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 MARCH 31, 2024

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 May 6, 2024, the registrant had 48,643,316 shares of Common Stock ($0.001 par value per share) outstanding.

CUE BIOPHARMA, INC.
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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;
- our ability to continue as a going concern; 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, 2023.

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 28, 2024 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 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 clinical trials, 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.
- Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.
- We plan to continue 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 successfully complete development of, 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(s) are 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.
- Even if we, or any collaborators we may have, obtain marketing approvals for any of our drug product candidates, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.
- We will need substantial additional financing to support our growth and ongoing operations.
- Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

- We have a loan agreement that requires us to meet certain operating covenants and place restrictions on our operating and financial flexibility.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,029	$ 48,514
Accounts receivable	1,400	1,698
Prepaid expenses and other current assets	2,240	1,242
Total current assets	44,669	51,454
Property and equipment, net	754	795
Operating lease right-of-use assets	5,573	6,323
Deposits	2,690	2,690
Restricted cash	151	151
Other long-term assets	114	117
Total assets	$ 53,951	$ 61,530
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,919	$ 3,501
Accrued expenses	5,208	4,137
Research and development contract liability, current portion	1,790	2,112
Operating lease liabilities, current	3,210	3,368
Current portion of long-term debt, net	3,963	3,963
Total current liabilities	18,090	17,081
Operating lease liabilities, non-current	2,579	3,162
Long-term debt, net	3,244	4,202
Total liabilities	$ 23,913	$ 24,445
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 48,643,316 and 47,215,116 shares issued and outstanding, at March 31, 2024 and December 31, 2023, respectively	48	47
Additional paid in capital	343,527	338,228
Accumulated deficit	(313,537)	(301,190)
Total stockholders' equity	30,038	37,085
Total liabilities and stockholders' equity	$ 53,951	$ 61,530

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

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

	Three Months Ended March 31,	
	2024	**2023**
Collaboration revenue	$ 1,717	$ 187
Operating expenses:		
General and administrative	4,186	4,176
Research and development	10,199	9,391
Total operating expenses	14,385	13,567
Loss from operations	(12,668)	(13,380)
Other income (expense):		
Interest income	562	641
Interest expense	(241)	(370)
Total other income (expense), net	321	271
Net loss	$ (12,347)	$ (13,109)
Unrealized gain from available-for-sale securities	—	57
Comprehensive loss	$ (12,347)	$ (13,052)
Net loss per common share – basic and diluted	$ (0.25)	$ (0.29)
Weighted average common shares outstanding – basic and diluted	49,466,711	44,652,353

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, December 31, 2022	43,042,548	$ 43	$ 316,192	$ (96)	$ (250,456)	$ 65,683
Stock-based compensation	—	—	1,998	—	—	1,998
Exercise of stock options	135,602	—	388	—	—	388
Unrealized gain from available-for-sale securities	—	—	—	57	—	57
Net loss	—	—	—	—	(13,109)	(13,109)
Balance, March 31, 2023	43,178,150	$ 43	$ 318,578	$ (39)	$ (263,565)	$ 55,017
Balance, December 31, 2023	47,215,116	$ 47	$ 338,228	$ —	$ (301,190)	$ 37,085
Issuance of common stock from ATM offering, net of sales agent commission and fees	1,428,200	1	3,353	—	—	3,354
Stock-based compensation	—	—	1,946	—	—	1,946
Net loss	—	—	—	—	(12,347)	(12,347)
Balance, March 31, 2024	48,643,316	$ 48	$ 343,527	$ —	$ (313,537)	$ 30,038

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

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (12,347)	$ (13,109)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	99	177
Stock-based compensation	1,946	1,998
Decrease in the carrying amount of right-of-use-assets	750	703
Gain on sale of property and equipment	—	(2)
Amortization of premium/discount on purchased securities	—	(149)
Amortization of debt issuance costs	9	9
Accretion of final payment on term loan	33	33
Changes in operating assets and liabilities:		
Accounts receivable	298	(139)
Prepaid expenses and other current assets	(998)	(1,518)
Deposits	—	139
Accounts payable	418	(580)
Accrued expenses	1,071	(709)
Research and development contract liability	(322)	2,966
Operating lease liability	(741)	(652)
Net cash used in operating activities	(9,784)	(10,833)
Cash flows from investing activities		
Purchases of property and equipment	(55)	—
Cash received from the sale of property and equipment	—	2
Redemption of marketable securities	—	15,000
Net cash (used in) provided by investing activities	(55)	15,002
Cash flows from financing activities		
Proceeds from ATM offering, net of sales agent commission and fees	3,354	—
Payment of term loan	(1,000)	—
Proceeds from exercise of stock options	—	388
Net cash provided by financing activities	2,354	388
Net (decrease) increase in cash, cash equivalents, and restricted cash	(7,485)	4,557
Cash, cash equivalents, and restricted cash at beginning of period	48,665	51,764
Cash, cash equivalents, and restricted cash at end of period	$ 41,180	$ 56,321
Supplemental disclosures of non-cash investing and financing activities:		
Cash paid for interest	$ 209	$ 330

The accompanying notes are an integral part of these condensed 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 therapeutic biologics to selectively modulate disease-specific T cells directly within the patient's body. The Company's vision is to translate nature's signals, or "cues", into protein therapeutics by generating a new class of T cell engagers for selective modulation of disease specific T cells. The Company's corporate office and research facilities are located in Boston, Massachusetts.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is in the development stage and has incurred recurring losses and negative cash flows from operations since inception. As of March 31, 2024, the Company had cash and cash equivalents of $41.0 million. Management believes that current cash and cash equivalents on hand at March 31, 2024 are sufficient to fund operations into the first quarter of 2025; 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 is exploring raising additional capital through a combination of equity offerings, collaborations, and other strategic alliances, and, depending on the availability and level of additional financings, and cash expenditure reduction, there is no guarantee that the Company will be successful in these mitigation efforts. 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. Therefore, management has determined that the Company's accumulated deficit, history of losses, negative cash flows from operations and future expected losses raise substantial doubt about the Company's ability to continue as a going concern within one year of the issuance date of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of March 31, 2024, and for the three months ended March 31, 2024 and 2023, 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 28, 2024.

Interim results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024, 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 March 31, 2024, the Company sold 1,428,200 shares of common stock under the October 2021 ATM Agreement for proceeds of $3.4 million, net of commission paid, but excluding transaction expenses. There were no sales under the October 2021 ATM Agreement during the three months ended March 31, 2023. As of March 31, 2024, the Company sold an aggregate of 9,028,573 shares of common stock under the October 2021 ATM Agreement for proceeds of $40.4 million, net of commission paid, but excluding transaction expenses, since its inception.

Consolidation

The accompanying condensed 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 date of the Company's condensed consolidated balance sheets. 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 comprehensive loss. Realized gains and losses are determined on a specific identification basis and are included in other income on the condensed consolidated statements of operations and comprehensive loss. Amortization and accretion of discounts and premiums is recorded in interest income. The Company had no marketable securities as of March 31, 2024 and December 31, 2023. At March 31, 2024, the Company invested available cash in money market funds, and at March 31, 2023 the Company invested available cash in U.S. Treasury securities.

