

**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, 2021

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**  
(State or other jurisdiction of  
incorporation or organization)  
  
**21 Erie Street**  
**Cambridge, Massachusetts**  
(Address of principal executive offices)

**47-3324577**  
(I.R.S. Employer  
Identification No.)

**02139**  
(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 registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of May 3, 2021, the registrant had 31,412,841 shares of Common Stock (\$0.001 par value) outstanding.

**CUE BIOPHARMA, INC.**  
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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 current and future 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 product candidates;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates, if approved;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, 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 establish collaborations or obtain additional funding; and
- the impacts of the COVID-19 pandemic.

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, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; our ability to advance our product candidates; potential setbacks in our research and development efforts, including negative or inconclusive results from our preclinical studies; our ability to secure required U.S. Food and Drug Administration (“FDA”) or other governmental approvals for our product candidates and the breadth of any approved indication; adverse effects on our business caused by public health pandemics, including the COVID-19 pandemic; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines, including potential delays in submitting required regulatory applications to the FDA; our reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; our ability to obtain adequate financing to fund our business operations in the future; our ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the availability of significant cash required to fund operations; competitive factors; general economic and market conditions; and the other risks and uncertainties described in the Risk Factors and in Management’s Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K, this Quarterly Report on Form 10-Q, and any subsequently filed Quarterly Report(s) on Form 10-Q. 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.

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

	March 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 73,257	\$ 74,866
Marketable securities	—	10,003
Accounts receivable	1,413	1,417
Prepaid expenses and other current assets	2,735	1,241
Total current assets	77,405	87,527
Property and equipment, net	2,786	2,108
Operating lease right-of-use	5,656	6,774
Deposits	2,575	2,572
Restricted cash	150	150
Other long-term assets	149	402
Total assets	\$ 88,721	\$ 99,533
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,523	\$ 2,070
Accrued expenses	1,976	2,787
Research and development contract liability, current portion	7,145	6,681
Operating lease liability, current portion	4,989	4,777
Total current liabilities	16,633	16,315
Research and development contract liability, net of current portion	1,334	1,938
Operating lease liability, net of current portion	1,085	2,369
Total liabilities	\$ 19,052	\$ 20,622
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred Stock, \$0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 30,499,803 and 30,351,366 shares issued and outstanding, at March 31, 2021 and December 31, 2020, respectively	31	30
Additional paid in capital	235,428	232,159
Accumulated other comprehensive income	—	7
Accumulated deficit	(165,790)	(153,285)
Total stockholders' equity	69,669	78,911
Total liabilities and stockholders' equity	\$ 88,721	\$ 99,533

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

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

	Three Months Ended	
	March 31,	
	2021	2020
<b>Collaboration revenue</b>	\$ 1,553	\$ 900
<b>Operating expenses:</b>		
General and administrative	4,255	3,989
Research and development	9,816	9,906
Total operating expenses	14,071	13,895
<b>Loss from operations</b>	(12,518)	(12,995)
<b>Other income:</b>		
Interest income, net	13	177
Total other income	13	177
<b>Net loss</b>	\$ (12,505)	\$ (12,818)
Unrealized (loss) gain from available-for-sale securities	(7)	259
<b>Comprehensive loss</b>	\$ (12,512)	\$ (12,559)
Net loss per common share – basic and diluted	\$ (0.41)	\$ (0.48)
Weighted average common shares outstanding – basic and diluted	30,434,525	26,569,681

