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

FORM 10-Q

(Mark One)

☒ **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: 001-38327

Cue Biopharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-3324577**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
40 Guest Street Boston, Massachusetts	**02135**
(Address of principal executive offices)	**(Zip Code)**

(617) 949-2680
(Registrant's telephone number, including area code)

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 $0.001 per share	CUE	Nasdaq Capital 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		Accelerated filer	
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company			

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

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 November 1, 2023, the registrant had 45,123,281 shares of Common Stock ($0.001 par value per share) outstanding.

CUE BIOPHARMA, INC.
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or other comparable terms. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the initiation, timing, progress and results of our ongoing and planned preclinical studies and clinical trials and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- our expectations regarding our ability to fund our projected operating requirements with our existing cash resources and the period in which we expect that such cash resources will enable us to fund such operating requirements;
- our plans to develop our drug product candidates;
- the timing of and our ability to submit applications for, and to obtain and maintain regulatory approvals for, our drug product candidates;
- the potential advantages of our drug product candidates;
- the rate and degree of market acceptance and clinical utility of our drug product candidates, if approved;
- our estimates regarding the potential market opportunity for our drug product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, drug product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry; and
- our ability to maintain and establish collaborations or obtain additional funding.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include the factors discussed below under the heading "Risk Factor Summary," and the risk factors detailed further in Item 1A., "Risk Factors" of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022.

This report includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates. All of the market data used in this report involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our drug product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

RISK FACTOR SUMMARY

Investment in our securities involves risk. You should carefully consider the following summary of what we believe to be the principal risks facing our business, in addition to the risks described more fully in Item 1A, "Risk Factors" of Part I of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 21, 2023 and other information included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations.

If any of the following risks occurs, our business, financial condition and results of operations and future growth prospects could be materially and adversely affected, and the actual outcomes of matters as to which forward-looking statements are made in this report could be materially different from those anticipated in such forward-looking statements.

- We are a clinical-stage biopharmaceutical company, have no history of generating commercial revenue, have a history of operating losses, and we may never achieve or maintain profitability.
- We currently do not have, and may never develop, any FDA-approved or commercialized products.
- We are substantially dependent on the success of our drug product candidates, only two of which are currently being tested in a clinical trial, and significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our drug product candidates.
- We have limited experience in conducting clinical trials and no history of commercializing biologic products, which may make it difficult to evaluate the prospects for our future viability.
- We plan to seek collaborations or strategic alliances. However, we may not be able to establish such relationships, and relationships we have established may not provide the expected benefits.
- Our collaboration agreement with LG Chem contains exclusivity provisions that restrict our research and development activities.
- We may not be successful in our efforts to identify additional drug product candidates. Due to our limited resources and access to capital, we must prioritize the development of certain drug product candidates; these decisions may prove to be wrong and may adversely affect our business.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug product candidates and our business could be substantially harmed.
- We rely completely on third parties to manufacture our preclinical and clinical drug supplies for our drug product candidates.
- If we or our licensor is unable to protect our or its intellectual property, then our financial condition, results of operations and the value of our technology and potential products could be adversely affected.
- We will be subject to stringent domestic and foreign regulation in respect of any potential products. The regulatory approval processes of the FDA and other comparable regulatory authorities outside the United States are lengthy, time-consuming and inherently unpredictable. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations.
- Even if a potential therapeutic is ultimately approved by the various regulatory authorities, it may be approved only for narrow indications which may render it commercially less viable.
- Even if we receive regulatory approval of our drug product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug product candidates.
- We have a loan agreement that requires us to meet certain operating covenants and places restrictions on our operating and financial flexibility.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Cue Biopharma, Inc.
Consolidated Balance Sheets
(in thousands, except shares and per share amounts)

	September 30, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 54,691	$ 51,614
Marketable securities	—	24,675
Accounts receivable	1,661	57
Prepaid expenses and other current assets	1,165	841
Total current assets	57,517	77,187
Property and equipment, net	1,064	1,499
Operating lease right-of-use	7,060	9,203
Deposits	2,977	3,116
Restricted cash	150	150
Other long-term assets	120	128
Total assets	$ 68,888	$ 91,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,480	$ 2,731
Accrued expenses	5,127	3,554
Research and development contract liability, current portion	2,238	—
Operating lease liability, current portion	3,399	3,300
Current portion of long-term debt, net	3,963	1,963
Total current liabilities	17,207	11,548
Operating lease liability, net of current portion	3,855	6,017
Long-term debt, net	5,160	8,035
Total liabilities	$ 26,222	$ 25,600
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 45,123,281 and 43,042,548 shares issued and outstanding, at September 30, 2023 and December 31, 2022, respectively	45	43
Additional paid in capital	330,376	316,192
Accumulated other comprehensive loss	—	(96)
Accumulated deficit	(287,755)	(250,456)
Total stockholders' equity	42,666	65,683
Total liabilities and stockholders' equity	$ 68,888	$ 91,283

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

Cue Biopharma, Inc.
Consolidated Statements of Operations and Other Comprehensive Loss
(Unaudited)
(in thousands, except shares and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 2,100	$ 68	$ 3,669	$ 1,094
Operating expenses (income):				
General and administrative	3,645	3,528	12,071	12,465
Research and development	9,874	7,571	29,915	27,246
Gain on right-of-use asset termination	—	—	—	(258)
Total operating expenses	13,519	11,099	41,986	39,453
Loss from operations	(11,419)	(11,031)	(38,317)	(38,359)
Other (expense) income:				
Interest income	700	200	1,756	296
Interest expense, net	(286)	(124)	(738)	(355)
Total other (expense) income	414	76	1,018	(59)
Net loss	$ (11,005)	$ (10,955)	$ (37,299)	$ (38,418)
Unrealized gain (loss) from available-for-sale securities	5	(92)	96	(92)
Comprehensive loss	$ (11,000)	$ (11,047)	$ (37,203)	$ (38,510)
Net loss per common share – basic and diluted	$ (0.24)	$ (0.31)	$ (0.82)	$ (1.11)
Weighted average common shares outstanding –basic and diluted	46,358,555	35,383,430	45,274,124	34,471,499

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

Cue Biopharma, Inc.
Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except shares and per share amounts)

Three Months Ended September 30, 2023 and 2022:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, June 30, 2022	35,381,743	$ 35	$ 284,630	$ —	$ (224,909)	$ 59,756
Stock-based compensation	—	—	2,064	—	—	2,064
Restricted stock awards released	6,667	—	—	—	—	—
Restricted stock awards withheld at vesting to cover taxes	(2,828)	—	(9)	—	—	(9)
Unrealized losses from available-for-sale securities	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	(10,955)	(10,955)
Balance, September 30, 2022	35,385,582	$ 35	$ 286,685	$ (92)	$ (235,864)	$ 50,764
Balance, June 30, 2023	43,744,414	$ 44	$ 322,715	$ (5)	$ (276,750)	$ 46,004
Issuance of common stock from ATM offering, net of sales agent commission and fees	1,378,867	1	5,588	—	—	5,589
Stock-based compensation	—	—	2,073	—	—	2,073
Unrealized gain from available-for-sale securities	—	—	—	5	—	5
Net loss	—	—	—	—	(11,005)	(11,005)
Balance, September 30, 2023	45,123,281	$ 45	$ 330,376	$ 0	$ (287,755)	$ 42,666

Nine Months Ended September 30, 2023 and 2022:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, December 31, 2021	32,202,496	$ 32	$ 262,906	$ -	$ (197,446)	$ 65,492
Issuance of common stock from ATM offering, net of sales agent commission and fees	3,117,220	3	16,595	—	—	16,598
Stock-based compensation	—	—	7,384	—	—	7,384
Issuance of common stock upon exercise of warrants, net	9,549	—	—	—	—	—
Restricted stock awards released	98,335	—	—	—	—	—
Restricted stock awards withheld at vesting to cover taxes	(42,018)	—	(200)	—	—	(200)
Unrealized losses from available-for-sale securities	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	(38,418)	(38,418)
Balance, September 30, 2022	35,385,582	$ 35	$ 286,685	$ (92)	$ (235,864)	$ 50,764
Balance, December 31, 2022	43,042,548	$ 43	$ 316,192	$ (96)	$ (250,456)	$ 65,683
Issuance of common stock from ATM offering, net of sales agent commission and fees	1,915,131	2	7,603	—	—	7,605
Stock-based compensation	—	—	6,108	—	—	6,108
Exercise of stock options	165,602	—	473	—	—	473
Unrealized gain from available-for-sale securities	—	—	—	96	—	96
Net loss	—	—	—	—	(37,299)	(37,299)
Balance, September 30, 2023	45,123,281	$ 45	$ 330,376	$ -	$ (287,755)	$ 42,666

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

Cue Biopharma, Inc.
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (37,299)	$ (38,418)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	443	719
Stock-based compensation	6,108	7,384
Decrease in the carrying amount of right-of-use-assets	2,142	507
Gain on right-of-use asset termination	—	(258)
Loss (gain) on sale of property and equipment	(2)	4
Amortization of premium/discount on purchased securities	(234)	(101)
Amortization of debt issuance costs	28	21
Accretion of final payment on term loan	98	76
Changes in operating assets and liabilities:		
Accounts receivable	(1,603)	2,347
Prepaid expenses and other current assets	(324)	(846)
Deposits	139	(395)
Accounts payable	(251)	(546)
Accrued expenses	1,573	(741)
Research and development contract liability	2,238	(645)
Operating lease liability	(2,064)	(397)
Accrued interest	5	(3)
Net cash used in operating activities	(29,003)	(31,292)
Cash flows from investing activities		
Purchases of property and equipment	—	(170)
Cash received from the sale of property and equipment	2	6
Redemption of short-term investments	25,000	—
Purchase of short-term investments	—	(29,445)
Net cash provided by (used in) investing activities	25,002	(29,609)
Cash flows from financing activities		
Proceeds from ATM offering, net of sales agent commission and fees	7,605	16,598
Proceeds from borrowings under term loan	—	10,000
Payment of term loan	(1,000)	—
Proceeds from exercise of stock options	473	—
Payment of debt issuance costs	—	(142)
Restricted stock awards withheld at vesting to cover taxes	—	(200)
Net cash provided by financing activities	7,078	26,256
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,077	(34,645)
Cash, cash equivalents, and restricted cash at beginning of period	51,764	64,521
Cash, cash equivalents, and restricted cash at end of period	$ 54,841	$ 29,876
Supplemental disclosures of non-cash investing and financing activities:		
Cash paid for interest	$ 768	$ 354
Right-of-use asset and lease liability (new lease)	$ —	$ 9,057
Operating lease modification	$ —	$ 7,119

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

1. Organization and Basis of Presentation

Cue Biopharma, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing a novel class of injectable biologics designed to selectively engage and modulate tumor-specific T cells within the body to treat a broad range of cancers, chronic infectious diseases, and autoimmune diseases. The Company's corporate office and research facilities are located in Boston, Massachusetts.

The Company is in the development stage and has incurred recurring losses and negative cash flows from operations since inception. As of September 30, 2023, the Company had cash and cash equivalents of approximately $54,691,000. Management believes that current cash and cash equivalents on hand at September 30, 2023 are sufficient to fund operations for at least the next twelve months from the date of issuance of these financial statements; however, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund research and development costs in order to seek approval for commercialization of its drug product candidates. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop and commercialize the Company's drug product candidates in order to generate future revenue streams.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements as of September 30, 2023, and for the three and nine months ended September 30, 2023 and 2022, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States ("U.S. GAAP") for financial information, which prescribes elimination of all significant intercompany accounts and transactions in the accounts of the Company and its wholly owned subsidiary, Cue Biopharma Securities Corp., which was incorporated in the Commonwealth of Massachusetts in December 2018. In the opinion of management, these financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2023.

Interim results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023, or any future periods.

Public Offerings

In October 2021, the Company entered into an open market sale agreement (the "October 2021 ATM Agreement") with Jefferies LLC ("Jefferies"), as agent, to sell shares of the Company's common stock for aggregate gross proceeds of up to $80 million, from time to time, through an at-the-market equity offering program. The October 2021 ATM Agreement will terminate upon the earliest of (a) the sale of $80 million of shares of the Company's common stock pursuant to the October 2021 ATM Agreement or (b) the termination of the October 2021 ATM Agreement by the Company or Jefferies. During the three months ended September 30, 2023, the Company sold 1,378,867 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $5,589,000 net of commission paid, but excluding transaction expenses. During the nine months ended September 30, 2023, the Company sold 1,915,131 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $7,605,000 net of commission paid, but excluding transaction expenses. As of September 30, 2023, the Company had sold an aggregate of 5,508,538 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $31.2 million, net of commission paid, but excluding transaction expenses, since its inception.

Consolidation

The accompanying consolidated financial statements include the Company and its wholly owned subsidiary, Cue Biopharma Securities Corp. The Company has eliminated all intercompany transactions.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates include estimates related to collaboration revenue, the accounting for potential liabilities and accrued expenses, the assumptions utilized in valuing stock-based compensation issued for services, the realization of deferred tax assets, and the useful life with respect to long-lived assets and intangibles. Actual results could differ from those estimates.

Cash Concentrations

The Company maintains its cash balances with financial institutions in federally insured accounts and may periodically have cash balances in excess of insurance limits. The Company maintains its accounts with financial institutions with a high credit rating. The Company has not experienced any losses to date from our deposits with these financial institutions and believes that it is not exposed to any significant credit risk on cash.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The Company currently invests available cash in money market funds.

Marketable Securities

Marketable securities consist of investments with original maturities greater than ninety days and less than one year from the balance sheet date. The Company classifies all of its investments as available-for-sale securities. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. Unrealized gains and losses are recognized and determined on a specific identification basis and are included in other comprehensive loss. Realized gains and losses are determined on a specific identification basis and are included in other income on the consolidated statement of operations and other comprehensive loss. Amortization and accretion of discounts and premiums is recorded in interest income. The Company has invested available cash in U.S. Treasury obligations.