Restricted Cash

The Company had $151,000 in restricted cash deposited with a separate commercial bank to collateralize Company credit cards as of March 31, 2024 and December 31, 2023.

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 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 condensed 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. The Company recorded $3,000 in amortization expense, on a straight-line basis, for each of the three months ended March 31, 2024 and 2023.

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 condensed consolidated statements of operations and 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 "expected value method" 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 Company's condensed consolidated balance sheets. 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 Company's condensed consolidated balance sheets 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 months ended March 31, 2024 and March 31, 2023, patent expenses were $537,000 and $632,000, respectively.

Licensing Fees and Costs

Licensing fees and costs consist primarily of costs relating to the acquisition of the Company's 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 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 Company's condensed consolidated balance sheets 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. There were no disposals of property and equipment for the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company sold fully depreciated lab equipment with an acquisition cost of $41,000 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 condensed consolidated statements of operations and comprehensive loss.

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

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 Financial Accounting Standards Board ("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 March 31, 2024.

At March 31, 2024 and 2023, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of EPS, as their effect would have been anti-dilutive.

	March 31,	
	2024	2023
Common stock warrants	9,188,406	9,188,406
Common stock options	9,270,666	7,044,599
Total	18,459,072	16,233,005

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 $41.0 million and $39.1 million in cash equivalents as of March 31, 2024 and December 31, 2023, respectively.

The carrying value of financial instruments (consisting of cash, a certificate of deposit, debt, 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 December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its condensed consolidated financial statements.

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 March 31, 2024 and December 31, 2023, and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2024 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 41,029	$ —	$ —	$ 41,029
Total	$ 41,029	$ —	$ —	$ 41,029

	Fair Value Measurements as of December 31, 2023 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 39,148	$ —	$ —	$ 39,148
Total	$ 39,148	$ —	$ —	$ 39,148

As of March 31, 2024, the Company had $41.0 million in cash equivalents. The Company measures the cash equivalents that are invested in money market funds using Level 1 inputs for identical securities. As of December 31, 2023, the Company had $39.1 million in cash equivalents. During the three months ended March 31, 2024, and the year ended December 31, 2023, there were no transfers between Level 2 and Level 3.

4. Property and Equipment

Property and equipment as of March 31, 2024 and December 31, 2023 consisted of the following:

	March 31, 2024	December 31, 2023
	(in thousands)	
Laboratory equipment	$ 4,097	$ 4,069
Furniture and fixtures	81	81
Computer equipment	169	143
Leasehold improvements	118	118
Total property and equipment	4,465	4,411
Less accumulated depreciation	(3,711)	(3,616)
Property and equipment, net	$ 754	$ 795

Depreciation expense was $96,000 and $174,000 for the three months ended March 31, 2024 and 2023, respectively. Depreciation expense for the three months ended March 31, 2024 and 2023 excludes trademark amortization expense of $3,000. There were no disposals of property and equipment for the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company sold fully depreciated lab equipment with an acquisition cost of $41,000 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 condensed consolidated statements of operations and comprehensive loss.

5. Loan with First Citizens Bank (formerly 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 March 31, 2024, the interest rate was 10.75% which is 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 condensed consolidated statements of operations and 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 and the FDIC was appointed receiver for the bank. The FDIC created a successor bridge bank, and all deposits and loans of SVB were transferred to the bridge bank under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. On March 27, 2023, First Citizens Bank & Trust Company (“First Citizens Bank”), assumed all of SVB’s deposits and certain other liabilities and acquired substantially all of SVB’s loans and certain other assets from the FDIC. First Citizens Bank continues to hold the Company’s Term Loans under the same existing terms and covenants which were in place with SVB.

During the three months ended March 31, 2024 and March 31, 2023, the Company recognized interest expense related to the Term Loans of $199,000 and $330,000, respectively. For each of the three months ended March 31, 2024 and March 31, 2023, the Company recognized $33,000 in interest expense related to accretion of the final payment.

The following table presents the aggregate maturities of long-term debt as of March 31, 2024 (in thousands):

Year		
2024	$	3,000
2025		4,000
Total	$	7,000

The following table presents long-term and current portions of debt as of March 31, 2024 (in thousands):

Long-term debt	$	3,000
Accretion of final payment		272
Less: unamortized debt issuance costs		(28)
Long-term debt, net	$	3,244
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 condensed consolidated statements of operations and comprehensive loss.

The Company has incurred $142,000 in debt issuance costs related to the Loan Agreement. For each of the three months ended March 31, 2024 and March 31, 2023, the Company recognized interest expense of $9,000 for amortization of debt issuance costs in the condensed consolidated statements of operations and comprehensive loss. The Company recorded $37,000 and $28,000 to short- and long-term debt issuance costs contra-liabilities as of March 31, 2024, respectively.

6. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	March 31, 2024	December 31, 2023
Employee and board compensation	$ 3,106	$ 2,219
Contract research services	1,816	1,411
Professional services	207	344
Contract manufacturing services	79	163
Total	$ 5,208	$ 4,137

7. Einstein License Agreement

On January 14, 2015, the Company entered into a license agreement (the “Einstein License”), with Albert Einstein College of Medicine (“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. On July 31, 2017, the Company entered into an amended and restated license agreement which modified certain obligations of the parties under the Einstein License. The Einstein License was further amended on January 13, 2024.

Under the Einstein License, the Company holds 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 covered by the Einstein License, including certain technology received from Einstein relating thereto (the "Licensed Products"). Under the Einstein License, the Company is 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 nonrefundable, 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. Payments made upon achievement of milestones are nonrefundable and are not creditable against any other payment due to Einstein. At March 31, 2024, the Company has made aggregate payments totaling $1.2 million since inception with respect to achievement of these milestones.
- Incur minimum product development costs until the first commercial sale of the first licensed product.

The Company was in compliance with its obligations under the Einstein License at March 31, 2024 and 2023.

The Einstein License expires upon the expiration of the Company's 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 if the Company fails to meet its obligations thereunder.

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

The Company accounts for license fees incurred in connection with the Einstein License in accordance with ASC 730, Research and Development. Please refer to Note 10 Collaboration Revenue.

8. Stock-Based Compensation

Stock Option Valuation

For stock options requiring an assessment of value during the three months ended March 31, 2024 and 2023, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	March 31, 2024
Risk-free interest rate	3.83% - 4.28%
Expected dividend yield	0%
Expected volatility	66.27% - 109.86%
Expected life	5.50 to 8.91 years

	March 31, 2023
Risk-free interest rate	3.40% - 3.99%
Expected dividend yield	0%
Expected volatility	97.0% - 100.4%
Expected life	5.50 to 6.25 years

A summary of stock option activity for the three months ended March 31, 2024 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2023	7,492,917	$ 8.41	6.12
Granted	1,869,500	2.02	—
Exercised	—	—	—
Cancelled	(91,751)	10.63	—
Stock options outstanding at March 31, 2024	9,270,666	7.10	6.74
Stock options exercisable at March 31, 2024	5,085,904	$ 9.85	4.72

The Company recognized $1.9 million and $2.0 million in stock-based compensation expense during the three months ended March 31, 2024 and 2023, respectively, related to stock options activity.