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

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

	For the three months ended March 31, 2021 and 2020:						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/ (Loss)	Accumulated Deficit	Total Stockholders' Equity	
	Shares	Par Value					
Balance, December 31, 2019	26,562,178	\$ 26	\$ 163,068	\$ (10)	\$ (108,500)	\$ 54,584	
Stock-based compensation	—	—	3,175	—	—	3,175	
Exercise of stock options	13,781	1	35	—	—	36	
Unrealized gains from available-for-sale securities	—	—	—	259	—	259	
Net loss	—	—	—	—	(12,818)	(12,818)	
Balance, March 31, 2020	<u>26,575,959</u>	<u>\$ 27</u>	<u>\$ 166,278</u>	<u>\$ 249</u>	<u>\$ (121,318)</u>	<u>\$ 45,236</u>	
Balance, December 31, 2020	30,351,366	\$ 30	\$ 232,159	\$ 7	\$ (153,285)	\$ 78,911	
Stock-based compensation	—	—	2,436	—	—	2,436	
Exercise of stock options	130,642	1	918	—	—	919	
Issuance of common stock upon exercise of warrants, net	8,048	—	—	—	—	—	
Restricted stock awards	16,666	—	—	—	—	—	
Repurchase of restricted stock awards	(6,919)	—	(85)	—	—	(85)	
Unrealized losses from available-for-sale securities	—	—	—	(7)	—	(7)	
Net loss	—	—	—	—	(12,505)	(12,505)	
Balance, March 31, 2021	<u>30,499,803</u>	<u>\$ 31</u>	<u>\$ 235,428</u>	<u>\$ —</u>	<u>\$ (165,790)</u>	<u>\$ 69,669</u>	

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

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

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
<b>Cash flows from operating activities</b>		
Net loss	\$ (12,505)	\$ (12,818)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	318	263
Stock-based compensation	2,436	3,175
Change in operating lease right-of-use asset	1,118	998
Other non-cash expense	-	30
Amortization of premium/discount on purchased securities	(5)	-
Changes in operating assets and liabilities:		
Account receivable	4	150
Prepaid expenses and other current assets	(1,590)	(994)
Other assets	250	—
Deposits	(2)	—
Accounts payable	203	717
Accrued expenses	(811)	(1,083)
Research and development contract liability	(139)	(295)
Operating lease liability	(1,072)	(1,087)
Net cash used in operating activities	<u>(11,795)</u>	<u>(10,944)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(648)	—
Redemption of short-term investments	10,000	—
Purchases of marketable securities	—	(9,950)
Net cash (used in) provided by investing activities	<u>9,352</u>	<u>(9,950)</u>
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	919	36
Restricted stock repurchase at vesting to cover taxes	(85)	—
Net cash provided by financing activities	<u>834</u>	<u>36</u>
<b>Net decrease in cash, cash equivalents, and restricted cash</b>	<u>(1,609)</u>	<u>(20,858)</u>
Cash, cash equivalents, and restricted cash at beginning of period	75,016	44,440
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 73,407</u>	<u>\$ 23,582</u>
<b>Supplemental disclosures of non-cash investing activities:</b>		
Income taxes	\$ 206	\$ —
Purchases of property and equipment in accounts payable or accrued expenses	\$ 250	\$ 141

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



**Notes to Consolidated Financial Statements (Unaudited)**

**For the three months ended March 31, 2021 and 2020**

**1. Organization and Basis of Presentation**

Cue Biopharma, Inc. (the “Company”) was incorporated in the State of Delaware on December 31, 2014 under the name Imagen Biopharma, Inc., and completed its organization, formation, and initial capitalization activities effective as of January 1, 2015. In October 2016, the Company changed its name to Cue Biopharma, Inc. The Company’s corporate office and research facilities are located in Cambridge, Massachusetts.

The Company is a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics designed to selectively engage and modulate targeted T cells within the body to treat a broad range of cancers, chronic infectious diseases, and autoimmune disorders.

The Company is in the development stage and has incurred recurring losses and negative cash flows from operations since inception. As of March 31, 2021, the Company had unrestricted cash, cash equivalents, and marketable securities of approximately \$73,257,000. Management believes that current cash and cash equivalents on hand at March 31, 2021 are sufficient to fund operations for at least the next twelve months from the date of issuance of these financial statements; however, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund increased research and development costs in order to seek approval for commercialization of its product candidates. The Company’s failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to commercialize the Company’s product candidates in order to generate future revenue streams.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying unaudited consolidated financial statements as of March 31, 2021, and for the three months ended March 31, 2021 and 2020, 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 Corporation, Inc., 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 9, 2021.