Restricted Cash

The Company had $150,000 in restricted cash deposited with separate commercial banks to collateralize a credit card as of September 30, 2023 and December 31, 2022.

Property and Equipment

Property and equipment is recorded at cost. Major improvements are capitalized, while maintenance and repairs are charged to expense as incurred. Gains and losses from dispositions of property and equipment are included in income and expense when realized. Amortization of leasehold improvements is provided using the straight-line method over the shorter of the lease term or the useful life of the underlying assets. Depreciation of property and equipment is provided using the straight-line method over the following estimated useful lives:

Laboratory equipment	5 years
Computer and office equipment	3 years
Furniture and fixtures	3-8 years

The Company recognizes depreciation and amortization expense in general and administrative expenses and in research and development expenses in the Company’s consolidated statements of operations and comprehensive loss, depending on how each category of property and equipment is utilized in the Company’s business activities.

Trademark

Trademark consists of the Company's right, title and interest to the CUE BIOLOGICS Mark, and any derivative mark incorporating CUE, throughout the world, together with all associated goodwill and common law rights appurtenant thereto, including, but not limited to, any right, title and interest in any corporate name, company name, business, name, trade name, dba, domain name, or other source identifier incorporating CUE.

The Company has classified the trademark as a component of other long-term assets, having a useful life of 15 years. The Company evaluates the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date. For each of the three and nine months ended September 30, 2023 and 2022, the Company recorded approximately $3,000 and $9,000, respectively, in amortization expense on a straight-line basis.

Debt Issuance Costs

Debt issuance costs are deferred and presented as a reduction to long-term debt. Debt issuance costs are amortized using the effective interest rate method over the term of the loan. Amortization of deferred debt issuance costs are included in interest expense in the consolidated statements of operations and other comprehensive loss.

Revenue Recognition

The Company recognizes collaboration revenue under certain of the Company's license and collaboration agreements that are within the scope of Accounting Standards Codification ("ASC"), Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company's contracts with customers typically include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the expected value method.

Research and Development Expenses

Research and development expenses consist primarily of compensation costs, fees paid to consultants, outside service providers and organizations (including research institutes at universities), facility costs, and development and clinical trial costs with respect to the Company's drug product candidates.

Research and development expenses incurred under contracts are expensed ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different pattern of performance is more appropriate. Other research and development expenses are charged to operations as incurred.

Nonrefundable advance payments are recognized as an expense as the related services are performed. The Company evaluates whether it expects the services to be rendered at each quarter end and year end reporting date. If the Company does not expect the services to be rendered, the advance payment is charged to expense. Nonrefundable advance payments for research and development services are included in prepaid and other current assets on the balance sheet. To the extent that a nonrefundable advance payment is for contracted services to be performed within 12 months from the reporting date, such advance is included in current assets; otherwise, such advance is included in non-current assets.

The Company evaluates the status of its research and development agreements and contracts, and the carrying amount of the related assets and liabilities, at each quarter end and year end reporting date, and adjusts the carrying amounts and their classification on the balance sheet as appropriate.

Patent Expenses

The Company is the exclusive worldwide licensee of, and has patent applications pending for, numerous domestic and foreign patents. Due to the significant uncertainty associated with the successful development of one or more commercially viable drug product candidates based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal fees, filing fees and other costs are charged to general and administrative expense as incurred. For the three and nine months ended September 30, 2023, patent expenses were approximately $503,000 and $1,649,000, respectively. For the three and nine months ended September 30, 2022, patent expenses were $395,000 and $1,625,000, respectively.

Licensing Fees and Costs

Licensing fees and costs consist primarily of costs relating to the acquisition of the Company's license agreement (the "Einstein License Agreement") with the Albert Einstein College of Medicine ("Einstein"), including related royalties, maintenance fees, milestone payments and product development costs. Licensing fees and costs are charged to research and development expense as incurred.

Long-Lived Assets

The Company reviews long-lived assets, consisting of property and equipment, for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs.

Leases

The Company accounts for leases under ASC 842, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability for most lease arrangements on the balance sheet. Under the standard, disclosure of key information about leasing arrangements to assist users of the financial statements with assessing the amount, timing and uncertainty of cash flows arising from leases are required.

Stock-Based Compensation

The Company periodically issues stock-based awards to officers, directors, employees, Scientific and Clinical Advisory Board members and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, employees, Scientific and Clinical Advisory Board members and consultants, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values. Stock option grants, which are generally time-vested, are measured at the grant date fair value and charged to operations on a straight-line basis over the service period, which generally approximates the vesting term. The Company also grants performance-based awards periodically to officers of the Company. The Company recognizes compensation costs related to performance awards over the requisite service period if and when the Company concludes that it is probable that the performance condition will be achieved.

The fair value of stock options and restricted stock units is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the life of the equity award, the exercise price of the stock option as compared to the fair value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award.

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading history for its common stock that approximates the expected term of the options, estimated volatility is based on the average historical volatility of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends and has no plans to do so for the foreseeable future. As permitted by Staff Accounting Bulletin No. 107, due to the Company's limited trading history and option activity, management

utilizes the simplified method to estimate the expected term of options at the date of grant. The exercise price is determined based on the fair value of our common stock at the date of grant. The Company accounts for forfeitures as they occur.

The Company recognizes the fair value of stock-based compensation in general and administrative expenses and in research and development expenses in the Company's consolidated statements of operations and comprehensive loss, depending on the type of services provided by the recipient of the equity award.

Comprehensive Income (Loss)

Components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Other comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss) are reported net of any related tax effect to arrive at comprehensive income (loss). Comprehensive income (loss) includes net income (loss) as well as changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income (loss) in periods presented was unrealized gain or loss on available-for-sale securities.

Earnings (Loss) Per Share

The Company's computation of earnings (loss) per share ("EPS") for the respective periods includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average number of common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares that would result from the exercise of outstanding stock options and warrants as if they had been exercised at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS. Basic and diluted loss per common share is the same for all periods presented because all outstanding stock options and warrants are anti-dilutive.

Per ASC 260-10-45-13, shares issuable for little to no consideration should be included in the number of outstanding shares used for basic EPS. The FASB proposed that warrants or options exercisable for little to no cost (sometimes referred to as "penny warrants") be included in the denominator of basic EPS (and therefore diluted EPS) once there were no further vesting conditions or contingencies associated with them. The Company included 1,531,440 pre-funded warrants in the denominator of basic EPS at September 30, 2023.

At September 30, 2023 and 2022, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	September 30,	
	2023	2022
Common stock warrants	10,719,846	789,358
Common stock options	7,500,480	6,268,729
Total	18,220,326	7,058,087

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active exchange-traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently traded non-exchange-based derivatives and commingled investment funds and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The Company had approximately $54,691,000 in cash equivalents as of September 30, 2023. The Company had approximately $45,423,000 in cash equivalents and approximately $24,675,000 in short-term marketable securities that were measured and recorded at fair value on the Company's balance sheet at December 31, 2022.

The carrying value of financial instruments (consisting of cash, a certificate of deposit, accounts payable, accrued compensation and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* (Topic 326) (CECL). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The new standard is effective for annual reporting periods beginning after December 15, 2022, including interim reporting periods within each annual reporting period for smaller reporting companies. The Company adopted ASU No. 2016-13 but there was no financial impact to the Company's consolidated financial statements for the year ended December 31, 2022 or for the nine months ended September 30, 2023.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

3. Fair Value

The Company accounts for its financial assets and liabilities using fair value measurements. The authoritative accounting guidance defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The following table presents information about the Company's assets that are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022, and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2023 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 54,691	$ —	$ —	$ 54,691
Marketable securities	—	$ —	—	—
Total	$ 54,691	$ —	$ —	$ 54,691

	Fair Value Measurements as of December 31, 2022 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 45,423	$ —	$ —	$ 45,423
Marketable securities	—	24,675	—	24,675
Total	$ 45,423	$ 24,675	$ —	$ 70,098

As of September 30, 2023, the Company reported approximately $54,691,000 in cash equivalents. The Company measures the cash equivalents that are invested in money market funds using Level 1 inputs for identical securities. The Company measures the fair value of marketable securities that are invested in U.S. Treasury securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. As of December 31, 2022, the Company reported approximately $45,423,000 and $24,675,000 in cash equivalents and marketable securities, respectively. During the three and nine months ended September 30, 2023, and the year ended December 31, 2022, there were no transfers between Level 2 and Level 3.

4. Marketable Securities

As of September 30, 2023, the Company had no marketable securities. The Company had marketable securities that consisted of $24,675,000 at December 31, 2022. The following table presents the Company's marketable securities at December 31, 2022:

	December 31, 2022			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	$ 24,771	$ —	$ (96)	$ 24,675
	$ 24,771	$ —	$ (96)	$ 24,675

At December 31, 2022, the Company's marketable securities consisted of $24,771,000 of investments that mature within 12 months and the Company recorded an unrealized loss on investments of $96,000 for the year ended December 31, 2022.

5. Property and Equipment

Property and equipment as of September 30, 2023 and December 31, 2022 consisted of the following:

	September 30, 2023	December 31, 2022
	(in thousands)	
Laboratory equipment	$ 5,205	$ 5,246
Furniture and fixtures	81	81
Computer and office equipment	296	296
Leasehold improvements	118	118
	5,699	5,741
Less accumulated depreciation	(4,635)	(4,242)
Net property and equipment	$ 1,064	$ 1,499

Depreciation expense for the three months ended September 30, 2023 and 2022 was approximately $128,000 and $198,000, respectively. Depreciation expense for the nine months ended September 30, 2023 and 2022 was approximately $434,000 and $630,000, respectively. Depreciation expense for the nine months ended September 30, 2023 excludes trademark amortization expense of approximately $9,000. Depreciation expense for the nine months ended September 30, 2022 excludes trademark amortization expense of approximately $9,000, and amortization of capitalized license expenses of approximately $80,000. During the nine months ended September 30, 2023, the Company sold fully depreciated lab equipment with an acquisition cost of $41,450 and collected cash of $2,000. The Company recorded a gain on the sale of fixed assets of $2,000, which is presented in other income on the consolidated statements of operations and other comprehensive loss. During the nine months ended September 30, 2022, the Company sold furniture and fixtures with an acquisition cost of $30,000 and collected cash of $5,800. The Company recorded a loss on the sale of fixed assets of $4,300, which is presented in other income on the consolidated statements of operations and other comprehensive loss.

6. Loan with Silicon Valley Bank

On February 15, 2022 (the “Closing Date”), the Company entered into a Loan and Security Agreement (the “Loan Agreement”), with Silicon Valley Bank, as lender (“SVB”). The Company drew $10,000,000 in term loans under the Loan Agreement (the "Term Loans") on the Closing Date. The Loan Agreement was amended in April 2023.

The Term Loans bear interest at a floating rate per annum equal to the greater of (A) the prime rate (as published in the money rates section of The Wall Street Journal) plus 2.25% and (B) 5.50%. The Term Loans were interest only from the Closing Date through June 30, 2023, after which the Company is required to pay 30 equal monthly installments of principal. At September 30, 2023, the interest rate was 10.75% based on the prime rate plus 2.25%.

The Term Loans may be prepaid in full prior to February 15, 2024 with payment of a 2.00% prepayment premium, on or after which they may be prepaid in full with payment of a 1.00% prepayment premium. Upon prepayment or repayment in full of the Term Loans, the Company will be required to pay a one-time final payment fee equal to 5.00% of the original principal amount of any funded Term Loans being repaid. This one-time final payment fee is recorded to interest expense using the effective interest method over the period of the Term Loans in the consolidated statements of operation and other comprehensive loss.

The Term Loans and related obligations under the Loan Agreement are secured by substantially all of the Company’s properties, rights and assets, except for its intellectual property which is subject to a negative pledge under the Loan Agreement.

The Loan Agreement contains customary representations, warranties, events of default and covenants, including a requirement that the Company maintain in accounts of the Company at SVB unrestricted and unencumbered cash equal to the lesser of all of the Company's cash or $20,000,000. On March 10, 2023, SVB was closed by state regulators and the Federal Deposit Insurance Company ("FDIC") was appointed receiver for the bank. The FDIC created a successor bridge bank, Silicon Valley Bridge Bank, N.A. ("SVBB") and all deposits of SVB were transferred to SVBB under a systemic risk exception approved by the U.S. Department of the Treasury, the Federal Reserve and the FDIC. SVBB continues to hold the Company's Term Loans under the same existing terms and covenants which were in place with SVB.

During the three and nine months ended September 30, 2023, the Company recognized interest expense related to the Term Loans of $254,000 and $848,000, respectively, and $33,000 and $98,000, respectively, in interest expense related to accretion of the final payment. During the three and nine months ended September 30, 2022, the Company recognized interest expense related to the Term Loans of $183,000 and $354,000, respectively, and $33,000 and $76,000 in interest expense related to accretion of the final payment for the three months and nine months ended September 30, 2022, respectively.

The following tables present the aggregate maturities of long-term and current portion of debt as of September 30, 2023 (in thousands):

Year	Aggregate Minimum Payments
2023	$ 1,000
2024	4,000
2025	4,000
Total maturities	$ 9,000

Total long-term debt	$ 5,000
Accretion of final payment	207
Less: unamortized debt issuance costs	(46)
Long-term debt, net	$ 5,160

Total current portion of long-term debt	$ 4,000
Less: unamortized debt issuance costs	(37)
Current portion of long-term debt, net	$ 3,963

Debt Issuance Costs

Debt issuance costs are deferred and presented as a reduction to long-term debt. Debt issuance costs are amortized using the effective interest rate method over the term of the loan. Amortization of deferred debt issuance costs are included in interest expense in the consolidated statements of operations and comprehensive loss. The Company incurred approximately $141,748 in debt issuance costs related to the Loan Agreement. For the three and nine months ended September 30, 2023, the Company recorded approximately $9,000 and $28,000, respectively, in amortization of debt issuance costs to interest expense in the consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2022, the Company recorded approximately $9,000 and $21,000, respectively, in amortization of debt issuance costs to interest expense in the consolidated statements of operations and comprehensive loss.