As of March 31, 2024, total unrecognized stock-based compensation expense was $10.6 million, which is expected to be recognized as an operating expense in the Company's condensed consolidated statements of operations and comprehensive loss over the weighted average remaining period of 2.55 years.

As of March 31, 2023, total unrecognized stock-based compensation expense was $12.8 million, which is expected to be recognized as an operating expense in the Company's condensed consolidated statements of operations and comprehensive loss over the weighted average remaining period of 2.62 years. During the three months ended March 31, 2023, the Company granted stock options to purchase 1,321,900 shares of common stock with a weighted average grant date fair value of $3.20 per share.

Stock-based Compensation

Stock-based compensation expense for the three months ended March 31, 2024 and 2023 was included in the Company's condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
(in thousands)	2024	2023
General and administrative	$ 956	$ 888
Research and development	990	1,110
Total stock-based compensation expense	$ 1,946	$ 1,998

9. Warrants

On November 16, 2022, the Company issued warrants exercisable for an aggregate of 9,188,406 shares of common stock with an exercise price of $3.93 and a 5-year term and pre-funded warrants exercisable for an aggregate of 1,531,440 shares of common stock ("Pre-Funded Warrants") at a nominal exercise price of $0.0001 per share. These November 2022 warrants remain outstanding at March 31, 2024.

The November 2022 warrants were 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.

10. 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 "expected value method" 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, $0.4 million was recognized as tax withholding, shown as income tax expense on the consolidated statement of operations and comprehensive loss.

On December 7, 2020, the Company earned a $1.3 million milestone payment on the selection of a preclinical candidate pursuant to the LG Chem Collaboration Agreement. The $1.3 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 $1.25 million milestone payment, $0.2 million was withheld as payment of foreign tax withholding and shown as income tax expense on the consolidated statement of operations and comprehensive loss.

On November 23, 2021, the Company earned a $3.0 million milestone payment for the selection of a clinical product candidate in partnership with LG Chem. The $3.0 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 $3.0 million milestone payment, $0.5 million was withheld as payment of foreign tax withholding and shown as income tax expense on the condensed consolidated statements of operations and comprehensive loss. Cash was collected in relation to this milestone payment in February 2022.

Aside from the $6.8 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 March 31, 2024. 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 March 31, 2024 and 2023, the Company recognized revenue of $34,000 and $36,000, respectively, related to the LG Chem Collaboration Agreement. The Company did not record short or long-term research and development liabilities on its balance sheets dated March 31, 2024 and December 31, 2023, as the performance obligation was met and completed. Research and development cost sharing provisions under the agreement expired on March 31, 2022, thereafter the Company recognized revenue on intellectual patent filing passthrough costs in the LG Chem Territory.

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 $220.0 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. The Company's decision to elect the co-development and co-commercialization option may be made within 30 days of Ono's option exercise to license CUE-401. The amount paid by Ono to the Company for the option exercise and future milestone payments will vary based upon the Company's decision to exercise the co-development and co-commercialization option.

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. Subsequently, the Company and Ono agreed to increase this cap for full time employee salaries to $2.8 million. 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 the first 18 months of the Research Term 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 March 31, 2024. 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 March 31, 2024 and 2023, the Company recognized revenue of $1.7 million and $0.2 million, respectively, related to the Ono Collaboration and Option Agreement. The Company recorded short-term research and development liabilities on its balance sheet dated March 31, 2024 of $1.8 million. The Company recorded short-term research and development liabilities on its balance sheet dated December 31, 2023, of $2.1 million.

11. Commitments and Contingencies

Einstein License Agreement

In 2015, the Company entered into the Einstein License 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. The Einstein License was further amended on January 13, 2024. For the three months ended March 31, 2024 and 2023, the Company incurred $25,000 and $44,000, respectively, in fees payable to Einstein in relation to this license.

The Company's remaining commitments with respect to the Einstein License are based on the attainment of future milestones. The aggregate amount of milestone payments made under the Einstein License may equal up to $1.9 million for each Licensed Product, and up to $1.9 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 $5.8 million. The Company is also party to a service agreement with Einstein to support the Company's ongoing research and development activities.

Collaboration Agreement with LG Chem

See discussion of the LG Chem Collaboration Agreement in Note 10.

Collaboration Agreement with Ono

See discussion of the Ono Collaboration and Option Agreement in Note 10.

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 condensed consolidated financial statements.

The Company may be subject to various legal proceedings from time to time as part of its business. As of March 31, 2024, 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.

12. 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.

The Company recognized a right of use asset of $9.1 million and an operating lease liability of $9.1 million 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. During the year ended December 31, 2022, the Company recognized a right of use asset of $369,000 and a short and long term operating lease liability of $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 are held in escrow and will be credited against future rent payments and the other of which was applied to the first month's rent. During the year ended December 31, 2022, the Company recognized a right of use asset of $1,307,000 and a short and long term operating lease liability of $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 Abandonments guidance. During the year ended December 31, 2022, 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 to gain on right of use asset and included in the consolidated statement of operations and comprehensive loss.

For the three months ended March 31, 2024, the Company recorded $0.1 million in interest expense to the lease liability.

At March 31, 2024, operating lease right-of-use assets were $5.6 million. Corresponding operating lease liabilities were $5.8 million as of March 31, 2024, of which $3.2 million were recorded in current liabilities and $2.6 million were recorded in long-term liabilities on the Company's condensed consolidated balance sheets.

As of March 31, 2023 and December 31, 2023, security deposits of $0.6 million related to the 40G Additional Laboratory Lease were included in deposits on the Company's consolidated balance sheets.

Future minimum lease payments under these leases at March 31, 2024 are as follows:

		(in thousands)
2024 (remaining 9 months)		2,529
2025		2,799
2026		818
Total lease payments		6,146
Less: imputed interest		(357)
Present value of lease payments	$	5,789

Rent expense of $0.9 million was included in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023. Other information pertaining to the Company's operating leases for the three months ended March 31, 2024 is summarized in the table below.

The weighted average remaining lease term and discount rate related to the Company's leases were as follows:

	March 31, 2024	**December 31, 2023**
Weighted average remaining lease term (years)	1.93	2.16
Weighted average discount rate	6.18%	6.25%

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, 2023 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 28, 2024, or the 2023 Annual Report.