Interim results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021, or any future periods.

**Public Offerings**

In March 2020, the Company entered into an “at-the-market” (“ATM”) equity offering sales agreement (the “March 2020 ATM Agreement”) with Stifel Nicolaus & Company, Inc. (“Stifel”) to sell shares of the Company’s common stock for aggregate gross proceeds of up to \$35 million, from time to time, through an ATM equity offering program under which Stifel would act as sales agent. As of March 31, 2021, the Company sold 1,824,901 shares of common stock under the March 2020 ATM Agreement for proceeds of approximately \$34.3 million, net of commissions paid, but excluding estimated transaction expenses. Due to the issuance and sale of all the shares of common stock available for sale, the March 2020 ATM Agreement terminated in accordance with its terms.

In June 2020, the Company entered into an ATM equity offering sales agreement with Stifel (the “June 2020 ATM Agreement”) to sell shares of the Company’s common stock for aggregate gross proceeds of up to \$40 million, from time to time, through an ATM equity offering program under which Stifel acts as sales agent. The June 2020 ATM Agreement will terminate upon the earliest of (a) the sale of \$40 million of shares of the Company’s common stock pursuant to the June 2020 ATM Agreement or (b) the termination of the June 2020 ATM Agreement by the Company or Stifel. As of March 31, 2021, the Company sold 1,192,000 shares of common stock under the June 2020 ATM Agreement for proceeds of approximately \$22.4 million, net of commissions paid, but excluding transaction expenses.

### **Consolidation**

The accompanying consolidated financial statements include Cue Biopharma Inc. and its wholly owned subsidiary, Cue Biopharma Securities Corporation, Inc (collectively “the Company”). The Company has eliminated all intercompany transactions.

### **Reclassifications**

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

### **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.

The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to issue “stay-at-home” or other similar orders, and enact restrictions on the performance of “non-essential” services, public gatherings and travel.

The extent to which the COVID-19 pandemic impacts the Company’s business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of the COVID-19 pandemic, the extent of its impact on worldwide macroeconomic conditions, the speed of the anticipated recovery, access to capital markets, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of the COVID-19 pandemic as of March 31, 2021 and through the date of the filing of this Quarterly Report on Form 10-Q. The accounting matters assessed included, but were not limited to, 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 assessments of impairment related to long-lived assets and intangibles. The Company’s future assessment of the magnitude and duration of the COVID-19 pandemic, as well as other factors, could result in material impacts to the Company’s consolidated financial statements in future reporting periods.

Despite the Company’s efforts, the ultimate impact of the COVID-19 pandemic depends on factors beyond the Company’s knowledge or control, including the duration and severity of the outbreak, as well as third-party actions taken to contain its spread and mitigate its public health effects. As a result, the Company is unable to estimate the extent to which the COVID-19 pandemic will negatively impact its financial results or liquidity.

### **Cash Concentrations**

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

### **Cash and Cash Equivalents**

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

### **Marketable Securities**

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

### **Restricted Cash**

The Company had \$150,000 in restricted cash deposited with a commercial bank to collateralize a credit card as of March 31, 2021 and December 31, 2020.

### **Property and Equipment**

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

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

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

### **Trademark**

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

The Company has classified the trademark as a component of other long-term assets, having a useful life of 15 years. The Company evaluates the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date. For each of the three months ended March 31, 2021 and 2020, the Company recorded approximately \$3,000 in amortization expense on a straight-line basis.

### **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 judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the most likely amount method. Currently, the Company has one contract with an option to acquire additional goods and/or services in the form of additional research and development services for additional product candidates which it evaluated and determined that the option to acquire additional goods and/or services was not a material right related to the LG Chem Collaboration Agreement.