7. Stock-Based Compensation

Stock Option Valuation

For stock options requiring an assessment of value during the nine months ended September 30, 2023 and 2022, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	September 30, 2023
Risk-free interest rate	3.4% - 4.16%
Expected dividend yield	0%
Expected volatility	97.03% - 110.4%
Expected life	5.50 to 6.25 years

	September 30, 2022
Risk-free interest rate	1.53% - 2.92%
Expected dividend yield	0%
Expected volatility	92.1% - 95.7%
Expected life	5.50 to 6.25 years

A summary of stock option activity for the nine months ended September 30, 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2022	6,173,867	$ 9.60	5.05
Granted	2,576,900	3.65	—
Exercised	(165,602)	2.86	—
Cancelled	(1,084,685)	4.78	—
Stock options outstanding at September 30, 2023	7,500,480	8.40	6.35
Stock options exercisable at September 30, 2023	4,365,960	$ 10.38	4.54

The Company recognized approximately $2,073,000 and $6,108,000 in stock-based compensation expense during the three and nine months ended September 30, 2023, respectively, related to stock options activity. As of September 30, 2023, total unrecognized stock-based compensation expense was approximately $12,141,000, which is expected to be recognized as an operating expense in the Company's consolidated statement of operations and other comprehensive loss over the weighted average remaining period of 2.16 years. During the three months ended September 30, 2023, the Company granted stock options to purchase 1,115,000 shares of common stock with a weighted average grant date fair value of $4.17 per share. During the nine months ended September 30, 2023, the Company granted stock options to purchase 2,576,900 shares of common stock with a weighted average grant date fair value of $3.65 per share.

The Company recognized approximately $2,045,000 and $6,537,000 in stock-based compensation expense during the three and nine months ended September 30, 2022, respectively, related to stock options activity. As of September 30, 2022, total unrecognized stock-based compensation expense was approximately $13,856,000, which is expected to be recognized as an operating expense in the Company's consolidated statements of operations and other comprehensive loss over the weighted average remaining period of 2.13 years. During the three months ended September 30, 2022, the Company granted stock options to purchase 12,500 shares of common stock with a weighted average grant date fair value of $2.45 per share. During the nine months ended September 30, 2022, the Company granted stock options to purchase 828,500 shares of common stock with a weighted average grant date fair value of $6.99 per share.

The intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2023 was approximately $0, based on a weighted average grant date fair value of $10.38 per share on September 30, 2023.

Restricted Stock Units

On October 3, 2019, the Company granted 100,000 restricted stock units ("RSUs") with time-based vesting conditions to an executive officer having an average grant date fair value of $7.53 per share. The RSUs vested in three equal installments beginning on the grant date, and annually on each anniversary of the grant date thereafter. Compensation expense is recognized on a straight-line basis.

On February 5, 2020, the Company granted 150,000 RSUs with time-based vesting conditions to an executive officer. One-half of the RSUs vested on September 30, 2021, and the balance vested on March 31, 2022. On March 31, 2020, the Company granted 50,000 RSUs with time-based vesting conditions to an executive officer. The RSUs vested in three equal installments beginning on the grant date, and annually on each anniversary of the grant date thereafter. Compensation expense is recognized on a straight-line basis.

On August 21, 2020, the Company granted 20,000 RSUs with time-based vesting conditions to an executive officer. The RSUs vest in three equal installments beginning on the grant date, and annually on each anniversary of the grant date thereafter, subject to the recipient's continued service on each applicable vesting date. Compensation expense is recognized on a straight-line basis.

The Company recognized $0 in stock-based compensation during the three and nine months ended September 30, 2023 related to RSU activity. As of September 30, 2023, total unrecognized stock-based compensation was fully recognized as an operating expense in the Company's consolidated statements of operations and other comprehensive loss. The Company recognized approximately $19,000 and $847,000 in stock-based compensation during the three and nine months ended September 30, 2022, respectively, related to RSU activity. As of September 30, 2022, total unrecognized stock-based compensation was fully recognized as an operating expense in the Company's consolidated statements of operations and other comprehensive loss.

Stock-based Compensation

Stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022 was included in the Company's consolidated statements of operations and other comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
General and administrative	$ 858	$ 1,003	$ 2,708	$ 3,650
Research and development	1,215	1,061	3,399	3,734
Total	$ 2,073	$ 2,064	$ 6,108	$ 7,384

8. Warrants

The Company has one tranche of common stock warrants outstanding at September 30, 2023. The Company issued warrants exercisable for 1,500 shares of common stock on June 15, 2015 with an exercise price of $2.70 per share, which warrants expired at the end of their 7-year term on June 15, 2022. The Company issued another tranche of warrants exercisable for an aggregate of 882,071 shares of common stock with an exercise price of $9.38 per share when issued on December 27, 2017, which warrants expired at the end of their 5-year term on December 26, 2022. On November 16, 2022, the Company issued in a private placement 9,188,406 warrants with an exercise price of $3.93 and 1,531,440 pre-funded warrants.

Each tranche of warrants was evaluated under ASC 480, Distinguishing Liabilities from Equity, and ASC 815, *Derivatives and Hedging*, and the Company determined that equity classification was appropriate. The Company determined equity classification for both warrants and pre-funded warrants as they do not embody an obligation for the Company to repurchase its shares and permit the holders to receive a fixed number of shares of common stock upon exercise. Per ASC 815-40-25, the Company accounts for the warrants and pre-funded warrants as equity, as the Company does not provide the holder a fixed or guaranteed return.

The Company recorded cash received from 1,531,440 pre-funded warrants to additional paid in capital in the amount of $4,999,999. The Company recorded placement fees and expenses related to the sale of pre-funded warrants in the amount of $299,999 as a charge to additional paid in capital in the consolidated balance sheet at December 31, 2022.

Per ASC 260-10-45-13, shares issuable for little to no consideration should be included in the number of outstanding shares used for basic EPS. The FASB proposed that warrants or options exercisable for little to no cost (sometimes referred to as "penny warrants") be included in the denominator of basic EPS (and therefore diluted EPS) once there were no further vesting conditions or contingencies associated with them. The Company included 1,531,440 pre-funded warrants in the denominator of basic EPS at September 30, 2023.

The following table shows common stock warrants outstanding as of September 30, 2023:

	Warrant Issued November 16, 2022	Total
Balance at December 31, 2022	10,719,846	10,719,846
Issued via cashless exercises	—	—
Withheld as payment to cover issued shares	—	—
Expired	—	—
Issued	—	—
Balance at September 30, 2023	10,719,846	10,719,846

9. Collaboration Revenue

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and if, over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company's contracts may include options to acquire additional goods and/or services.

The terms of the Company's arrangements with customers typically include the payment of one or more of the following: (i) non-refundable, up-front payment, and pass through costs related to research activities, (ii) development, regulatory and commercial milestone payments, (iii) future options and (iv) royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of pass through costs and milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of the Company or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company reevaluates the probability of achievement of each milestone and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, the Company recognizes revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any development, regulatory or commercial milestones or royalty revenue resulting from any of its collaboration arrangements. Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

The Company allocates the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis, when applicable. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contact to the extent both of the following criteria are met: (i) the terms of the payment relate specifically to the efforts to satisfy the performance obligation or transfer the distinct good or service and (ii) allocating the variable amount of consideration entirely to the performance obligation or the distinct good or service is consistent with the allocation objective of the standard whereby the amount allocated depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services. The Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenues, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

Revenue is recognized based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good and/or service to the customer. For performance obligations that are satisfied over time, the Company recognizes revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. The Company uses input methods to measure progress toward the complete satisfaction of performance obligations satisfied over time. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. The Company measures progress toward satisfaction of the performance obligation over time as effort is expended.

Collaboration Agreement with LG Chem

On November 6, 2018, the Company entered into a collaboration agreement (the “LG Chem Collaboration Agreement”) with LG Chem Ltd. (“LG Chem”) related to the development of the Company’s Immuno-STATs focused in the field of oncology. Pursuant to the LG Chem Collaboration Agreement, the Company granted LG Chem an exclusive license to develop, manufacture and commercialize the Company’s lead product, CUE-101, as well as Immuno-STATs that target T cells against two additional cancer antigens, in certain Asian countries (collectively, the “LG Chem Territory”). On April 30, 2021, LG Chem’s option pursuant to the Global License and Collaboration Agreement entered into between the Company and LG Chem on December 18, 2019 and as amended on November 5, 2020 (the "Global License and Collaboration Agreement"), expired, and accordingly the Company no longer has any material obligations under the Global License and Collaboration Agreement. In June 2021, after ongoing discussions regarding the selection of the second of the two additional cancer antigens, LG Chem and the Company agreed to let the selection period expire without a second antigen being selected. The Company retains rights to develop and commercialize all assets included in the LG Chem Collaboration Agreement in the United States and in global markets outside of the LG Chem Territory. In exchange for the licenses and other rights granted to LG Chem under the LG Chem Collaboration Agreement, LG Chem made a $5.0 million equity investment in common stock of the Company and a $5.0 million nonrefundable up-front cash payment. The Company is also eligible to receive up to an additional $400.0 million in research, development, regulatory and sales milestones. In addition, the LG Chem Collaboration Agreement also provides that LG Chem will pay the Company tiered single-digit percentage royalties on net sales of commercialized drug product candidates in the LG Chem Territory.

On May 16, 2019, LG Chem paid the Company a $2.5 million milestone payment for the U.S. Food and Drug Administration’s (“FDA”) acceptance of the investigational new drug application (“IND”) for the Company’s lead drug product candidate, CUE-101, pursuant to the LG Chem Collaboration Agreement. The $2.5 million milestone payment was recorded as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Of the $2.5 million milestone payment, approximately $412,500 was recognized as tax withholding, shown as income tax expense on the consolidated statement of operations and other comprehensive loss.

On December 7, 2020, the Company earned a $1.25 million milestone payment on the selection of a pre-clinical candidate pursuant to the LG Chem Collaboration Agreement. The $1.25 million milestone payment was recorded as a contract liability upon receipt. Revenue related to this milestone payment was recognized by the Company pursuant to the Company’s revenue recognition policy in relation to the performance of its obligations related to the development of this pre-clinical candidate. Of the $1.25 million milestone payment, approximately $206,250 was withheld as payment of foreign tax withholding and shown as income tax expense on the consolidated statement of operations and other comprehensive loss.

On November 23, 2021, the Company earned a $3 million milestone payment for the selection of a clinical product candidate in partnership with LG Chem. The $3 million milestone payment was recorded as a contract liability upon receipt. Revenue related to this milestone payment was recognized by the Company pursuant to the Company’s revenue recognition policy in relation to the performance of its obligations related to the development of this preclinical candidate. Of the $3 million milestone payment,

approximately $495,000 was withheld as payment of foreign tax withholding and shown as income tax expense on the consolidated statements of operations and comprehensive loss. Cash was collected in relation to this milestone payment in February 2022.

Aside from the $6.75 million in milestone payments earned to date, the Company does not believe that any variable consideration should be included in the transaction price as of September 30, 2023. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur. For the three months ended September 30, 2023 and 2022, the Company recognized revenue of approximately $178,000 and approximately $68,000, respectively, related to the LG Chem Collaboration Agreement. For the nine months ended September 30, 2023 and 2022, the Company recognized revenue of approximately $243,000 and approximately $1,094,000, respectively, related to the LG Chem Collaboration Agreement. The Company did not record short- or long-term research and development liabilities on its balance sheet dated September 30, 2023 and December 31, 2022 as the performance obligation was met and completed. Research and development cost sharing provisions under the agreement expired on March 31, 2022.

Collaboration and Option Agreement with Ono

On February 22, 2023, the Company entered into a strategic collaboration agreement (the "Ono Collaboration and Option Agreement") with Ono Pharmaceutical Co., Ltd. ("Ono") to further develop CUE-401 and provide dedicated resources and capabilities to help advance CUE-401 toward the clinic. Under the terms of the Ono Collaboration and Option Agreement, Ono paid the Company an upfront payment and agreed to fully fund all research activities related to CUE-401 through a specified option period. During this option period, the Company will be responsible for the research and development of CUE-401. Upon Ono's exercise of its option to license CUE-401, the Company will receive an option exercise payment and be eligible for development and commercial milestone payments up to an aggregate of approximately $220 million, as well as tiered royalties on sales. Upon any such exercise, Ono will receive worldwide rights to develop and commercialize CUE-401, with the Company retaining a 50% co-development and co-commercialization right in the United States.

Under the terms of the Ono Collaboration and Option Agreement, the Company will perform research activities related to CUE-401 through a specified option period of 24 months (the "Research Term"). During this Research Term, the Company will be responsible for the execution of scientific investigation, nonclinical, preclinical, and clinical drug research and development activities designed to progress CUE-401 toward a potential IND and regulatory approval (such activities, collectively referred to as "R&D"). Ono is responsible for the funding of R&D activities performed by the Company. Per the agreement, as consideration for the R&D activities performed by the Company, Ono (i) made a one-time, non-refundable, non-creditable upfront payment of $3.0 million to the Company and (ii) will reimburse the Company for all costs incurred in conducting research, including (a) pass through costs from third party contractors and (b) full time employee salaries capped at $2.1 million in the first 18 months of the Research Term. The term of the Ono Collaboration and Option Agreement extends until the expiration of the Research Term which cannot exceed a 24-month period. The Company has forecasted that it will be able to complete the R&D activities in 18 months based on the initial research and development plans it has established. The Company received the $3.0 million upfront payment in March 2023.

Aside from the $3.0 million upfront payment and funding related to pass through costs, the Company does not believe that any variable consideration should be included in the transaction price as of September 30, 2023. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent the Company had a high degree of confidence that revenue would not be reversed in a subsequent reporting period. The Company will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur. For the three months ended September 30, 2023 and 2022, the Company recognized revenue of approximately $1,922,000 and $0, respectively, related to the Ono Collaboration and Option Agreement. For the nine months ended September 30, 2023 and 2022, the Company recognized revenue of approximately $3,426,000 and $0, respectively, related to the Ono Collaboration and Option Agreement. The Company recorded short-term research and development liabilities on its balance sheet dated September 30, 2023, of approximately $2,238,000. The Company did not recognize short or long-term research and development liabilities on its balance sheet as of December 31, 2022, as the agreement was executed in February 2023.

