.6 million from previous sales of our preferred stock and as of September 30, 2023, we had cash, cash equivalents and investments of \$144.3 million.

On November 14, 2022, we filed a shelf registration statement on Form S-3 (the Shelf Registration Statement) 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 up to a maximum price of \$500 million. We simultaneously entered into an Open Market Sale AgreementSM (the Sales Agreement) with Jefferies LLC (Jefferies), 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 (the ATM Program). The Shelf Registration Statement became effective on November 22, 2022. 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. 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, 2023, no sales have been made pursuant to the ATM Program.

On July 5, 2023, we completed an underwritten public offering (the Follow-on Offering) of 15,000,000 shares of our common stock at a price to the public of \$5.00. The aggregate net proceeds from the Follow-on Offering totaled approximately \$71.6 million after deducting underwriting discounts and commissions, as well as other offering expenses. The underwriters did not exercise any portion of their 30-day over-allotment option to purchase up to an additional 2,250,000 shares of the Company’s common stock at the public offering price, which expired on July 29, 2023, and therefore no additional proceeds from the Follow-on Offering were received.

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,	
	2023	2022
Cash used in operating activities	\$ (52,761)	\$ (63,143)
Cash provided by investing activities	4,097	51,044
Cash provided by financing activities	71,978	205
Net increase (decrease) in cash and cash equivalents	\$ 23,314	\$ (11,894)

Operating activities

During the nine months ended September 30, 2023, we used cash in operating activities of \$52.8 million, primarily resulting from our net loss of \$63.0 million, partially offset by the non-cash charge related to stock compensation expense of \$8.1 million.

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.

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, 2023, we had cash provided by investing activities of \$4.1 million primarily from the sales and maturities of investments, netted against our purchase of investments.

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.

Financing activities

During the nine months ended September 30, 2023, we had cash provided by financing activities of \$72.0 million, consisting of proceeds from the participation in the employee stock purchase plan as well as the Follow-on Offering in July 2023.

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.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance 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 and BDTX-4933 through clinical trials;
- manufacture, or have manufactured on our behalf, our drug material and develop processes for late stage 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, 2023, we had cash, cash equivalents and investments of \$144.3 million. We believe that our existing cash, cash equivalents and investments, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2025. 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 developing our product candidates, and conducting 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 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 collaborations 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, 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, and such sales may be on unfavorable terms. Similarly, adverse macroeconomic conditions and market volatility resulting from global economic developments, political unrest, high inflation, global health crises, 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, 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 rights 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, 2023:

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
	(in thousands)				
Property leases - commenced	\$ 4,330	\$ 9,015	\$ 9,280	\$ 8,864	\$ 31,489
Total	\$ 4,330	\$ 9,015	\$ 9,280	\$ 8,864	\$ 31,489

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, 2023. 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, 2022, which was filed with the SEC on March 9, 2023. During the nine months ended September 30, 2023, 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 (the JOBS Act) 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 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2023.

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 have materially affected, or are 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 11 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

We are updating and supplementing our risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023 to add the following new risk factor:

Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank after it was unable to continue its operations. This event exposed vulnerabilities in the banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market prices of regional bank stocks to plummet.

We are unable to predict the extent or nature of the impacts of evolving circumstances in the financial services industry at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

There have been no other material changes to the risk factors previously disclosed in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the year ended December 31, 2022. Please refer to the complete Part I, Item 1A of our Annual Report for additional risks and uncertainties we are facing that may have a material adverse effect on our business prospects, financial condition and results of operations. In addition to the risks described in our Annual Report on Form 10-K, you should carefully consider the other information set forth in this Form 10-Q and the information in our other filings with the SEC, as they could materially affect our business, financial condition or future results of operations.

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 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 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 6, 2023

By: /s/ Mark A. Velleca

Mark A. Velleca
President and Chief Executive Officer
(Principal Executive Officer)

Black Diamond Therapeutics, Inc.

Date: November 6, 2023

By: /s/ Fang Ni

Fang Ni
Chief Business Officer and 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, Mark A. Velleca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 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 6, 2023

By: /s/ Mark A. Velleca

Mark A. Velleca
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, 2023 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 6, 2023

By: /s/ Fang Ni
Fang Ni
Chief Business Officer and Chief 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, Mark A. Velleca, 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, 2023 (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 6, 2023

By: /s/ Mark A. Velleca
Mark A. Velleca
President, Chief Executive Officer
and Director
(Principal Executive Officer)

Date: November 6, 2023

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