### **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 product candidates.

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

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

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

### **Patent Expenses**

The Company is the exclusive worldwide licensee of, and has patent applications pending for, numerous domestic and foreign patents. Due to the significant uncertainty associated with the successful development of one or more commercially viable 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 expense as incurred. For the three months ended March 31, 2021 and 2020, patent expenses were \$520,000 and \$655,000, respectively. Patent expenses are included in general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

### **Licensing Fees and Costs**

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

### **Long-Lived Assets**

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

### **Leases**

The Company adopted Accounting Standards Update 2016-02, *Leases* ("ASC 842") as of January 1, 2019, which supersedes the existing guidance for lease accounting, ASC, Topic 840, *Leases*. ASC 842 requires a lessee to record a right-of-use asset and a corresponding lease liability for most lease arrangements on the balance sheet. Under the standard, disclosure of key information about leasing arrangements to assist users of the financial statements with assessing the amount, timing and uncertainty of cash flows arising from leases are required.

## Stock-Based Compensation

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

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

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading market for its common stock, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends and has no plans to do so for the foreseeable future. As permitted by Staff Accounting Bulletin No. 107, due to the Company's lack of trading history and option activity, management utilizes the simplified method to estimate the expected term of options at the date of grant. The exercise price is determined based on the fair value of the Company's common stock at the date of grant. The Company accounts for forfeitures as they occur.

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

## Comprehensive Income (Loss)

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

At March 31, 2021 and 2020, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	March 31,	
	2021	2020
Common stock warrants	851,969	1,189,827
Common stock options	5,738,757	5,507,572
Nonvested restricted stock units	213,336	250,001
Total	6,804,062	6,947,400

### **Fair Value of Financial Instruments**

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

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

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

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

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

The Company had approximately \$67,997,000 in cash equivalents that was measured and recorded at fair value on the Company's balance sheet as of March 31, 2021. The Company had approximately \$72,943,000 in cash equivalents and \$10,003,000 in short-term marketable securities that were measured and recorded at fair value on the Company's balance sheet as of December 31, 2020.

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

### **Recent Accounting Pronouncements**

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* (Topic 326) (CECL). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The new standard is effective for annual reporting periods beginning after December 15, 2022, including interim reporting periods within each annual reporting period for smaller reporting companies. The Company is still evaluating the impact of ASU 2016-13 on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. The pronouncement became effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2020. ASU No. 2019-12 is effective for the Company beginning in fiscal 2021. The Company adopted ASU No. 2019-12 on January 1, 2021 and it did not have a material impact on the Company's financial position, results of operations or disclosures.

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, 2021 and December 31, 2020, and indicate the level of the fair value hierarchy utilized to determine such fair value:

Fair Value Measurements as of March 31, 2021				
(in thousands)				
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	\$ 67,997	\$ —	\$ —	\$ 67,997
<b>Total</b>	<b>\$ 67,997</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 67,997</b>

Fair Value Measurements as of December 31, 2020				
(in thousands)				
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	\$ 72,943	\$ —	\$ —	\$ 72,943
Marketable securities	—	10,003	—	10,003
<b>Total</b>	<b>\$ 72,943</b>	<b>\$ 10,003</b>	<b>\$ —</b>	<b>\$ 82,946</b>

As of March 31, 2021, the Company reported approximately \$67,997,000 of cash equivalents. The Company's cash equivalents that are invested in money market funds are valued using Level 1 inputs for identical securities. As of December 31, 2020, the Company reported approximately \$82,946,000 of cash equivalents and marketable securities. During the year ended December 31, 2020, there were no transfers between Level 2 and Level 3.

The carrying values of accounts receivable, prepaid expenses, other current assets, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances.

#### 4. Marketable Securities

As of December 31, 2020, the fair value of available-for-sale marketable securities by type of security was as follows:

December 31, 2020				
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury Securities	\$ 9,995	\$ 7	\$ —	\$ 10,003
	<u>\$ 9,995</u>	<u>\$ 7</u>	<u>\$ —</u>	<u>\$ 10,003</u>

At March 31, 2021, the Company had redeemed its entire investment in marketable securities. At December 31, 2020, marketable securities consisted of approximately \$10,003,000 of investments that mature within twelve months.