Capitalization of Contract Costs

The Company considered the capitalization of contract costs under the guidance in ASC 340-40, *Other Assets and Deferred Costs: Contracts with Customers*. As it related to the LG Chem Collaboration Agreement, the Company capitalized license expenses of approximately $908,000 as of September 30, 2023, paid to Einstein pursuant to the Einstein License Agreement which requires the Company to pay a percentage of sublicenses related to the Company's patent rights for components of its core technology that is

licensed from Einstein. This amount is comprised of approximately $438,000 of capitalized license expenses related to the up-front payment received from LG Chem in December 2018, approximately $313,000 in capitalized license expenses related to the milestone payment received in June 2019, and approximately $157,000 in capitalized license expenses related to the milestone payment received in December 2020, net of accumulated amortization on all capitalized license expenses of approximately $908,000. As of September 30, 2023 and December 31, 2022, no capitalized license expenses net of accumulated amortization were included in prepaid expenses and other short-term assets related to the LG Chem Collaboration Agreement.

10. Commitments and Contingencies

Einstein License Agreement

In 2015, the Company entered into the Einstein License Agreement with Einstein for certain patent rights relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory drug product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides. The Company entered into an amended and restated license agreement on July 31, 2017, as amended on October 2018, which modified certain obligations of the parties under the Einstein License Agreement. For each of the three months ended September 30, 2023 and 2022, the Company incurred $0 in fees and expenses to Einstein related to this license. For each of the nine months ended September 30, 2023 and 2022, the Company incurred $0 in fees and expenses to Einstein related to this license.

The Company's remaining commitments with respect to the Einstein License Agreement are based on the attainment of future milestones. The aggregate amount of milestone payments made under the Einstein License Agreement may equal up to $1.85 million for each product, process or service that use the patents covered by the Einstein License Agreement, including certain technology received from Einstein related thereto (the "Licensed Product"), and up to $1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products may equal up to $5.75 million. The Company is also party to a material transfer agreement with Einstein focusing on infectious disease and assessing the application of the Company's Neo-STAT asset for the treatment of infectious disease.

Collaboration Agreement with LG Chem

See discussion of the LG Chem Collaboration Agreement in Note 9.

Collaboration Agreement with Ono

See discussion of the Ono Collaboration and Option Agreement in Note 9.

Contingencies

The Company accrues contingent liabilities to the extent that the liability is probable and estimable. There are no accruals for contingent liabilities in the Company's consolidated financial statements.

The Company may be subject to various legal proceedings from time to time as part of its business. As of September 30, 2023, the Company was not a party to any legal proceedings or threatened legal proceedings, the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on its business, financial condition or results of operations.

11. Leases

On March 28, 2022, the Company entered into a License Agreement (the "License") with MIL 40G, LLC (the "Licensor"), pursuant to which the Company leases approximately 13,000 square feet of office, research and development and laboratory space located at 40 Guest Street, Boston, Massachusetts 02135 (the "Premises"). The Company relocated its corporate headquarters to the Premises in April 2022. On March 28, 2022, the Company terminated its office and lab space lease in Cambridge Massachusetts (the "Laboratory and Office Lease") effective April 30, 2022. The Company performed an analysis of the accounting implications of this termination based on ASC 360 Impairments and Abandonments guidance. At March 31, 2022, the Company recorded an adjustment to decrease the right-of-use asset and lease liability of approximately $8,124,000 and $8,382,000, respectively, and recorded a gain on right-of-use asset termination included in the consolidated statement of operations and other comprehensive loss of approximately $258,000.

The Company recognized a right of use asset of approximately $9,056,000 and an operating lease liability of approximately $9,056,000 which were recorded as of the Term Commencement Date (as defined below) related to the License.

The term of the License commenced on April 15, 2022 (the “Term Commencement Date”) and expires on April 14, 2026 (the “Term”). The License has a monthly rental rate of $200,700 for the first year of the Term, $208,728 for the second year of the Term, $217,077 for the third year of the Term and $225,760 for the remainder of the Term. Pursuant to the License, the Company prepaid two months of rent and a security deposit. The Licensor is obligated under the License to provide certain services to the Company, including providing certain gases, chemicals and equipment to the Premises’ laboratory space, IT support, security, office support and health and safety training. The Licensor has the right to terminate the License for Cause (as defined in the License).

On May 3, 2022, the Company entered into the First Amendment to the License ("First Amendment”) with the Licensor, pursuant to which the License was expanded to include an additional room effective July 15, 2022. In consideration of the First Amendment, the security deposit was increased from $225,760 to $235,884 effective July 15, 2022. Upon execution of the First Amendment, the Company prepaid three months of rent, two of which will be held in escrow and credited against future rent payments and the other of which was applied to the first month’s rent. Effective July 15, 2022, the monthly rental rate under the First Amendment increased to $209,700 from $200,700. The Company recognized a right of use asset of approximately $369,000 and a short- and long-term operating lease liability of approximately $100,300 and $260,600, respectively, using the weighted average discount rate of 8%, which were recorded as of the Term Commencement Date related to the License.

On May 31, 2022, the Company entered into an operating lease for additional laboratory space at 40 Guest Street, Boston, Massachusetts for the period from December 1, 2022 through December 1, 2024 (the “40G Additional Laboratory Lease”). The 40G Additional Laboratory Lease contains escalating payments during the lease period. The monthly rental rate under the 40G Additional Laboratory Lease is $59,152 for the first 12 months and $61,519 for the remainder of the term. Under the terms of this lease agreement, the Company prepaid three months of rent, two of which will be held in escrow and credited against future rent payments and the other of which was applied to the first month’s rent. The Company recognized a right of use asset of approximately $1,307,000 and a short- and long-term operating lease liability of approximately $712,000 and $535,000, respectively, using the weighted average discount rate of 10%, which were recorded as of the Term Commencement Date related to the 40G Additional Laboratory Lease.

On September 9, 2022, the Company terminated its lab space lease in Cambridge, Massachusetts with MIL 21E, LLC with an effective termination date of December 6, 2022. The Company performed an analysis of the accounting implications of this termination based on ASC 360 Impairments and Abandonment guidance. The Company recorded an entry to remove the remaining lease liability and right of use asset of $963,000 and $945,000, respectively. The difference between the carrying amounts of the right of use asset and lease liability of $19,000 was recorded at termination in September 2022, to gain on right of use asset and included in the consolidated statements of operations and other comprehensive loss.

For the three and nine months ended September 30, 2023, the Company recorded approximately $122,000 and $402,000, respectively, in non-cash interest expense to the lease liability. For the three and nine months ended September 30, 2022, the Company recorded approximately $146,000 and $309,000, respectively, in non-cash interest expense to the lease liability.

At September 30, 2023, the Company recorded approximately $7,060,000 to operating lease right-of-use asset, and approximately $3,399,000 and $3,855,000 to the short-term and long-term operating lease liability, respectively. At December 31, 2022, the Company recorded approximately $9,203,000 to operating lease right-of-use asset, and approximately $3,300,000 and $6,018,000 to short-term and long-term operating lease liability, respectively. As of September 30, 2023 and December 31, 2022, a security deposit of approximately $595,000 was included in deposits on the Company’s consolidated balance sheet related to the 40G Additional Laboratory Lease. Cash was collected in the amount of $0 and approximately $199,000 for the Company's former Cambridge 21 Erie Laboratory space during the three and nine months ended September 30, 2023, respectively.

Future minimum lease payments under the leases in effect at September 30, 2023 are as follows:

Year	(in thousands)
2023 (3 months remaining)	835
2024	3,368
2025	2,799
2026	818
Total lease payments	$ 7,820
Less: present value discount	(566)
Total	$ 7,254

Total rent expense of approximately $853,000 and $860,000 was included in the consolidated statements of operations and other comprehensive loss for the three months ended September 30, 2023 and 2022, respectively. Total rent expense of approximately $2,566,000 and $3,309,000 was included in the consolidated statements of operations and other comprehensive loss for the nine months ended September 30, 2023 and 2022, respectively. Other information pertaining to the Company's operating leases for the three and nine months ended September 30, 2023 is summarized in the table below.

Other information	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases (in thousands)	$ (709)	$ (2,064)
Operating lease cost (in thousands)	$ 853	$ 2,566
Weighted average discount rate	5.75%	5.75%
Weighted average remaining lease term	2.39 years	2.39 years

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

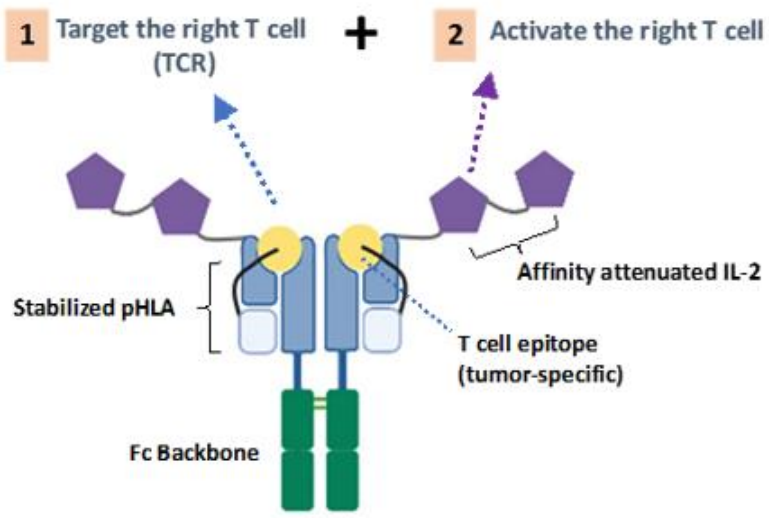
The following Management's Discussion and Analysis of Financial Condition and Results of Operations of Cue Biopharma, Inc. and its subsidiary ("Cue Biopharma", "we", "us", "our" or the "Company") should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 21, 2023, or the 2022 Annual Report.

Overview

We are a clinical-stage biopharmaceutical company developing a novel series of T cell engagers, termed Immuno-STAT™ (*Selective Targeting and Alteration of T Cells*), that are engineered to selectively engage and modulate disease-relevant T cells while avoiding the deleterious side effects of non-selective, systemic immune activation. This unique property of selectivity provides Immuno-STATs with the potential for providing superior clinical efficacy along with favorable tolerability. We believe that Immuno-STATs, as described below, build upon our core expertise in rational protein engineering to emulate nature's signals, or "cues", for selective T cell modulation. We believe our proprietary Immuno-STAT platform, as described below, will enable us to enhance the potential of the patient's own immune system to restore health while avoiding the negative side effects of broad indiscriminate immune activation, in the case of cancer, and broad immune suppression in the case of autoimmune disease. Our selective immune modulation approach may be deployed for treating cancer, autoimmune diseases and chronic infections. In addition to the selective modulation of T cell activity, we believe core features of Immuno-STATs offer differentiated competitive advantages, including modularity, manufacturability, and convenient administration enabling the versatility to treat a broad range of disease. The unique property of Immuno-STATs to be T cell receptor, or TCR, -selective engagers provides core strategic advantages and differentiation from other classes of non-specific T cell engagers, as highlighted below.

The core framework of an Immuno-STAT molecule has a stabilized peptide human leukocyte antigen, or pHLA, component that selectively engages T cells harboring TCRs for binding to the tumor-specific peptide-HLA complex (representing Signal 1 in the orange box of the image below). In addition, Immuno-STATs contain activating signals (representing Signal 2 in the orange box of the image below), including modified interleukin 2, or IL-2, in the case of the CUE-100 series, the first series from our biologics platform, that can be selectively delivered to tumor-specific T cells. We believe Immuno-STATs provide an attractive solution for generation of a therapeutic index for immune activation signals, such as IL-2. The unique property of Immuno-STATs as TCR-selective engagers provides core strategic advantages and differentiation from other classes of non-specific T cell engagers, due to the targeting of specific TCRs via Signal 1, as highlighted below.

The Immuno-STAT Framework: CUE-100 Series



We believe the data generated from our ongoing clinical trials with CUE-101, our lead clinical drug product candidate from our IL-2 based CUE-100 series, has demonstrated the potential of the Immuno-STAT platform to improve cancer patient outcomes beyond that of the current standard of care. As described below, CUE-101 has demonstrated evidence of anti-tumor activity in our ongoing clinical trials through selective activation of the anti-cancer T-cells repertoires. Furthermore, CUE-101 has demonstrated a favorable tolerability profile in approximately 80 patients treated to date with doses of up to 8mg/kg. Importantly, the CUE-101 neoadjuvant trial that is currently being conducted by Washington University School of Medicine in patients with newly diagnosed, locally advanced oropharyngeal squamous-cell carcinoma will allow for the evaluation of the tumor tissue microenvironment, or TME, pre and post treatment to shed mechanistic insights into the anti-tumor cellular response. In addition to our encouraging CUE-101 clinical data generated to date, we also have emerging data from our ongoing Phase 1 dose escalation trial of CUE-102, which further enhances our confidence in the platform's versatility and potential for addressing a broad range of cancer types. Through these ongoing trials, we continue to develop datasets differentiating the CUE-100 series Immuno-STATs from competing approaches.

We have also recently observed promising preclinical data pertaining to the potential application of our platform for the treatment of a broad range of autoimmune diseases. In February 2023 we announced the establishment of a strategic collaboration with Ono Pharmaceuticals Co., Ltd., or Ono, focused on the development of CUE-401 for the potential treatment of autoimmune and inflammatory diseases through the induction and expansion of regulatory T cells, or Tregs.