Overview

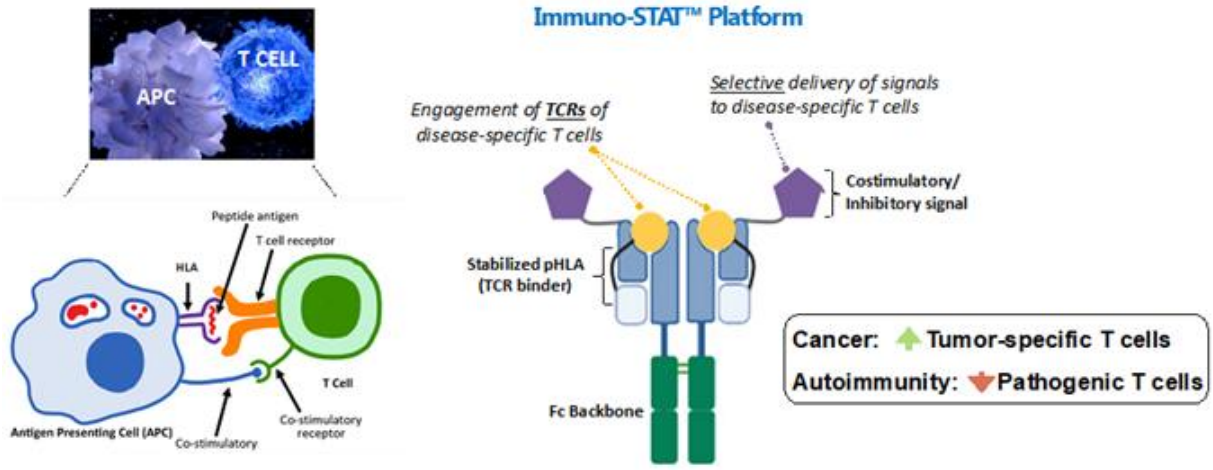
We are a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively modulate disease-specific T cells directly within the patient's body. Our vision is to translate nature's signals, or "cues", into protein therapeutics by generating a new class of T cell engagers for selective modulation of disease specific T cells.

We believe our proprietary Immuno-STAT™ (*Selective Targeting and Alteration of T Cells*) platform and derivative molecules, as described below, will enable us to enhance the potential of the patient's own immune system to restore health while avoiding the deleterious side effects of broad 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 two of the major diseases causing debilitating human suffering and mortality, namely cancer and autoimmune disease.

Cancer and autoimmune disease are major areas of disease that affect large populations across the globe and shorten the life expectancy of those afflicted. There are approximately 20 million new cancer diagnoses worldwide each year with approximately 2 million in the United States, or U.S., alone. Of these new cases, approximately 50% will progress to recurrent metastatic disease ultimately resulting in death. In addition, approximately 4% of the world's population is diagnosed with an autoimmune disease resulting in approximately 24 million cases in the U.S. alone. Recognizing that T cells, as the heavy artillery of the immune system, are regulated with a highly selective "command and control" instruction process through interactions with the antigen-presenting cells, we have engineered the Immuno-STAT platform to emulate this "command and control" system.

Specificity, or the control in the "command and control" system, is achieved through the T cell receptor, or TCR, binding to a specific, targeted epitope, depicted by the yellow circle in the figure on the right below, along with a "command" co-stimulatory signal, such as interleukin 2, or IL-2, depicted as the purple pentagon in the figure on the right below. These two "cues", or signals, when engaged concurrently, as is the case with our Immuno-STATs, are able to "dial-in" selective activation of targeted tumor-specific T cells to attack cancer while avoiding potentially harmful broad immune activation of T cells. Conversely, in autoimmunity, our autoimmune drug product candidates are designed to deploy inhibitory signals to selectively dampen autoreactive T cells while avoiding broad immune suppression that can increase susceptibility to other diseases. The figure to the left below depicts the interaction of the antigen presenting cell, or APC, with a specific T-cell as seen in nature.

Immuno-STAT Platform: Emulating Nature's Selectivity



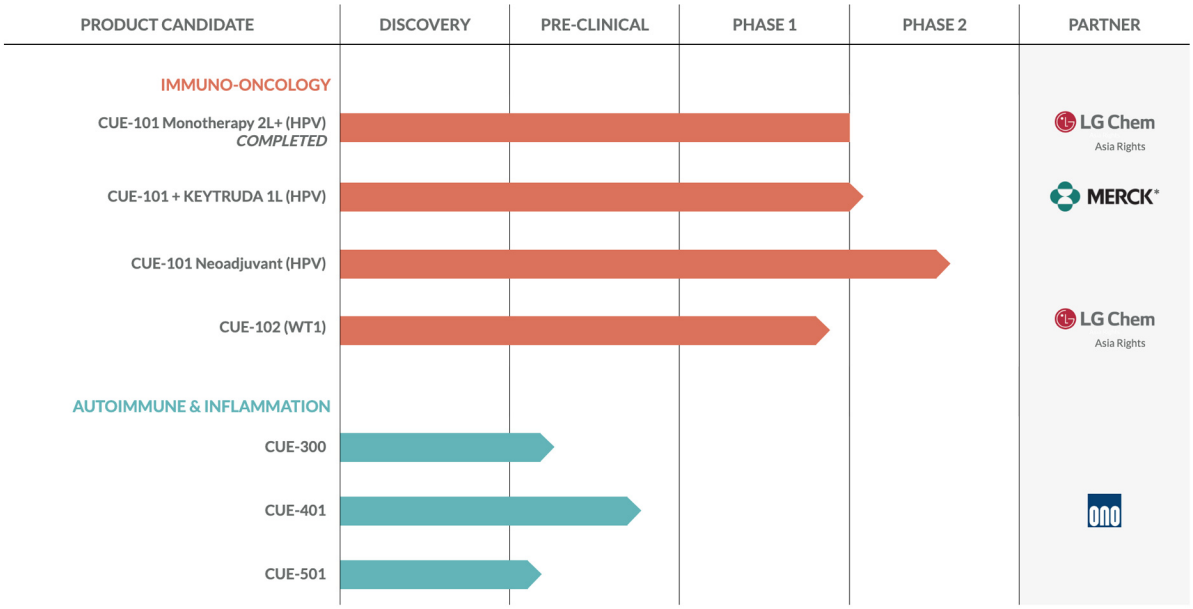
Our first two oncology drug product candidates, CUE-101 and CUE-102, are exemplary programs from the IL-2 based CUE-100 series, and are representative of the HLA-A02 allele, which is the predominant allele in the U.S. and western European territories, i.e., approximately 50% of the patient population, and also prevalent, albeit at lower frequencies, in other global populations. We have developed preclinically additional HLA alleles, which could enable broader expansion of patient coverage globally. CUE-101 HLA-A02 is engineered for the treatment of human papillomavirus positive, or HPV+, head and neck squamous cell carcinoma, or HNSCC, and by changing the epitope 9-amino acid sequence depicted as the yellow circle in the above illustration, we have CUE-102 HLA-A02, targeting Wilms' Tumor 1 protein, or WT1, an oncofetal antigen known to be over-expressed in more than 20 different cancers. Based upon the clinical observations to date, we believe we have demonstrated that our Immuno-STAT platform can be deployed across a wide spectrum of cancers by selectively activating the patient's own immune system to combat cancer. We have also developed drug product candidates designed to address a broad spectrum of autoimmune disease by dampening or turning down self-reactive T cells that attack a patient's body. We have a strategic collaboration with Ono Pharmaceutical Co., Ltd., or Ono, focused on the development of CUE-401 for the potential treatment of a wide spectrum of autoimmune disease through the induction and expansion of regulatory T cells, or Tregs. Furthermore, we also have recently developed a drug product candidate for targeting B cell induced autoimmune diseases, such as lupus, with CUE-501, which would potentially enable B cell ablation to destroy autoreactive B cells followed by natural repopulation thus restoring immune balance.