#### 5. Property and Equipment

Property and equipment as of March 31, 2021 and December 31, 2020 consisted of the following:

	March 31, 2021	December 31, 2020
(in thousands)		
Laboratory equipment	\$ 5,022	\$ 4,148
Furniture and fixtures	93	93
Computer equipment	268	268
Leasehold improvements	7	-
Construction in progress	421	405
	<u>5,811</u>	<u>4,915</u>
Less accumulated depreciation	(3,025)	(2,807)
Net property and equipment	<u>\$ 2,786</u>	<u>\$ 2,108</u>

Depreciation expense for the three months ended March 31, 2021 and 2020 was approximately \$218,000 and \$194,000, respectively. Depreciation expense for the three months ended March 31, 2021 excludes trademark amortization expense of approximately \$3,000, and amortization of capitalized license expenses of approximately \$97,000. Depreciation for the three months ended March 31, 2020 excludes trademark amortization expense of approximately \$3,000, and amortization of capitalized license expenses of approximately \$66,000 for the three months ended March 31, 2020. There were no disposals of property and equipment for the three months ended March 31, 2021 and 2020.

## 6. Stock-Based Compensation

### Stock Option Valuation

For stock options requiring an assessment of value during the three months ended March 31, 2021, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	<u>March 31, 2021</u>
Risk-free interest rate	0.61 to 1.18%
Expected dividend yield	0%
Expected volatility	92.2-94.7%
Expected life	5.50 to 6.25 years
	<u>March 31, 2020</u>
Risk-free interest rate	1.00-1.56%
Expected dividend yield	0%
Expected volatility	98.0-99.6%
Expected life	4.0 to 6.25 years

A summary of stock option activity for the three months ended March 31, 2021 is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>
Stock options outstanding at December 31, 2020	5,030,899	\$ 9.10	5.51
Granted	868,500	14.73	
Exercised	(130,642)	7.02	
Cancelled	(30,000)	12.51	
Stock options outstanding at March 31, 2021	<u>5,738,757</u>	<u>9.79</u>	<u>6.01</u>
Stock options exercisable at March 31, 2021	<u>3,131,938</u>	<u>\$ 7.53</u>	<u>4.15</u>

The Company recognized approximately \$2,069,000 in stock-based compensation expense during the three months ended March 31, 2021, related to stock options activity. As of March 31, 2021, total unrecognized stock-based compensation expense was approximately \$23,048,000, which is expected to be recognized as an operating expense in the Company's consolidated statement of operations and other comprehensive loss over the weighted average remaining period of 2.6 years. During the three months ended March 31, 2021, the Company granted stock options to purchase 868,500 shares of common stock with an average grant date fair value of \$11.26. During the three months ended March 31, 2020, the Company granted stock options to purchase 728,100 shares of common stock with an average grant date fair value of \$13.02.

The intrinsic value of exercisable but unexercised in-the-money stock options at March 31, 2021 was approximately \$16,435,000, based on a fair value of \$12.20 per share on March 31, 2021.

### Restricted Stock Units

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



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

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

The following table summarizes the RSU activity under the Company's 2016 Omnibus Incentive Plan for the three months ended March 31, 2021:

Restricted Stock Units	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance at December 31, 2020	230,002	\$ 16.66
Vested/Released	(16,666)	\$ 14.19
Nonvested balance at March 31, 2021	213,336	\$ 16.86

The Company recognized approximately \$367,000 in stock-based compensation during the three months ended March 31, 2021 related to RSU activity. As of March 31, 2021, total unrecognized stock-based compensation was approximately \$2,406,000, which is expected to be recognized as an operating expense in the Company's consolidated statement of operations and other comprehensive loss with a weighted average remaining period of 1 year.