Our drug product candidates are in various stages of clinical and preclinical development. The emerging preliminary clinical data for CUE-101 and CUE-102 bolsters our belief that we have developed a potential breakthrough approach for modulating cancer-specific T cells directly in the patient’s body. However, our activities are also subject to significant risks and uncertainties. We have not yet commenced any commercial revenue-generating operations, have limited cash flows from operations, and will need to access substantial additional capital to fund our growth and ongoing business operations.

Our Pipeline

The pipeline chart below details our current portfolio of oncology and autoimmune assets and their stages of development. In oncology, we have prioritized and strategically focused resources on our CUE-101 and CUE-102 programs in our IL-2 based CUE-100 series, and we are actively assessing strategic options for third party support through partnerships and collaborations, or alternative funding structures, to further develop CUE-103 and our Neo-STAT™ and RDI-STAT™ programs.

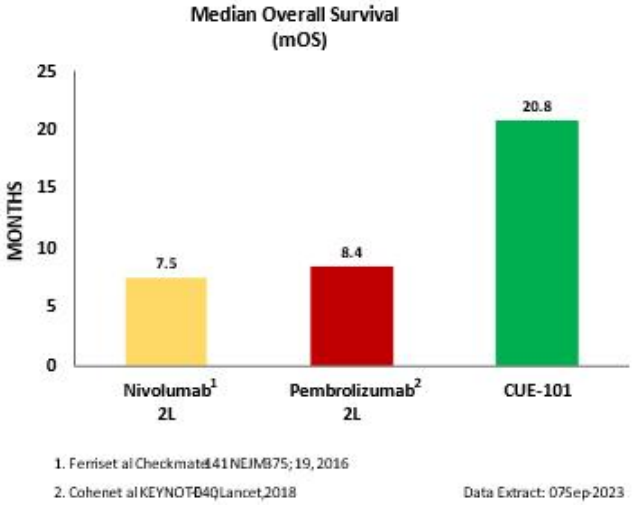
We continue to progress forward in our strategic collaboration with Ono to develop CUE-401, a preclinical IL-2/transforming growth factor beta (TGF-beta) based drug product candidate for autoimmune disease. Based on its unique mechanism of action, we believe CUE-401 has the potential to be a highly differentiated molecule for the induction and expansion of Tregs, and is distinct from the vast majority of other IL-2 muteins that are being pursued in this space. We are also assessing strategic alternatives for furthering the development of our CUE-300 series for the treatment of specific autoimmune diseases, such as type 1 diabetes and celiac disease.

CUE-101

CUE-101 is our most advanced clinical stage asset in oncology and is being investigated for the treatment of human papillomavirus positive, or HPV+, head and neck cancer. We completed enrollment of the patient expansion phase of our monotherapy Phase 1 clinical trial of CUE-101 at the 4 mg/kg recommended Phase 2 dose, or RP2D, for the treatment of third line, or 3L, and beyond recurrent/metastatic head and neck squamous cell cancer, or R/M HNSCC patients. These patients had received and failed several prior lines of systemic therapy, including chemotherapy and checkpoint inhibitors, or CPIs, such as KEYTRUDA®. Patients at this stage of disease progression have a high unmet medical need for alternative therapies that can extend life without the often severe side effects of traditional cancer therapies.

In this non-comparator monotherapy trial, CUE-101 has demonstrated evidence of anti-tumor clinical activity as a single agent, a favorable tolerability profile and an extension of median overall survival, or mOS. Of the 19 evaluable patients treated at the RP2D of 4 mg/kg, we observed a confirmed partial response, or PR, lasting for more than 36 weeks as well as six patients with durable stable disease, defined as stable disease on at least two consecutive post-treatment scans lasting at least 12 weeks. We have also observed promising preliminary data with respect to CUE-101's pharmacokinetic, or PK, and pharmacodynamic, or PD, profile, as well as biomarker data with respect to HPV circulating free DNA, or cfDNA, as a potential proxy of anti-tumor response. Of note, one of the patients demonstrated stable disease for 24 months with no detectable evidence of HPV cfDNA in their blood after commencing treatment with CUE-101 and demonstrated an unconfirmed PR at the end of therapy. Importantly, a long overall survival has been observed in patients treated with CUE-101 as a monotherapy in 3L and beyond. For the patients treated at the RP2D in the monotherapy expansion cohort, the current Kaplan-Meier, or KM, estimate of mOS is 20.8 months, which compares favorably to the historical mOS of approximately eight months that was observed with pembrolizumab as a monotherapy in second line patients in Merck Sharp & Dohme Corp.'s, or Merck's, KEYNOTE-040 trial and the historical mOS of approximately seven months that was observed with nivolumab as a monotherapy in the CHECKMATE 141 trial sponsored by Bristol-Myers Squibb. We continue to follow the patients treated in the monotherapy trial and anticipate this overall survival data to continue to mature through 2023.

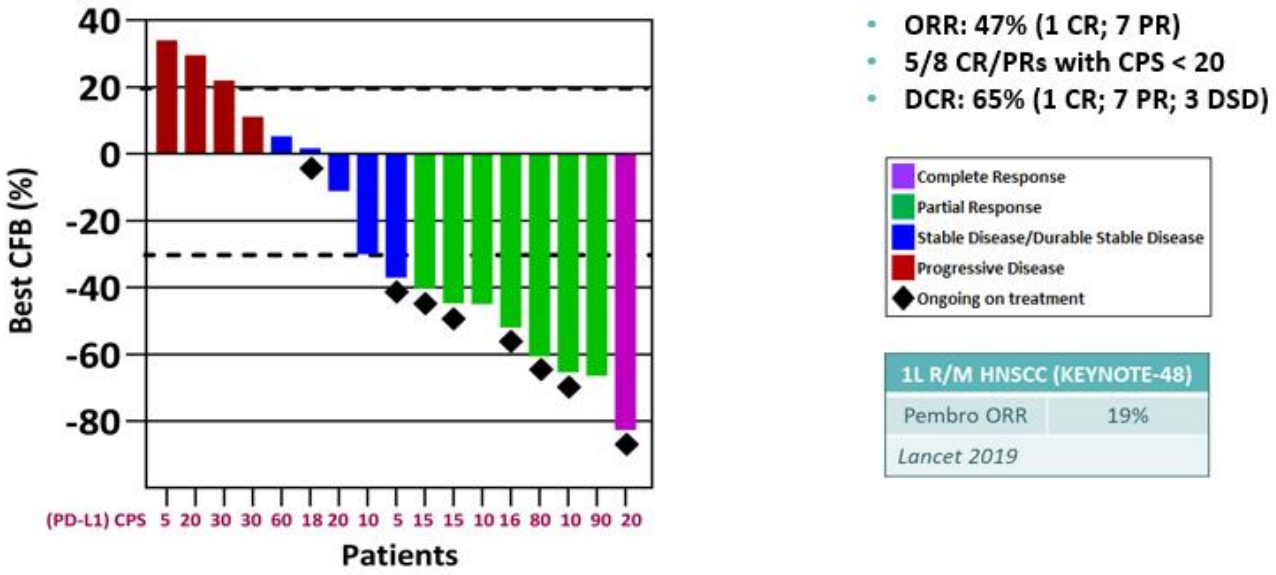
CUE-101 Monotherapy in 3L+ R/M HNSCC: Kaplan-Meier mOS Estimate 20.8 Months



We have completed enrollment in our Phase 1 trial of CUE-101 in combination with Merck's anti-PD-1 therapy KEYTRUDA (pembrolizumab), the current standard of care for first line, or 1L, R/M HNSCC. We completed the dose escalation portion of this trial without observing any dose-limiting-toxicity and enrolled patients in the patient expansion phase at the RP2D dose of 4 mg/kg of CUE-101 in combination with the approved dose of KEYTRUDA. The waterfall plot below was presented at the Society for Immunotherapy of Cancer, or SITC, meeting in November 2023. As shown below, as of the September 27, 2023 data cut-off date, the

overall response rate, or ORR, based on the best change from baseline, or CFB, in the sum of diameters of target lesions with best overall response as measured by RECIST 1.1 in the trial is 47% in the 17 evaluable patients treated with combination therapy at the RP2D of 4 mg/kg of CUE-101 and 200 mg of KEYTRUDA, including one patient with a confirmed complete response, or CR, and seven additional patients with confirmed PRs with a disease control rate, or DCR, of 65%, calculated by adding patient overall responses, partial responses and stable disease . The ORR of 47% in all patients with a combined positive score, or CPS, of ≥ 1, which reflects the levels of PD-L1 expression in the tumor, compares favorably to the historical ORR of 19% observed in all patients with CPS of ≥ 1 treated with pembrolizumab monotherapy in Merck's KEYNOTE-048 trial. Notably, five out of the eight objective responses in the CUE-101 Phase 1 combination trial with pembrolizumab were observed in patients with tumors with low PD-L1 expression, as evidenced by CPS of less than 20, i.e. an ORR of 56% versus 14% historical ORR observed in patients with CPS>1 and <20 treated with pembrolizumab monotherapy in Merck's KEYNOTE-048 trial.

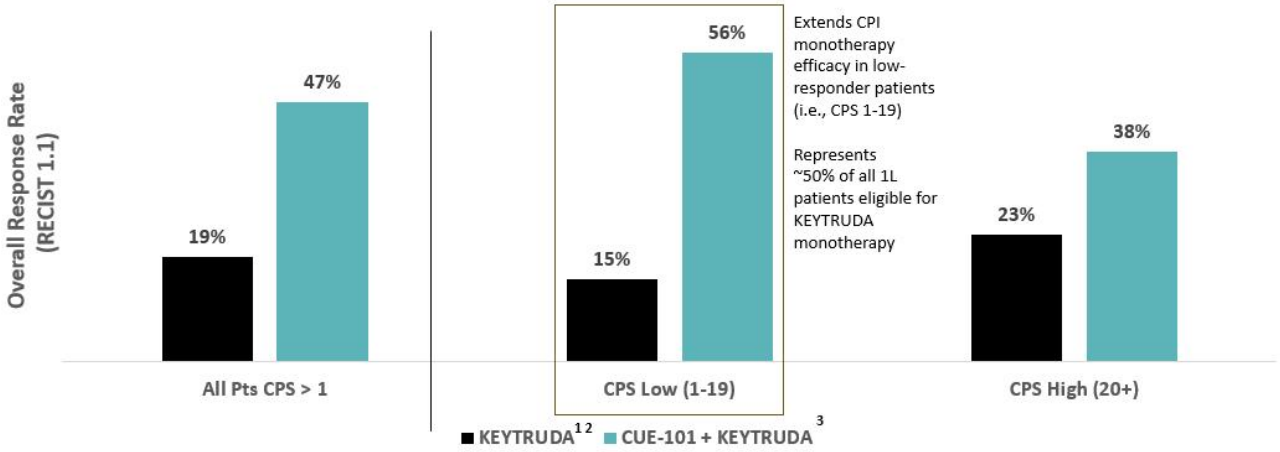
CUE-101 in Combination with Pembrolizumab in 1L R/M HNSCC (data cut-off date September 27, 2023)



As shown below, patients with low CPS (1-19) treated with pembrolizumab alone in the KEYNOTE-48 trial had a lower ORR than all treated patients with CPS ≥1. Patients with low CPS (1-19), treated with CUE-101 and pembrolizumab in our ongoing Phase 1 combination trial demonstrated an ORR of 56%, compared to approximately 15% observed with pembrolizumab monotherapy in the KEYNOTE-048 trial. We believe that this supports the premise that CUE-101 and pembrolizumab given in combination could expand patient reach in HPV16+ R/M HNSCC patients with low PD-L1 expression. This is particularly important since patients with low CPS scores (CPS 1-19) represent approximately 50% of all patients that are CPS positive.

First-line (1L) R/M HNSCC Treated with CUE-101 4mg/kg in Combination with Pembrolizumab

vs. Pembrolizumab Monotherapy



Source: 1) KEYNOTE-048 Study Burtness B et al, Lancet 2019. 2) Harrington et al J Clin Oncol 41:790-802, 2022. 3) CUE-101 SITC Poster Nov 2023

We believe the evidence of combination activity of CUE-101 with KEYTRUDA is likely due to their complementary mechanisms of action, enabling anti-tumor T cells to effectively recognize and kill target tumor cells. We believe that CUE-101 has the potential to enhance the clinical activity of KEYTRUDA as well as other CPIs since the presence of expanded tumor-specific T cells is an obligatory pre-requisite for anti-PD-1 therapy. As such, we believe that CUE-101 has the potential to expand patient reach and enhance the therapeutic benefit of CPIs. On October 3, 2022, we received Fast Track Designation of CUE-101 for the treatment of R/M HPV+ HNSCC as a monotherapy and in combination with KEYTRUDA. As the data from the CUE-101 monotherapy trial and CUE-101 in combination with pembrolizumab trial matures, we are working to define potential registration paths for CUE-101, including a planned meeting with the FDA regarding CUE-101 as a monotherapy.

Importantly, it is our position that the CUE-101 clinical data generated to date has reduced the risk profile of the entire IL-2 based CUE-100 series due to the core framework of the CUE-100 series being conserved for each drug product candidate, with the only substantive modification being the targeting peptide epitope within the human leukocyte antigen, or HLA, pocket. Therefore, the core IL-2 scaffold is a shared molecular feature of all molecules generated within this series, including CUE-102 as described below which shares 99% sequence identity with CUE-101.

CUE-102

The second drug product candidate in our CUE-100 series, CUE-102, targets Wilms' Tumor 1 protein, or WT1, an oncofetal antigen known to be over-expressed in more than 20 different cancers, including both solid tumors (such as colorectal, ovarian, pancreatic, gastric and lung tumors) and hematologic malignancies (such as acute myeloid leukemia, multiple myeloma and myelodysplastic syndromes). Based on the premise that CUE-102 shares the same core molecular framework as CUE-101, except for the T cell epitope pertaining to HPV-E7 versus WT1, its IND was supported by clinical and safety data from the ongoing CUE-101 monotherapy trial and did not require additional IND-enabling toxicology studies. This supports our premise that each CUE-100 series Immuno-STAT molecule provides further de-risking and acceleration of subsequent drug product candidates. With CUE-102 we believe there is a potential to reach an even larger patient population than for CUE-101 as WT1 can potentially treat a broad range of cancer types with significant unmet medical need. We are enrolling patients in a Phase 1 monotherapy dose-escalation trial with CUE-102 focused on WT1-positive recurrent/metastatic gastric, pancreatic, ovarian and colorectal cancers. As of October 1, 2023, 18 patients have received CUE-102 in doses ranging from 1 mg/kg to 8 mg/kg given every three weeks, 14 of the patients have at least one post dose scan and were evaluable for disease response and nine remain on treatment. CUE-102 has been well tolerated with no dose limiting toxicities observed.