Our drug product candidates are in various stages of clinical and preclinical development. The ongoing generation of clinical data for CUE-101 and CUE-102, as well as the emerging preclinical data for CUE-401 and CUE-501 continues to bolster our belief that we have developed a modular approach for "restoring immune balance" representing a potential breakthrough for enhancing clinical outcomes for patient's suffering from cancer and autoimmune disease.

Our Pipeline

The pipeline chart below details our portfolio of oncology and autoimmune assets that we are currently focusing on 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 options for third party support to further develop the CUE-100 series 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 other IL-2 muteins that are being pursued in this space.

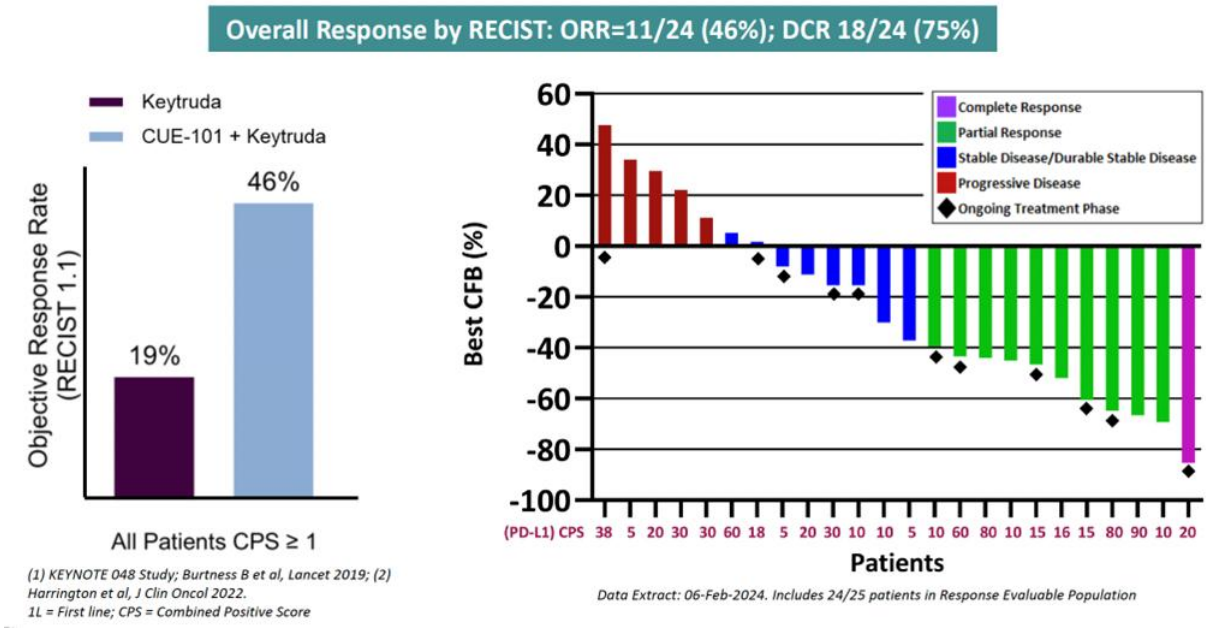


CUE-101

CUE-101 is our most advanced clinical stage asset and is being clinically investigated for the treatment of human papillomavirus positive, or HPV+, head and neck squamous cell carcinoma, or HNSCC, in patients compatible with the human leukocyte antigen, HLA-A02. Our first Phase 1 clinical trials are investigating CUE-101 in the treatment of R/M, HPV+ HNSCC as a monotherapy and in combination with KEYTRUDA. We received Fast Track Designation of CUE-101 for the treatment of recurrent metastatic, or R/M, HPV+ HNSCC, as both a monotherapy in 2L+ patients and in combination with KEYTRUDA, the current standard of care, or SoC, for 1L R/M HNSCC patients. We also have ongoing and planned investigator sponsored clinical trials in the neoadjuvant and adjuvant settings. This series of trials allows CUE-101 to be investigated in multiple patient populations with broad market opportunities.

Both the CUE-101 monotherapy trial in 2L+ R/M HNSCC and CUE-101 trial in 1L in combination with KEYTRUDA have completed enrollment and have demonstrated metrics of clinical activity. Most notably in our ongoing Phase 1b trial of CUE-101 in combination with current SoC, KEYTRUDA, as described in more detail in our 2023 Annual Report, we have observed one confirmed complete response and ten confirmed partial responses, as well as seven patients with durable stable disease resulting in an overall response rate, or ORR, for the 24 patients dosed in the Phase 1b trial of 46% and a disease control rate of 75%. This ORR represents a greater than doubling of the historical ORR of 19% that was observed with KEYTRUDA alone, as reported in the KEYNOTE 048 study. Importantly, these responses include multiple patients with low PD-L1 expression (combined positive score less than 20), a patient population known to be less likely to respond to KEYTRUDA.

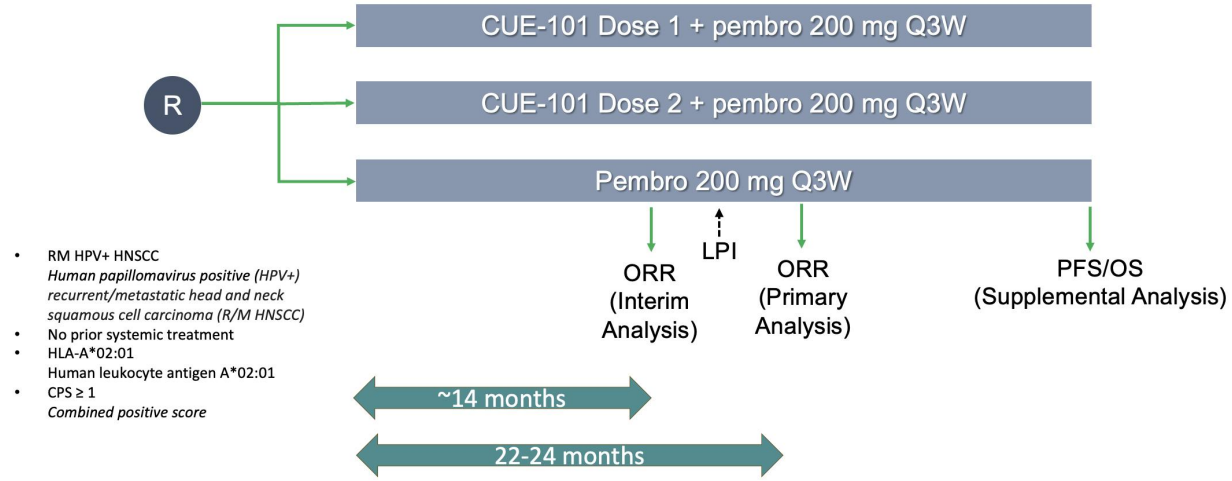
Best Change from Baseline and Response in Patients Treated with 4 mg/kg of CUE-101 in Combination with KEYTRUDA



We continue to follow the patients treated in both the CUE-101 Phase 1 dose-escalation and expansion monotherapy and combination trials and anticipate providing a further update and substantive analysis at the upcoming American Society of Clinical Oncology meeting in June 2024.