### Stock-based Compensation

Stock-based compensation expense for the three months ended March 31, 2021 and 2020 was included in the consolidated statement of operations and other comprehensive loss as follows:

(in thousands)	Three Months Ended March 31,	
	2021	2020
General and administrative	\$ 1,114	\$ 1,017
Research and development	1,322	2,158
Total	\$ 2,436	\$ 3,175

### 7. Warrants

The Company had two tranches of common stock warrants outstanding at March 31, 2021. The first tranche was exercisable for an aggregate of 370,370 shares of common stock and was issued on June 15, 2015 with an exercise price of \$2.70 per share. These warrants were issued with a 7-year term and expire on June 15, 2022. The second tranche was exercisable for an aggregate of 882,071 shares of common stock and was issued on December 27, 2017 with an exercise price of \$9.38 per share. These warrants were issued with a 5-year term and expire on December 26, 2022. The intrinsic value of exercisable but unexercised in-the-money common stock warrants at March 31, 2021 was approximately \$2,825,000 based on a fair value of \$12.20 per share on March 31, 2021.

Each tranche of warrants was evaluated under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and the Company determined that equity classification was appropriate.

The following table shows common stock warrants outstanding as of March 31, 2021:

	Warrant Issued June 15, 2015- Tranche 1	Warrant Issued December 27, 2017- Tranche 2	Total
Shares remaining to be issued as of December 31, 2020	72,611	789,358	861,969
Issued via cashless exercises	(8,048)	—	(8,048)
Withheld as payment to cover issued shares	(1,952)	—	(1,952)
Shares remaining to be issued	62,611	789,358	851,969

## 8. 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 judgement 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, (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 milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled for its one open contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of the Company or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company reevaluates the probability of achievement of each milestone and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

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

The Company allocates the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis, when applicable. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contract 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 judgement 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 the 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.

On November 14, 2017, the Company entered into a collaboration agreement (the "Merck Collaboration Agreement") with Merck Sharp & Dohme Corp. ("Merck") for a partnership to research and develop certain of the Company's proprietary biologics that target certain autoimmune disease indications (the "Initial Indications"). The Company views the Merck Collaboration Agreement as a component of its development strategy since it will allow the Company to advance its autoimmune programs in partnership with a world class pharmaceutical company, while also continuing its focus on its more advanced cancer programs. The research program outlined in the Merck Collaboration Agreement entails (1) the Company's research, discovery and development of certain Immuno-STAT™ drug candidates up to the point of demonstration of certain biologically relevant effects ("Proof of Mechanism") and (2) the further development by Merck of the Immuno-STAT drug candidates that have demonstrated Proof of Mechanism (the "Proposed Product Candidates") up to the point of demonstration of all or substantially all of the properties outlined in such Proposed Product Candidates' profiles as described in the Merck Collaboration Agreement.

In exchange for the licenses and other rights granted to Merck under the Merck Collaboration Agreement, Merck paid to the Company a \$2.5 million nonrefundable up-front payment. Additionally, the Company may be eligible to receive funding in developmental milestone payments, as well as tiered royalties, if all research, development, regulatory and commercial milestones agreed upon by both parties are successfully achieved. Excluding the up-front payment described above, the Company is eligible to earn up to \$101.0 million for the achievement of certain research and development milestones, \$120.0 million for the achievement of certain regulatory milestones and \$150.0 million for the achievement of certain commercial milestones, in addition to tiered royalties on sales, if all pre-specified milestones associated with multiple products across the primary disease indication areas are achieved. The Merck Collaboration Agreement requires the Company to use the first \$2.5 million of milestone payments it receives under the agreement to fund contract research. The amount of the royalty payments is a percentage of product sales ranging in the single digits based on the amount of such sales.

As it relates to the Merck Collaboration Agreement, the Company recognized the up-front payment associated with its one open contract 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. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as contract liabilities, net of current portion. The Company determined that there was one performance obligation, consisting of the license and research development services. Thus, the transaction price of \$2.5 million was allocated to the single performance obligation.

Aside from the \$2.8 million in milestone payments earned to date, the Company does not believe that any variable consideration should be included in the transaction price at March 31, 2021. The Company's assessment ensured 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, 2021 and 2020, the Company recorded approximately \$765,000 and \$55,000, respectively, in collaboration revenue related to the Merck Collaboration Agreement. As of March 31, 2021, the Company recorded short- and long-term research and development liabilities on its balance sheet of approximately \$570,000 and \$0, respectively. As of December 31, 2020, the Company recorded short and long-term research and development liabilities on its balance sheet of approximately \$607,000 and \$0, respectively.