As shown below, a DCR of 75-80% has been observed in patients treated with 2 mg/kg and 4 mg/kg of CUE-102. Monotherapy anti-tumor activity observed as of the data cut-off date of October 1, 2023 includes decreases in target tumor lesions, decreases in tumor biomarkers and durable stable disease in several patients.

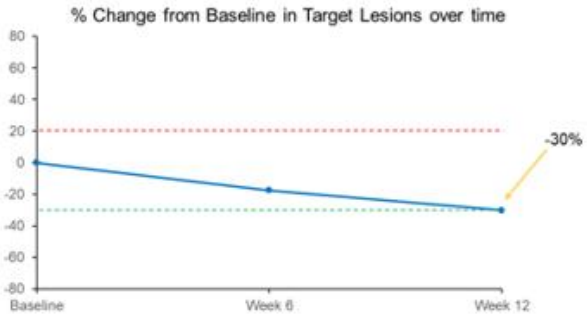
CUE-102 Monotherapy Patient Status by Cohort (as of data cut-off date)

Patient Status to Date by Cohort					
Cohort	Treated	Evaluable	SD	DCR	Status
C1 (1 mg/kg)	3	3	1	33%	0/3 on treatment
C2 (2 mg/kg)	6	5	4	80%	3/6 on treatment
C3 (4 mg/kg)	5	4	3	75%	4/5 on treatment
C4 (8 mg/kg)	4	2	1	50%	2/4 on treatment

Two patients in dose escalation cohort 2 (treated with 2 mg/kg of CUE-102) demonstrated reductions in target tumor lesions as shown in the figures below. Both of these patients remain on treatment at the time of data cut-off. Both patients have advanced disease and were heavily pre-treated prior to enrollment in the CUE-102 monotherapy trial.

Tumor Reduction Observed in Heavily Pre-treated Gastric Cancer Patient treated with CUE-102 2 mg/kg

Tumor Reduction Observed in Heavily Pre-treated Ovarian Cancer Patient treated with CUE-102 2 mg/kg



We anticipate opening the patient expansion cohort, or the Phase 1b portion of the trial, in patients with colorectal cancers as well as other indications in early 2024.

We believe that the modularity of our CUE-100 series platform enables the generation of new drug product candidates for tumor antigens that have already been clinically validated in adoptive cellular therapy approaches, resulting in further potential de-risking and accelerated development of future molecules to address a broad range of cancer types. For example, we have generated preclinical proof of concept data supporting the manufacturability and selective biologic activity of Immuno-STATs targeting mutated driver antigens (such as KRAS) and broadly expressed cancer antigens (such as MAGE-A4 and PRAME). These Immuno-STAT molecules contain peptide antigens presented on different HLA alleles, including HLA-A02, -A03, and -A11. Generating Immuno-STATs across these additional HLA alleles will enhance potential patient coverage and market reach globally. Based on the successful validation of the modularity of the core Immuno-STAT scaffold, multiple potential Immuno-STAT candidate molecules may be considered for nomination as subsequent clinical development programs. We are also exploring the application of our Immuno-STAT platform to CAR-T and TCR-T therapies to further expand and maintain T-cell levels in the patient's body to potentially increase efficacy of these therapies.

Furthermore, we have expanded the potential reach of the Immuno-STAT platform to address the heterogeneity and diversity present in many cancers by developing a derivative scaffold of the CUE-100 series containing stable “peptide-less” or “empty” HLA molecules, to which defined peptides of interest may be covalently attached. We refer to this derivative scaffold as Neo-STAT™. Neo-STAT is designed to provide greater flexibility for targeting multiple tumor epitopes, enhancing production efficiencies, and decreasing time and cost associated with manufacturing. We have also generated a derivative biologic designed to address a primary resistance mechanism found in a subset of solid tumors. This escape mechanism is based upon evading immune surveillance through down-regulation of HLA, thereby making the tumor “invisible” to T cells. This derivative of the CUE-100 series, referred to as RDI-STAT™, takes advantage of the clinical validation of the Immuno-STAT platform via the CUE-100 series by deploying an antibody-like targeting moiety binding to tumor specific antigens found on the surface of tumor cells. Through this approach, we believe we may be able to “paint” the tumor with a viral epitope placed within the HLA pocket of the CUE-100 series Immuno-STAT with the

objective of "redirecting" high frequency anti-viral T cells to attack the targeted tumor cells. As noted above, we are seeking partnerships to further develop our Neo-STAT and RDI-STAT assets.

In addition to these novel potential approaches to cancer immunotherapy, we have leveraged the modularity of the Immuno-STAT platform to develop additional biologic series outside of oncology. For example, CUE-300 and CUE-400 have been specifically designed through rational protein engineering to address distinct therapeutic approaches for treating autoimmune disease. The CUE-300 series incorporates the inhibitory PD-L1 co-modulator for selective inhibition of an autoreactive T cell repertoire. For example, CUE-301 has been engineered with an epitope known to be expressed in Type 1 diabetes. The CUE-400 series represents a novel class of bispecific molecules designed to selectively induce and expand Tregs. In February 2023, we announced a partnership with Ono supporting the development of CUE-401 for the potential treatment of autoimmune and inflammatory diseases.

Plan of Operation

Our technology is in the development phase. We believe that our platforms have the potential for creating a diverse pipeline of promising drug product candidates addressing multiple medical indications. We intend to maximize the value and probability of commercialization of our Immuno-STAT drug product candidates by focusing on researching, testing, optimizing, conducting pilot studies, performing early-stage clinical development and potentially partnering, where appropriate, for more extensive, later stages of clinical development, as well as seeking extensive patent protection and intellectual property development.

Since we are a development-stage company, the majority of our business activities to date have been, and our planned future activities will be, devoted to furthering research and development.

A fundamental part of our corporate development strategy is to establish strategic partnerships with leading pharmaceutical or biotechnology organizations that will allow us to more fully exploit the potential of our technology platform in the areas of oncology and autoimmune disease and accelerate and expand our CUE-100 series pipeline, such as our collaborations described below under the heading “Collaboration Agreement with LG Chem" and "Collaboration and Option Agreement with Ono”.

Critical Accounting Estimates and Significant Judgments

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones 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 value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the estimates, assumptions and judgments involved in the accounting policies described in Management’s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our 2022 Annual Report have the greatest potential impact on our financial statements, so we consider those estimates, assumptions and judgments to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2023.

Recent Accounting Pronouncements and Adopted Standards

A discussion of recent accounting pronouncements is included in Note 2 to our consolidated financial statements in this Quarterly Report on Form 10-Q.

Significant Contracts and Agreements Related to Research and Development Activities

Einstein License Agreement

On January 14, 2015, we entered into a license agreement, as amended and restated on July 31, 2017, and as amended on October 30, 2018, or the Einstein License, with Albert Einstein College of Medicine, or Einstein, for certain patent rights, or the Patents, relating to our core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory drug product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides.

We hold an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the Patents, including certain technology received from Einstein related thereto, which we refer to as the Licensed Products. Under the Einstein License, we are required to:

- Pay royalties and amounts based on a certain percentage of proceeds, as defined in the Einstein License, from sales of Licensed Products and sublicense agreements.
- Pay escalating annual maintenance fees, which are non-refundable, but are creditable against the amount due to Einstein for royalties.
- Make significant payments based upon the achievement of certain milestones, as defined in the Einstein License. As of September 30, 2023, two of these milestones had been achieved, as we had filed an IND in 2019, and initiated the investigator sponsored Phase 1b neoadjuvant clinical trial for CUE-101 in 2021.
- Incur minimum product development costs per year and meet certain diligence obligations until the first commercial sale of the first Licensed Product.

As of September 30, 2023, we were in compliance with our obligations under the Einstein License.

The Einstein License expires upon the expiration of the last obligation to make royalty payments to Einstein which may be due with respect to certain Licensed Products, unless terminated earlier under the provisions thereof. The Einstein License includes certain termination provisions that will be triggered if we fail to meet our obligations thereunder.

We account for the costs incurred in connection with the Einstein License in accordance with Accounting Standards Codification, or ASC, 730, *Research and Development*. For each of the three months ended September 30, 2023 and 2022, costs incurred with respect to the Einstein License were $0. For each of the nine months ended September 30, 2023 and 2022, costs incurred with respect to the Einstein License were $0. Such costs, if any, are included in research and development costs in our consolidated statements of operations and other comprehensive loss.

Pursuant to the Einstein License, we issued to Einstein 671,572 shares of our common stock in connection with the consummation of the initial public offering of our common stock on December 27, 2017.

Collaboration Agreement with LG Chem

Effective November 6, 2018, we entered into a Collaboration, License and Option Agreement, or the LG Chem Collaboration Agreement, with LG Chem Ltd., or LG Chem, related to the development of Immuno-STATs focused in the field of oncology.

Pursuant to the LG Chem Collaboration Agreement, we granted LG Chem an exclusive license to develop, manufacture and commercialize our lead product, CUE-101, as well as Immuno-STATs that target T cells against two additional cancer antigens, or the Drug Product Candidates, in Australia, Japan, Republic of Korea, Singapore, Malaysia, Vietnam, Thailand, Philippines, Indonesia, China (including Macau and Hong Kong) and Taiwan, which we refer to collectively as the LG Chem Territory. We retain rights to develop and commercialize all assets included in the LG Chem Collaboration Agreement in the United States and in global markets outside of the LG Chem Territory. Under the LG Chem Collaboration Agreement, we will engineer the selected Immuno-STATs for up to three alleles, which are expected to include the predominant alleles in the LG Chem Territory, thereby enhancing our market reach by providing for greater patient coverage of populations in global markets, while LG Chem will establish a chemistry, manufacturing and controls, or CMC, process for the development and commercialization of selected Drug Product Candidates. In addition, LG Chem has the option to select one additional Immuno-STAT for an oncology target, or an Additional Immuno-STAT, for an exclusive worldwide development and commercialization license. On December 18, 2019, we and LG Chem entered into a global license and collaboration agreement, which was amended on November 5, 2020. We refer to such agreement, as amended, as the Global License and Collaboration Agreement. The Global License and Collaboration Agreement supersedes the provisions of the LG Chem Collaboration Agreement related to LG Chem's option for an Additional Immuno-STAT, which agreement provided for effectiveness if and when LG Chem exercised its option, other than certain select provisions including the length of the option period and representations, warranties and covenants of the parties. On April 30, 2021, LG Chem's option pursuant to the Global License and Collaboration Agreement expired.

Under the terms of the LG Chem Collaboration Agreement, LG Chem paid us a $5.0 million non-refundable, non-creditable upfront payment and purchased approximately $5.0 million of shares of our common stock at a price per share equal to a 20% premium to the volume weighted-average closing price per share over the 30 trading day period immediately prior to the effective date of the LG Chem Collaboration Agreement. We are also eligible to receive additional aggregate payments of up to approximately $400.0 million if certain research, development, regulatory and commercial milestones are successfully achieved. On May 16, 2019, we earned a $2.5 million milestone payment for the FDA's acceptance of the IND for our lead drug product candidate, CUE-101,

pursuant to the LG Chem Collaboration Agreement. On December 7, 2020, we earned a $1.25 million milestone payment on the selection of a preclinical candidate pursuant to the LG Chem Collaboration Agreement. On November 23, 2021, we earned a $3.0 million milestone payment for the selection of a Drug Product Candidate. In addition, the LG Chem Collaboration Agreement also provides that LG Chem will pay us tiered single-digit royalties on net sales of commercialized Drug Product Candidates, or Collaboration Products, in the LG Chem Territory on a product-by-product and country-by-country basis, until the later of expiration of patent rights in a country, the expiration of regulatory exclusivity in such country, or ten years after the first commercial sale of a Collaboration Product in such country, subject to certain royalty step-down provisions set forth in the LG Chem Collaboration Agreement.

Pursuant to the LG Chem Collaboration Agreement, the parties will share research costs related to Collaboration Products, and LG Chem will provide CMC process development for selected Drug Product Candidates and potentially additional downstream manufacturing capabilities, including clinical and commercial supply for Collaboration Products. In return for performing CMC process development, LG Chem is eligible to receive low-single digit percentage royalty payments on the sales of Collaboration Products sold in all countries outside the LG Chem Territory. For the three months ended September 30, 2023 and 2022, we recognized revenue of approximately $178,000 and approximately $68,000, respectively, related to the LG Chem Collaboration Agreement. For the nine months ended September 30, 2023 and 2022, we recognized revenue of approximately $243,000 and approximately $1,094,000, respectively, related to the LG Chem Collaboration Agreement. As of September 30, 2023, we had recorded approximately $19.8 million in collaboration revenue related to this agreement since the agreement was entered into. The majority of the research phase of the collaboration agreement was substantially complete on March 31, 2022.

The LG Chem Collaboration Agreement includes various representations, warranties, covenants, indemnities and other customary provisions. LG Chem may terminate the LG Chem Collaboration Agreement for convenience or change of control of us on a program-by-program, product-by-product or country-by-country basis, or in its entirety, at any time following the notice period set forth in the LG Chem Collaboration Agreement. Either party may terminate the LG Chem Collaboration Agreement, in its entirety or on a program-by-program, product-by-product or country-by-country basis, in the event of an uncured material breach. The LG Chem Collaboration Agreement is also terminable by either party (i) upon the bankruptcy, insolvency or liquidation of the other party or (ii) for certain activities involving the challenge of certain patents controlled by the other party. Unless earlier terminated, the LG Chem Collaboration Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the applicable royalty term.