In January 2024, we met with the FDA in a Type B meeting to clarify potential paths to registrational trials in both the 2L+ monotherapy and 1L combination settings. An overview of the proposed CUE-101 Phase 2 trial is shown below. In the

proposed trial, treatment naïve, front-line patients with R/M HPV+ HNSCC will be randomized to one of three treatment arms: two CUE-101 doses in combination with 200mg of pembrolizumab or 200mg of pembrolizumab alone, in each case, with dosing to occur every three weeks. Overall response rate, or ORR, will be the primary endpoint with progression free survival, or PFS, and overall survival, or OS, as secondary endpoints. The interim analysis of ORR is anticipated to occur approximately 14 months after the first patient is dosed in this proposed Phase 2 trial, and the primary analysis of ORR is anticipated to occur approximately 22-24 months after the first patient is dosed in this proposed Phase 2 trial.



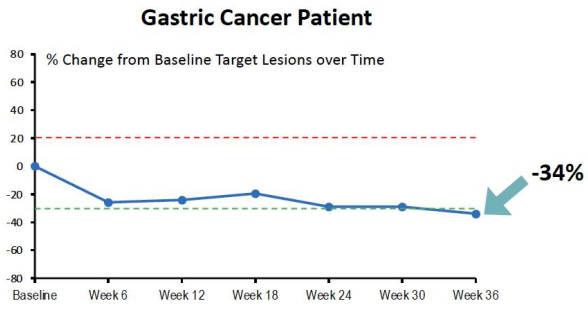
We believe this Phase 2 trial design and the resulting data will provide a clear estimation of treatment effect, confirmation of the dose to be tested in Phase 3 and increase the overall probability of success for a potential registrational trial and will also provide further risk reduction of the CUE-100 series. We are currently assessing the resource and funding requirements needed to conduct this proposed Phase 2 trial.

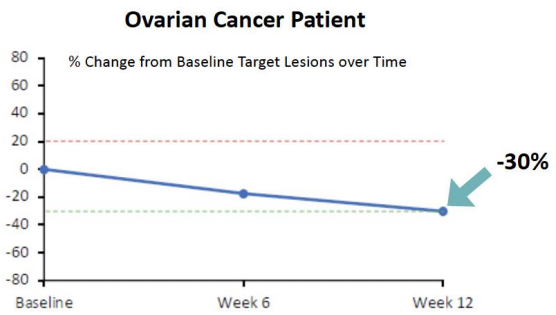
CUE-102

CUE-102, the second HLA-A02 drug product candidate in our CUE-100 series, 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 and lung) and hematologic malignancies (such as acute myeloid leukemia, multiple myeloma and myelodysplastic syndromes). We are conducting a Phase 1 monotherapy clinical trial of CUE-102 in second line R/M WT1+ colorectal, gastric, ovarian, and pancreatic cancer. Similar to CUE-101, CUE-102 may be investigated in multiple patient populations including, as a combination with current standard of care therapies, in first line R/M cancers, as well as, R/M locally advanced settings.

Consistent with our preclinical datasets, selective and robust expansion of WT1+ specific T cells has been observed in treated patients in our ongoing CUE-102 monotherapy trial. Expansion of these WT1 tumor specific T cells is expected to enhance anti-tumor immunity with the potential to drive tumor reductions. The graphs below show reductions in tumor burden that have been observed in patients treated in the dose-escalation portion of the Phase 1 CUE-102 monotherapy clinical trial. As shown in the graph on the left, a patient with gastric cancer that progressed on three prior lines of therapy, including a CPI, experienced a decrease in the sum of three target lesions of 34% at week 36, as depicted by the blue line crossing the -30% hash line in green. This gastric cancer patient remained on treatment as of the data cut-off date. The graph on the right shows a reduction in tumor burden observed in an ovarian cancer patient in the 2 mg/kg dose-escalation cohort as depicted by the blue line intersecting the -30% hash line in green. Both of these patients subsequently experienced progressive disease due to the emergence of new lesions. We have also observed disease control in patients with pancreatic cancer, including a pancreatic cancer patient who, as of the data cut-off date, remained on treatment and exhibited durable stable disease for greater than six months.

Reduction of Target Lesions in Patients Treated with CUE-102





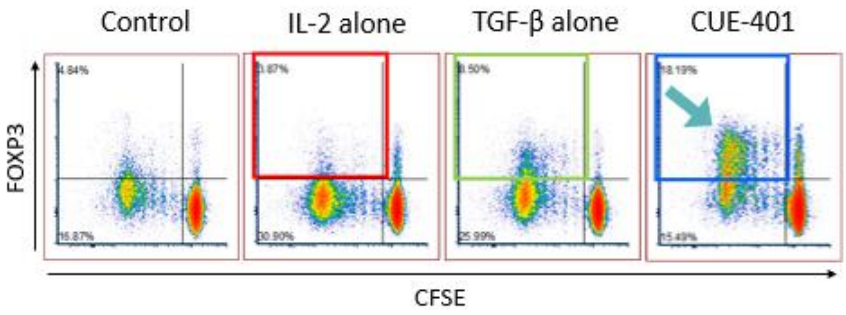
Given the encouraging signs of clinical activity observed across all four indications in the Phase 1 dose escalation portion of the trial, we are conducting the Phase 1 expansion portion of the monotherapy trial in more than one WT1 positive cancer type. We anticipate providing a further update and substantive analysis of this ongoing trial at the upcoming scientific American Society of Clinical Oncology meeting in June 2024.

In addition to the CUE-100 series, we have leveraged the modularity and versatility of the Immuno-STAT platform to develop additional biologic series outside of oncology, including CUE-400 and CUE-500, which are specifically designed through rational protein engineering to address distinct therapeutic approaches for treating autoimmune disease. The CUE-400 series represents a novel class of bispecific molecules designed to selectively induce and expand regulatory T cells, or Tregs, for chronic autoimmune diseases. The CUE-500 series represents a novel approach to develop a bispecific Immuno-STAT that can selectively direct memory T cells to deplete B cells, which has been demonstrated through the ablation of B cells with CAR T therapy and is now recognized as an important axis for treatment of autoimmune and inflammatory diseases. We believe preclinical data generated from our evaluation of CUE-401 and the CUE-500 series demonstrates evidence of the desired mechanistic effect of these novel approaches for the treatment of autoimmune disease.

CUE-401

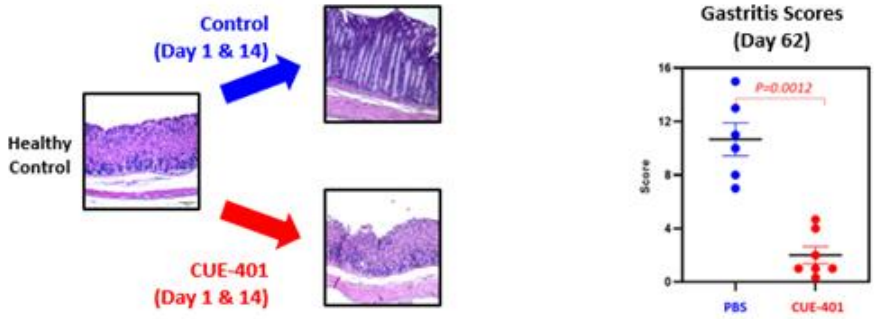
CUE-401 is a bispecific molecule which has the two key signals, IL-2 and transforming growth factor beta, or TGF beta, for selective induction of Tregs. The structure of CUE-401 is similar to that utilized in the CUE-100 series and incorporates the same IL-2 variant. The TGF beta variant was designed to improve the safety profile, enhance manufacturability, and mechanistically align with IL-2 signaling for effective Treg induction and expansion. Co-delivery of IL-2 and TGF beta signals in naïve CD4+ T cells results in the induction of Fox P3 which is the master gene transcription factor for Tregs. The panels below demonstrate Treg induction in human peripheral blood mononuclear cells and exemplify the need for both the IL-2 and TGF beta signals to induce Tregs. As shown below, neither IL-2 nor TGF beta alone can generate substantial numbers of new Tregs. In contrast, CUE-401, which has both IL-2 and TGF beta, demonstrated in preclinical studies the ability to generate a robust population of Fox P3+ Tregs by delivering both required signals.

CUE-401 Harnessed Multiple Signals to Induce Tregs in Preclinical Studies



We have generated preclinical data in our labs and in collaboration with Dr. Richard DiPaolo of St. Louis University supporting the premise that CUE-401 may be able to expand and induce Tregs. The resulting Tregs are functionally suppressive and maintain a stable phenotype, whereby CUE-401 treatment suppressed the proliferation of self-reactive T cells in a mouse model of autoimmune gastritis. The therapeutic potential of CUE-401 has also been observed in a T cell transfer model of autoimmune gastritis, wherein treatment with CUE-401 led to a prolonged suppression of self-reactive T cells and significantly reduced pathological evidence of disease in the stomachs of treated mice. As shown in the figure below, short-term treatment with CUE-401 resulted in long-term protection from autoimmune gastritis and tissue destruction in a pre-clinical animal model. The histopathology, as shown on the left side, and the compiled gastritis scores, as shown on the right side, demonstrated significant protection from tissue destruction in animals treated with CUE-401.

Short-term Treatment with CUE-401 Resulted in Significant Long-Term Protection from Gastritis and Tissue Destruction

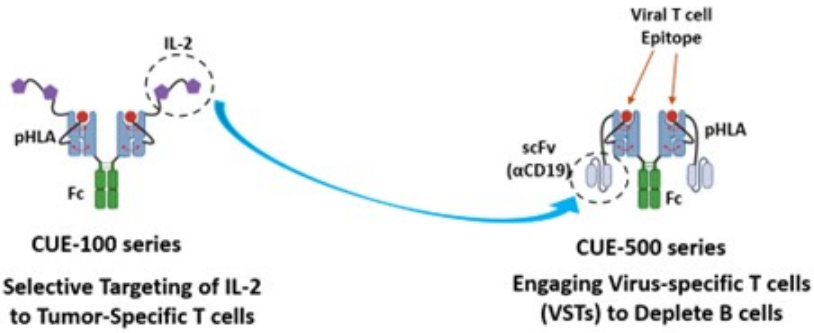


CUE-401 is being developed in strategic collaboration with Ono Pharmaceuticals wherein Ono is supporting all of our ongoing preclinical work to identify a lead clinical candidate toward the clinic.

CUE-500 Series

The CUE-500 series focuses on autoimmne diseases caused by autoreactive, or self reactive B cells. CUE-500 series Immuno-STAT biologics are designed to selectively harness the protective anti-viral T cell repertoire (virus-specific T cells, or VSTs) and re-direct them to target and deplete B cells. We believe that our approach to deploy a biologic to selectively re-direct “killer” T cells, while avoiding the systemic engagement and activation of all T cells, to essentially accomplish T cell-mediated B cell depletion has similarities to what has been exemplified with CD19-CAR-T cell therapy approaches. We believe that addressing this important mechanism of autoimmune diseases with a biologic will offer significant advantages over cell therapy-based strategies. Our lead CUE-500 series candidate, CUE-501, is a bispecific engineered to direct selective memory T cells to deplete B cells to address autoimmune and inflammatory diseases. The CUE-500 series builds upon the de-risking accomplished with the CUE-100 series and leverages the same modified IL-2. This further supports our premise that each CUE-100 series Immuno-STAT molecule provides further de-risking and potential acceleration of subsequent drug product candidate. The figures below highlight the design and mechanism of action of the CUE-500 series.

CUE-500 Series Leveraging a derisked, validated framework for T cell mediated B cell depletion



Plan of Operation

Our technology is in the clinical development phase for oncology and preclinical development phase for autoimmune disease. 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, as well as business development to foster strategically important alliances for resource enhancement.

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 headings “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 condensed 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 2023 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 three months ended March 31, 2024.

Recent Accounting Pronouncements and Adopted Standards

A discussion of recent accounting pronouncements is included in Note 2 to our condensed 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 March 31, 2024, 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 March 31, 2024, 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 the three months ended March 31, 2024 and 2023, we incurred $25,000 and $44,000, respectively, in fees payable to Einstein in relation to this license. Such costs, if any, are included in research and development costs in our condensed consolidated statements of operations and 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 $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 $400 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 March 31, 2024 and 2023, we recognized revenue of $34,000 and $36,000, respectively, related to the LG Chem Collaboration Agreement. As of March 31, 2024, we had recorded $19.9 million in collaboration revenue related to this agreement since the agreement was entered into. The majority of the research phase of the LG Chem 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 $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. Our decision to elect the co-development and co-commercialization option may be made within 30 days of Ono's option exercise to license CUE-401. The amount paid by Ono to us for the option exercise and future milestone payments will vary based upon our decision to exercise the co-development and co-commercialization option.

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) has made a one-time, non-refundable, non-creditable upfront payment of $3.0 million to us in March 2023, 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. Subsequently, the Company and Ono agreed to increase this cap for full time employee salaries to $2.8 million. 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 the first 18 months of the Research Term based on the initial research and development plans we have established.

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 March 31, 2024. 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 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 March 31, 2024 and 2023, we recognized revenue of $1.7 million and $0.2 million, respectively, related to the Ono Collaboration and Option Agreement. We recorded short-term research and development liabilities on our balance sheet dated March 31, 2024, of $1.8 million. As of December 31, 2023, we recorded short-term research and development liabilities of $2.1 million on our consolidated balance sheet.