To date, LG Chem has selected one additional cancer antigen, WT1, which is the focus of the CUE-102 research program. We are currently developing two Collaboration Products with LG Chem pursuant to this agreement.

Collaboration and Option Agreement with Ono

On February 22, 2023, we entered into a strategic collaboration agreement, or the Ono Collaboration and Option Agreement, with Ono Pharmaceutical Co., Ltd., or Ono, to further develop CUE-401 and provide dedicated resources and capabilities to help advance CUE-401 toward the clinic. Under the terms of the Ono Collaboration and Option Agreement, Ono paid us an upfront payment and agreed to fully fund all research activities related to CUE-401 through a specified option period. During this option period, we will be responsible for the research and development of CUE-401. Upon Ono's exercise of its option to license CUE-401, we will receive an option exercise payment and be eligible for development and commercial milestone payments up to an aggregate of approximately $220 million, as well as tiered royalties on sales. Upon any such exercise, Ono will receive worldwide rights to develop and commercialize CUE-401, with us retaining a 50% co-development and co-commercialization right in the United States.

Under the terms of the Ono Collaboration and Option Agreement, we will perform research activities related to CUE-401 through a specified option period of 24 months, or the Research Term. During this Research Term, we will be responsible for the execution of scientific investigation, nonclinical, preclinical, and clinical drug research and development activities designed to progress CUE-401 toward a potential IND and regulatory approval, collectively referred to as R&D. Ono is responsible for the funding of R&D activities performed by us. Per the Ono Collaboration and Option Agreement, as consideration for the R&D activities performed by us, Ono (i) made a one-time, non-refundable, non-creditable upfront payment of $3.0 million to us and (ii) will reimburse us for all costs incurred in conducting research, including (a) pass through costs from third party contractors and (b) full time employee salaries capped at $2.1 million in the first 18 months of the Research Term. The term of the Ono Collaboration and Option Agreement extends until the expiration of the Research Term which cannot exceed a 24-month period. We have forecasted that we will be able to complete the R&D activities in 18 months based on the initial research and development plans we have established. We received the $3.0 million upfront payment in March 2023.

Aside from the $3.0 million upfront payment and funding related to pass through costs, we do not believe that any variable consideration should be included in the transaction price as of September 30, 2023. Such assessment considered the application of the constraint to ensure that estimates of variable consideration would be included in the transaction price only to the extent we have had a

high degree of confidence that revenue would not be reversed in a subsequent reporting period. We will re-evaluate the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as other changes in circumstances occur. For the three months ended September 30, 2023 and 2022, we recognized revenue of approximately $1,922,000 and $0, respectively, related to the Ono Collaboration and Option Agreement. For the nine months ended September 30, 2023 and 2022, we recognized revenue of approximately $3,426,000 and $0, respectively, related to the Ono Collaboration and Option Agreement. We recorded short-term research and development liabilities on our balance sheet dated September 30, 2023, of approximately $2,238,000. We did not recognize short- or long-term research and development liabilities on our balance sheet as of December 31, 2022, as the agreement was executed in February 2023.

Results of Operations

Collaboration Revenue

We have not generated commercial revenue from product sales. To date, we have generated collaboration revenue from our former collaboration agreement with Merck, the LG Chem Collaboration Agreement and the Ono Collaboration and Option Agreement. Collaboration revenue may vary from period to period depending on the progress of our work in connection with either or both of our collaboration agreements.

Operating Expenses

We generally recognize operating expenses as they are incurred in two general categories, general and administrative expenses and research and development expenses. Our operating expenses also include non-cash components related to depreciation and amortization of property and equipment and stock-based compensation, which are allocated, as appropriate, to general and administrative expenses and research and development expenses.

General and administrative expenses consist of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as professional fees, insurance costs, and other general corporate expenses. We expect general and administrative expenses to increase in future periods as we incur additional expenses related to our operation as a public company which requires our compliance with certain regulatory and legal procedures. We expect activities supporting our operations including legal, accounting, insurance, employee compensation and other expenses to increase.

Research and development expenses consist primarily of compensation expenses, fees paid to consultants, outside service providers and organizations (including research institutes at universities), facility expenses, and development and clinical trial expenses with respect to our drug product candidates. We charge research and development expenses to operations as they are incurred. We expect research and development expenses to increase in the future as we continue to advance the clinical development of CUE-101 and CUE-102, including our ongoing and planned clinical trials, and develop potential future drug product candidates based on our technology and research. We also believe that rising inflation, supply chain disruptions and labor shortages may also contribute to increased research and development costs.

Three and Nine Months Ended September 30, 2023 and 2022

Our consolidated statements of operations and other comprehensive loss for the three and nine months ended September 30, 2023 and 2022, as discussed herein, are presented below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Collaboration revenue	$ 2,100	$ 68	$ 3,669	$ 1,094
Operating expenses:				
General and administrative	3,645	3,528	12,071	12,465
Research and development	9,874	7,571	29,915	27,246
Gain on right-of-use asset termination	—	—	—	(258)
Total operating expenses	13,519	11,099	41,986	39,453
Loss from operations	(11,419)	(11,031)	(38,317)	(38,359)
Other (expense) income:				
Interest income, net	700	200	1,756	296
Interest expense, net	(286)	(124)	(738)	(355)
Total other (expense) income	414	76	1,018	(59)
Net loss	$ (11,005)	$ (10,955)	$ (37,299)	$ (38,418)
Unrealized gain (loss) from available-for-sale securities	5	(92)	96	(92)
Comprehensive loss	$ (11,000)	$ (11,047)	$ (37,203)	$ (38,510)
Net loss per common share – basic and diluted	$ (0.24)	$ (0.31)	$ (0.82)	$ (1.11)
Weighted average common shares outstanding –basic and diluted	46,358,555	35,383,430	45,274,124	34,471,499

Collaboration Revenue

Collaboration revenue was approximately $2,100,000 and $68,000 for the three months ended September 30, 2023 and 2022, respectively. We recognized collaboration revenue of $3,669,000 and $1,094,000 for the nine months ended September 30, 2023 and 2022, respectively. The increase of approximately $2,032,000 and $2,575,000 during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022, respectively, was due to the Ono Collaboration and Option Agreement executed in February 2023. All collaboration revenue recognized in the three and nine months ended September 30, 2023 was related to the performance of services under our collaboration agreements with Ono and LG Chem, including a $3.0 million upfront payment received pursuant to the Ono Collaboration and Option Agreement and pass through costs related to research activities. All collaboration revenue recognized in the three and nine months ended September 30, 2022 was related to the performance of services under our collaboration agreement with LG Chem.

General and Administrative

General and administrative expenses totaled approximately $3,645,000 and $3,528,000 for the three months ended September 30, 2023 and 2022, respectively. This increase of approximately $117,000 during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was due primarily to higher professional and consulting fees, offset by a decrease in rent expense.

General and administrative expenses for the three months ended September 30, 2023 consisted of expenses related to employee and board compensation of $1,209,000, professional and consulting fees of $1,071,000, stock-based compensation of $858,000, rent of $173,000, insurance expense of $71,000 and other expenses of $263,000. General and administrative expenses for the three months ended September 30, 2022 consisted of expenses related to employee and board compensation of $1,140,000, stock-based compensation of $1,003,000, professional and consulting fees of $906,000, rent of $182,000, insurance expense of $95,000 and other expenses of $202,000.

General and administrative expenses totaled approximately $12,071,000 and $12,465,000 for the nine months ended September 30, 2023 and 2022, respectively. This decrease of approximately $394,000 during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was due primarily to lower stock-based compensation related to executive management.

General and administrative expenses for the nine months ended September 30, 2023 consisted of expenses related to employee and board compensation of $4,100,000, professional and consulting fees of $3,833,000, stock-based compensation of $2,708,000, rent

of $544,000, insurance expense of $227,000, and other expenses of $659,000. General and administrative expenses for the nine months ended September 30, 2022 consisted of expenses related to employee and board compensation of $3,682,000, stock-based compensation of $3,650,000, professional and consulting fees of $3,555,000, rent of $716,000, insurance expense of $267,000, and other expenses of $595,000.

Research and Development

Research and development expenses totaled approximately $9,874,000 and $7,571,000 for the three months ended September 30, 2023 and 2022, respectively. This increase of approximately $2,303,000 during the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was due primarily to higher clinical expenses, stock-based compensation and research and laboratory expenses.

Research and development expenses for the three months ended September 30, 2023 included expenses related to clinical expenses of $3,429,000, employee and board compensation of $2,272,000, research and laboratory expenses of $1,560,000, stock-based compensation expense of $1,215,000, rent expense of $679,000, insurance expense of $203,000, depreciation and amortization of $126,000, and other expenses of $390,000. Research and development expenses for the three months ended September 30, 2022 included expenses related to employee compensation of $2,368,000, clinical expenses of $1,495,000, research and laboratory expenses of $1,286,000, stock-based compensation expense of $1,061,000, rent of $677,000, insurance expense of $252,000, depreciation and amortization of $196,000, and other expenses of $236,000.

Research and development expenses totaled approximately $29,915,000 and $27,246,000 for the nine months ended September 30, 2023 and 2022, respectively. This increase of approximately $2,669,000 was due primarily to clinical expenses related to the CUE-101 clinical trial and expenses related to the initiation of the Phase 1 monotherapy clinical trial of CUE-102. Rising inflation, supply chain disruptions, and labor shortages may also contribute to future increases in research and development expense.

Research and development expenses for the nine months ended September 30, 2023 included expenses related to research and laboratory expenses of $7,736,000, employee and board compensation of $7,404,000, clinical expenses of $7,029,000, stock-based compensation of $3,399,000, rent expense of $2,022,000, insurance expense of $615,000, other professional fees of $539,000, depreciation and amortization of $426,000, and other expenses of $745,000. Research and development expenses for the nine months ended September 30, 2022, included expenses related to employee compensation of $7,920,000, research and laboratory expenses of $5,619,000, clinical expenses of $4,570,000, stock-based compensation of $3,734,000, rent of $2,592,000, insurance expense of $756,000, depreciation and amortization of $687,000, and other expenses of $1,368,000.

Gain on Right-of-use Asset Termination

Gain on right-of-use asset termination was $0 and $258,000 for the three and nine months ended September 30, 2023 and 2022, respectively. This decrease of $258,000 was due to the gain on right-of-use asset related to the termination of our operating lease agreement for our laboratory and office space in Cambridge, Massachusetts at 21 Erie Street, effective on April 30, 2022.

Interest Income

Interest income was approximately $700,000 for the three months ended September 30, 2023 as compared to approximately $200,000 for the three months ended September 30, 2022. Interest income for the three months ended September 30, 2023 included approximately $576,000 in income resulting from amortization of discounts received on certain of our marketable securities and approximately $124,000 of interest income from our operating sweep account, compared to approximately $200,000 of interest income for the three months ended September 30, 2022.

Interest income was approximately $1,756,000 for the nine months ended September 30, 2023 as compared to approximately $296,000 for the nine months ended September 30, 2022. Interest income for the nine months ended September 30, 2023 included approximately $1,490,000 in income resulting from amortization of discounts received on certain of our marketable securities and approximately $266,000 of interest income from our operating sweep account, compared to approximately $296,000 of interest income for the nine months ended September 30, 2022.

Interest Expense

Interest expense was approximately $286,000 and $124,000 for the three months ended September 30, 2023 and 2022, respectively. This increase of $162,000 was primarily due to cash paid for interest expense related to the proceeds from borrowings under our Loan and Security Agreement, as amended, or the Loan Agreement, with Silicon Valley Bridge Bank, N.A., or SVBB, of

$288,000, and amortization of deferred issuance costs of $9,000, offset by approximately $11,000 from amortization/accretion on investments.

Interest expense was approximately $738,000 and $355,000 for the nine months ended September 30, 2023 and 2022, respectively. This increase of $383,000 was primarily due to cash paid for interest expense related to the proceeds from borrowings under the Loan Agreement with SVBB of $946,000, and amortization of deferred issuance costs of $28,000, offset by cash received on the sale of property and equipment of $2,000 and approximately $234,000 from amortization/accretion on investments.

Liquidity and Capital Resources

We have financed our working capital requirements primarily through private and public offerings of equity securities, cash received from Merck, LG Chem, and Ono under the respective collaboration agreements and borrowings under the Loan Agreement. At September 30, 2023, we had cash and cash equivalents totaling $54,691,000 available to fund our ongoing business activities. Additional information concerning our financial condition and results of operations is provided in the financial statements included in this Quarterly Report on Form 10-Q.

The amounts that we actually spend for any specific purpose may vary significantly and will depend on a number of factors, including, but not limited to, our research and development activities and programs, clinical testing, regulatory approval, market conditions, and changes in or revisions to our business strategy and technology development plans.

On May 9, 2023, we filed a registration statement on Form S-3, which was declared effective on May 26, 2023 (File No. 333-271786), to register for sale from time to time up to $300.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and/or units in one or more offerings.

In October 2021, we entered into an open market sale agreement, or the October 2021 ATM Agreement, with Jefferies LLC, or Jefferies, to sell shares of our common stock for aggregate gross proceeds of up to $80.0 million, from time to time, through an "at-the-market" equity offering program under which Jefferies acts as sales agent. The October 2021 ATM Agreement will terminate upon the earliest of (a) the sale of $80.0 million of shares of our common stock pursuant to the October 2021 ATM Agreement or (b) the termination of the October 2021 ATM Agreement by us or Jefferies. During the three months ended September 30, 2023,we sold 1,378,867 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $5,589,000 net of commission paid, but excluding transaction expenses. During the nine months ended September 30, 2023, we sold 1,915,131 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $7,605,000, net of commission paid, but excluding transaction expenses. As of September 30, 2023, we had sold an aggregate of 5,508,538 shares of common stock under the October 2021 ATM Agreement for proceeds of approximately $31.2 million, net of commission paid, but excluding transaction expenses, since its inception.

On February 15, 2022, we entered into the Loan Agreement, pursuant to which we have borrowed $10.0 million. The Loan Agreement was amended in April 2023. The term loans under the Loan Agreement, or the Term Loans, bear interest at a floating rate per annum equal to the greater of (A) the prime rate (as published in the money rates section of The Wall Street Journal) plus 2.25% and (B) 5.50%. On the first calendar day of each month, we will be required to make monthly interest payments and commencing on June 30, 2023, we are required to repay the Term Loans in (i) 30 consecutive installments of principal plus monthly payments of accrued interest if the additional term loans are not advanced and (ii) 24 months if the additional term loans are advanced. All outstanding principal and accrued and unpaid interest under the Term Loans and all other outstanding obligations with respect to the Term Loans are due and payable in full on December 1, 2025.

The Loan Agreement permits voluntary prepayment of all, but not less than all, of the Term Loans, subject to a prepayment premium except if the facility is refinanced with another SVBB facility. Such prepayment premium would be 2.00% of the principal amount of the Term Loans if prepaid on or after the first anniversary of the date on which we entered the Loan Agreement but prior to the second anniversary of the date on which we entered the Loan Agreement, and 1.00% of the principal amount of the Term Loans if prepaid on or after the second anniversary of the date on which we entered the Loan Agreement. Upon prepayment or repayment in full of the Term Loans, we will be required to pay a one-time final payment fee equal to 5.00% of the original principal amount of any funded Term Loans being repaid. The Loan Agreement also requires us to maintain in our accounts at the Lender unrestricted and unencumbered cash equal to the lesser of all of our cash or $20,000,000.

On March 10, 2023, Silicon Valley Bank, or SVB, was closed and the Federal Deposit Insurance Company, or FDIC, was appointed receiver for the bank. The FDIC created a successor bridge bank, SVBB, and all deposits of SVB were transferred to SVBB under a systemic risk exception approved by the U.S. Department of the Treasury, the Federal Reserve and the FDIC. SVBB continues to hold our Term Loans under the same existing terms and covenants which were in place with SVB. The vast majority of our cash and cash equivalents reside in custodial accounts at US Bank for which SVB Asset Management is the advisor.

On November 14, 2022, we entered into securities purchase agreements with accredited investors pursuant to which, on November 16, 2022, we issued and sold to such investors in a private placement an aggregate of 7,656,966 shares of common stock and, in lieu of shares of common stock to certain investors, pre-funded warrants, or Pre-Funded Warrants, to purchase an aggregate of 1,531,440 shares of common stock, and, in each case, accompanying warrants, or Warrants, to purchase an aggregate of up to 9,188,406 additional shares of common stock (or Pre-Funded Warrants in lieu thereof) at a price of $3.265 per share and accompanying Warrant (or $3.2649 per Pre-Funded Warrant and accompanying Warrant), or the PIPE Financing. The exercise price of the Warrants is $3.93 per share, or if exercised for a Pre-Funded Warrant in lieu thereof, $3.9299 per Pre-Funded Warrant. The Warrants are exercisable at any time after they are issued and ending on the fifth anniversary of the closing. The Pre-Funded Warrants are exercisable at any time after they are issued and will not expire. We received aggregate gross proceeds from the PIPE Financing of approximately $30 million, before deducting placement agent fees and offering expenses of $2.6 million. Piper Sandler & Co. acted as lead placement agent and Public Ventures LLC acted as co-placement agent for the PIPE Financing.

If we issue additional equity securities to raise funds, the ownership percentage of our existing stockholders would be reduced. New investors may demand rights, preferences or privileges senior to those of existing holders of our common stock. If we issue debt securities, we may be required to grant security interests in our assets, could have substantial debt service obligations, and lenders may have a senior position (compared to stockholders) in any potential future bankruptcy or liquidation. Additionally, corporate collaboration and licensing arrangements may require us to incur non-recurring and other charges, give up certain rights relating to our intellectual property and research and development activities, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, issue debt which may require liens on our assets and which will increase our monthly expense obligations, or disrupt our management and business.

Cash Flows

The following table summarizes our changes in cash, cash equivalents, and restricted cash for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (29,003)	$ (31,292)
Investing activities	25,002	(29,609)
Financing activities	7,078	26,256
Net increase in cash, cash equivalents, and restricted cash	$ 3,077	$ (34,645)

Operating Activities

During the nine months ended September 30, 2023 and 2022, we used cash of $29,003,000 and $31,292,000, respectively, to fund our operating activities. Cash used in operating activities during the nine months ended September 30, 2023 consisted primarily of our net loss of $37,299,000 and decreases of $2,064,000 in operating lease liability, $1,603,000 in accounts receivable, $324,000 in prepaid expenses and other current assets, $251,000 in accounts payable, $234,000 in amortization of discount on purchased securities and $2,000 in gain on sale of property and equipment. Cash used in operating activities was offset by increases of $6,108,000 in stock-based compensation, $2,238,000 in research and development contract liability, $2,142,000 in amortization of operating lease right-of-use asset, $1,573,000 in accrued expenses, $443,000 in depreciation and amortization, $139,000 in deposits, $98,000 in accretion on final payment of Term Loans, $28,000 in amortization of debt issuance costs and $5,000 in accrued interest.

Cash used in operating activities during the nine months ended September 30, 2022 consisted primarily of our net loss of $38,418,000 and decreases of $741,000 in accrued expenses, $645,000 in research and development contract liability, $258,000 in gain on right-of-use asset termination, $546,000 in accounts payable, $395,000 in deposits, $397,000 in operating lease liability, $101,000 in amortization of discount on purchased securities, $3,000 in accrued interest on purchased securities, and $846,000 in prepaid expenses and other current assets. Cash used in operating activities was partially offset by increases of $7,384,000 in stock-based compensation, $507,000 in amortization of operating lease right-of-use asset, $21,000 in amortization of debt issuance costs, $76,000 in accretion on final payment of Term Loans, $719,000 in depreciation and amortization, $2,347,000 in accounts receivable, and $4,000 in loss on disposal of fixed assets.

Investing Activities

During the nine months ended September 30, 2023, our investing activities provided $25,002,000 in cash, compared to cash used in investing activities of $29,609,000 during the nine months ended September 30, 2022. Cash provided in investing activities during the nine months ended September 30, 2023 consisted of the net redemption of short-term investments in marketable securities of $25,000,000 and the cash received from the sale of property and equipment of $2,000. Cash used in investing activities during the nine months ended September 30, 2022 consisted of the purchase of property and equipment of $170,000, and the purchase of short-term investments in marketable securities of $29,500,000, offset by cash received from the sale of fixed assets of $6,000.

Financing Activities

During the nine months ended September 30, 2023 and 2022, we generated cash from financing activities of $7,078,000 and $26,256,000, respectively, a decrease of $19,178,000. Cash from financing activities during the nine months ended September 30, 2023 consisted of cash proceeds from the sale of common stock pursuant to the October 2021 ATM Agreement of $7,605,000 net of sales agent commissions and fees, and cash proceeds from the exercise of stock options of $473,000. Cash from financing activities during the nine months ended September 30, 2022 consisted of cash proceeds from the sale of common stock pursuant to the October 2021 ATM Agreement of $16,598,000 net of sales agent commissions and fees, and proceeds from borrowings under the Loan Agreement of $10,000,000, partially offset by cash used for restricted stock buy-back at vesting of $200,000 and payment of debt issuance costs of $142,000.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of our Immuno-STAT platform, continue ongoing and initiate new clinical trials of and seek marketing approval for our drug product candidates. In addition, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- continue the clinical development of our CUE-100 series, including CUE-101 and CUE-102;
- leverage our programs to advance our other drug product candidates into preclinical and clinical development;
- seek regulatory approvals for any drug product candidates for which we successfully complete clinical trials;
- seek to discover and develop additional drug product candidates in the CUE-100 series, including Neo-STATs;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any drug product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, quality control and scientific personnel;
- expand our manufacturing, quality, operational, financial and management systems;
- increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drug product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating as a public company.

In the first quarter of 2022, we prioritized our strategic focus on our CUE-101 and CUE-102 oncology programs in our CUE-100 series. The data generated from our ongoing clinical trials provides a sound basis for establishing strategic partnerships to enhance our capacity by subsidizing development of these highly promising programs. We are actively seeking third party support through partnerships and collaborations, or alternative funding structures, to more fully exploit the potential of our technology platform in the areas of oncology and autoimmune disease, accelerate and expand our CUE-100 series pipeline including the further development of CUE-103 and our Neo-STAT and RDI-STAT programs as well as our CUE-300 and CUE-400 series. In 2022, we also took proactive steps to decrease our office and lab footprint and to restructure our research and development functions in support of prioritized corporate objectives and strategies. These steps have realized cost savings to date that have been allocated to our key programs.

We believe that our existing cash and cash equivalents as of September 30, 2023 will enable us to fund our operating requirements for at least the next 12 months. 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.

We will need to raise additional capital or incur additional indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, many of which are outside of our control, and we may be unable to raise financing when needed, or on terms favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market drug product candidates that we would otherwise prefer to develop and market ourselves, which could adversely affect our business prospects, and we may be unable to continue our operations. Because of numerous risks and uncertainties associated with the research, development and commercialization of our drug product candidates, we are unable to estimate the exact amount of our working capital requirements. Factors that may affect our planned future capital requirements and accelerate our need for additional working capital include the following:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our ongoing, planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA and other comparable regulatory authorities, including the potential that the FDA or other comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the number and characteristics of drug product candidates that we may in-license and develop;
- our ability to successfully commercialize our drug product candidates, if approved;
- the amount of sales and other revenues from drug product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other drug product candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- any disputes which may occur between us and Einstein, employees, collaborators or other prospective business partners; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these or other variables with respect to the development of any of our drug product candidates could significantly change the costs and timing associated with the development of that drug product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties and grants from organizations and foundations. If we raise additional funds by selling shares of our common stock or other equity-linked securities, the ownership interest of our current stockholders will be diluted. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or drug product candidates or to grant licenses on terms that may not be acceptable to us. If we raise additional funds through debt financing, we may have to grant a security interest on our assets to the future lenders, our debt service costs may be substantial, and the lenders may have a preferential position in connection with any future bankruptcy or liquidation.

If we are unable to raise additional capital when needed, we may be required to curtail the development of our technology or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail, dissolve and liquidate with little or no return to investors.

Principal Commitments

During the three and nine months ended September 30, 2023, there were no material changes to our contractual obligations and commitments as of December 31, 2022 described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2022 Annual Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective as of September 30, 2023, the end of the period covered by this report.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and our principal financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of control effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2023 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

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In evaluating us and our business, you should carefully consider the information included in this Quarterly Report on Form 10-Q and in other documents we file with the SEC and the risk factors previously disclosed in "Part I, Item 1A. Risk Factors" of our 2022 Annual Report.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit	Filing Date	Registration/File No.
10.1	Amendment No. 1 to Consulting Agreement between Cue Biopharma, Inc. and Peter A. Kiener, dated September 1, 2023	X				
31.1	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
31.2	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS	Inline eXtensible Business Reporting Language (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.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X				
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, has been formatted in Inline XBRL.	X				

SIGNATURES

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

Cue Biopharma, Inc.

Dated: November 3, 2023

By: /s/ Daniel R. Passeri

Daniel R. Passeri
Chief Executive Officer
(Principal Executive Officer)

Dated: November 3, 2023

By: /s/ Kerri-Ann Millar

Kerri-Ann Millar
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 10.1

AMENDMENT NO. 1 TO CONSULTING AGREEMENT

THIS AMENDMENT NO. 1 TO CONSULTING AGREEMENT (this "Amendment No. 1") effective September 1, 2023 is entered into between Cue Biopharma, Inc., a Delaware corporation having an address of 40 Guest Street, Boston MA 02135 (the "Company"), and Peter Kiener D.Phil, ("Consultant") whose address is [**}. Company and Consultant may be referred to herein individually as "Party" or jointly as "Parties."

Whereas the Parties executed a Consulting Agreement having an effective date of June 7, 2023, and now wish to revise Exhibit A of the Consulting Agreement to amend the monthly retainer to be provided to the Consultant, the Parties hereby agree as follows:

1. Exhibit A is amended as follows:

Consultant will provide agreed upon services for at least 20 hours per month for a monthly retainer of $9,166.67

2. Except as amended herein, all of the terms, provisions and conditions set forth in the original Consulting Agreement are hereby confirmed and shall remain in full force and effect. The original Consulting Agreement and this Amendment No. 1 shall be read and construed together as a single agreement and the term "Agreement" as used shall henceforth be deemed a reference to the original Consulting Agreement as amended by this Amendment No. 1.

3. Counterparts. This Amendment No. 1 may be signed in any number of counterparts, each of which shall be deemed to be an original and all of which together shall constitute one and the same instrument.

THE COMPANY

Cue Biopharma, Inc.

CONSULTANT

Peter A Kiener, D.Phil

/s/ Daniel R. Passeri	/s/ Peter Kiener
Name: Daniel R. Passeri	Name: Peter A Kiener, D. Phil
Title: Chief Executive Officer (Principal Executive Officer)	Title: Consultant

EXHIBIT 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel R. Passeri, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cue Biopharma, 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(s) 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(s) 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 3, 2023

/s/ Daniel R. Passeri
Name: Daniel R. Passeri
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kerri-Ann Millar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cue Biopharma, 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(s) 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(s) 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 3, 2023

/s/ Kerri-Ann Millar

Name: Kerri-Ann Millar

Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

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

In connection with this Quarterly Report on Form 10-Q of Cue Biopharma, Inc. (the "Company") for the three months ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Daniel R. Passeri, Chief Executive Officer of the Company, and Kerri-Ann Millar, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

1. The Report 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.

/s/ Daniel R. Passeri	/s/ Kerri-Ann Millar
Name: Daniel R. Passeri	Name: Kerri-Ann Millar
Title: Chief Executive Officer	Title: Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer and Principal Accounting Officer)
Date: November 3, 2023	Date: November 3, 2023