Results of Operations

Collaboration Revenue

We have not yet generated commercial revenue from product sales. To date, we have generated revenue from collaboration agreements with Merck Sharp & Dohme Corp. (which terminated in December 2022), LG Chem, and Ono. Collaboration revenue may vary from period to period depending on the progress of our work in connection with 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.

Interest Income

We earn interest income from cash invested in money market funds.

Three Months Ended March 31, 2024 and 2023

Our condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, as discussed herein, are presented below.

	Three Months Ended March 31,	
	2024	**2023**
	(in thousands)	
Collaboration revenue	$ 1,717	$ 187
Operating expenses:		
General and administrative	4,186	4,176
Research and development	10,199	9,391
Total operating expenses	14,385	13,567
Loss from operations	(12,668)	(13,380)
Other income (expense):		
Interest income	562	641
Interest expense	(241)	(370)
Total other income (expense), net	321	271
Net loss	$ (12,347)	$ (13,109)

Collaboration Revenue

Collaboration revenue increased by $1.5 million to $1.7 million for the three months ended March 31, 2024, from $0.2 million for the three months ended March 31, 2023. The increase was due to revenue earned from the Ono Collaboration and Option Agreement, which was executed in February 2023.

General and Administrative Expenses

General and administrative expenses were $4.2 million for each of the three months ended March 31, 2024 and 2023.

Research and Development Expenses

Research and development expenses increased by $0.8 million to $10.2 million for the three months ended March 31, 2024, from $9.4 million for the three months ended March 31, 2023. The increase was primarily due to an increase of $0.9 million in clinical expenses, offset by a decrease of $0.1 million in external manufacturing costs.

Interest Income

Interest income was $0.6 million for each of the three months ended March 31, 2024 and 2023.

Interest Expense

Interest expense decreased by $0.2 million to $0.2 million for the three months ended March 31, 2024, from $0.4 million for the three months ended March 31, 2023. The decrease was due to a reduction of our principal balance of borrowings under our Loan and Security Agreement, as amended, or the Loan Agreement, with First Citizens Bank & Trust Company, or First Citizens Bank (and formerly with Silicon Valley Bank, or SVB).

Liquidity and Capital Resources

We have financed our working capital requirements primarily through private and public offerings of equity securities, cash received from Merck Sharp & Dohme Corp., LG Chem, and Ono under the respective collaboration agreements and borrowings under the Loan Agreement. At March 31, 2024, we had cash and cash equivalents totaling $41.0 million 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 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, as agent, to sell shares of our 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 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 March 31, 2024, we sold 1,428,200 shares of common stock under the October 2021 ATM Agreement for proceeds of $3.4 million, net of commission paid, but excluding transaction expense. There were no sales under the October 2021 ATM Agreement during the three months ended March 31, 2023. As of March 31, 2024, we sold an aggregate of 9,028,573 shares of common stock under the October 2021 ATM Agreement for proceeds of $40.4 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 began repayment of 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 First Citizens Bank 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, and all deposits of SVB were transferred to the bridge bank under a systemic risk exception approved by the U.S. Department of the Treasury, the Federal Reserve and the FDIC. On March 27, 2023, First Citizens Bank assumed all of SVB's deposits and certain other liabilities and acquired substantially all of SVB's loans and certain other assets from the FDIC. First Citizens Bank 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 $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

Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents, as of March 31, 2024, will enable us to fund our operations into the first quarter of 2025. However, we will need to raise additional capital to fund our future operations and remain as a going concern. We expect to finance our future cash needs through a combination of equity offerings, collaborations, and other strategic alliances. Volatility in capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds and, as a result, we may be unable to secure the necessary funding on acceptable terms. This raises substantial doubt about our ability to continue as a going concern.

The following table summarizes our changes in cash, cash equivalents, and restricted cash for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (9,784)	$ (10,833)
Investing activities	(55)	15,002
Financing activities	2,354	388
Net change in cash, cash equivalents, and restricted cash	$ (7,485)	$ 4,557

Operating Activities

Net cash used in operating activities totaled $9.8 million for the three months ended March 31, 2024 compared to $10.8 million for the three months ended March 31, 2023. The change of $1.0 million was primarily due to a decrease in net loss of $0.8 million.

Investing Activities

Net cash used in investing activities totaled $0.1 million for the three months ended March 31, 2024 compared to net cash provided by investing activities of $15.0 million during the three months ended March 31, 2023. The change of $15.1 million was primarily due to redemptions of marketable securities during the three months ended March 31, 2023.

Financing Activities

Net cash provided by financing activities totaled $2.4 million for the three months ended March 31, 2024 compared to $0.4 million for the three months ended March 31, 2023. The change of $2.0 million was due to proceeds received from sales under our ATM offering of $3.4 million, offset by payments of our term loan totaling $1.0 million during the three months ended March 31, 2024, as well as proceeds from the exercise of stock options of $0.4 million during the three months ended March 31, 2023.

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. We believe that the data generated from our ongoing clinical trials provides a sound basis for our objective of establishing strategic partnerships to enhance our capacity for further clinical development of these programs, particularly through registration. 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 discussed in Note 1 of the notes to the condensed consolidated financial statements under Accounting Standards Update, or ASU, 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), or, ASC 205-40, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. Under ASC 205-40, this evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. Since we currently believe that our existing cash and cash equivalents, as of March 31, 2024, will enable us to fund our operations into the first quarter of 2025, we have determined that this cash runway of less than 12 months from the date of issuance of our financial statements included in this Quarterly Report on Form 10-Q, along with our accumulated deficit, history of losses, and future expected losses meet the ASC 205-40 standard for raising substantial doubt about our ability to continue as a going concern within one year of the issuance date of our financial statements included in this Quarterly Report on Form 10-Q. While we have plans in place to mitigate this risk, which primarily consist of raising additional capital through a combination of equity offerings, collaborations, and other strategic alliances, and, depending on the availability and level of additional financings, and cash expenditure reduction, there is no guarantee that we will be successful in these mitigation efforts.

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 our employees, collaborators, including Einstein, LG Chem and Ono, 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 months ended March 31, 2024, there were no material changes to our contractual obligations and commitments as of December 31, 2023 as described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our 2023 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 March 31, 2024, 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 March 31, 2024 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 2023 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

(c) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit	Filing Date	Registration/File No.
10.1#	Second Amendment to the Amended and Restated License Agreement with Albert Einstein College of Medicine dated January 13, 2024		10-K	10.38	3/28/2024	001-38327
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 March 31, 2024, has been formatted in Inline XBRL.	X				

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: May 9, 2024

By: /s/ Daniel R. Passeri

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

Dated: May 9, 2024

By: /s/ Kerri-Ann Millar

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

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: May 9, 2024

/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: May 9, 2024

/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 March 31, 2024 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
Name: Daniel R. Passeri
Title: Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2024

/s/ Kerri-Ann Millar
Name: Kerri-Ann Millar
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: May 9, 2024