On November 6, 2018, the Company entered into a collaboration agreement (the "LG Chem Collaboration Agreement") with LG Chem Life Sciences ("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, as amended on November 5, 2020, expired. The Company retains rights to develop and commercialize all assets included in the agreement in the United States and in global markets outside of Asia. 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 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 ("FDA") acceptance of the investigational new drug application ("IND") for the Company's lead drug candidate, CUE-101, pursuant to the LG Chem Collaboration Agreement. The \$2.5 million milestone payment was recorded as a contract liability upon receipt of payment as it requires deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Of the \$2.5 million milestone payment, approximately \$412,500 was recognized as tax withholding, shown as income tax expense on the consolidated statement of operations and other comprehensive loss.

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

Aside from the \$3.75 million in milestone payments under the LG Chem Collaboration Agreement, the Company does not believe that any variable consideration should be included in the transaction price as of March 31, 2021. The Company's assessment ensured 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, 2021 and 2020, the Company recognized revenue of approximately \$788,000 and approximately \$844,000, respectively, related to the LG Chem Collaboration agreement. As of March 31, 2021, the Company recorded short- and long-term research and development liabilities on

its balance sheet of approximately \$6,575,000 and \$1,334,000, respectively. As of December 31, 2020, the Company recorded short- and long-term research and development liabilities on its balance sheet of approximately \$6,074,000 and \$1,938,000, respectively.

The Company considered the capitalization of contract costs under the guidance in ASC 340-40, *Other Assets and Deferred Costs: Contracts with Customers*. There were no contract costs identified in the Merck Collaboration Agreement. As it related to the LG Chem Collaboration Agreement, the Company capitalized license expenses of approximately \$908,000 as of March 31, 2021, paid to Einstein pursuant to the Einstein License Agreement which requires the Company to pay a percentage of sublicenses related to the Company's patent rights for components of its core technology that is licensed from Einstein. This amount is comprised of approximately \$438,000 of capitalized license expenses related to the up-front payment received from LG Chem in December 2018, approximately \$313,000 in capitalized license expenses related to the milestone payment received in June 2019, and approximately \$157,000 in capitalized license expenses related to the milestone payment received in December 2020, net of accumulated amortization of approximately \$588,000. As of March 31, 2021, \$320,000 was included in prepaid expenses and other short-term assets related to the LG Chem Collaboration Agreement. As of December 31, 2020, \$416,900 was included in prepaid expenses and other short-term assets.

## **9. Commitments and Contingencies**

### ***Einstein License Agreement***

In 2015, the Company entered into the Einstein License Agreement with Einstein for certain patent rights relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory drug 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 Agreement. For each of the three months ended March 31, 2021 and 2020, the Company incurred approximately \$18,750 in fees and expenses to Einstein in relation to this license.

The Company's remaining commitments with respect to the Einstein License Agreement are based on the attainment of future milestones. The aggregate amount of milestone payments to be made under the Einstein License Agreement equals up to \$1.85 million for each product, process or service that use the patents covered by the Einstein License Agreement, including certain technology received from Einstein relating thereto ("Licensed Products"), and up to \$1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products equals up to \$5.75 million.

### ***Collaboration Agreement with Merck***

See discussion of the Merck Collaboration Agreement in Note 8.

### ***Collaboration Agreement with LG Chem Life Sciences***

See discussion of the LG Chem Collaboration Agreement in Note 8.

### ***Contingencies***

The Company accrues for contingent liabilities to the extent that the liability is probable and estimable. There are no accruals for contingent liabilities in these 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, 2021, 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.

## **10. Leases**

The Company leases approximately 19,900 square feet of office space in Cambridge, Massachusetts under a lease that began in May 2018 and is scheduled to expire on June 14, 2022 (the "Lease"), as discussed further below. Upon adoption of ASC 842, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 6%, the Company's estimated incremental borrowing rate annually, over the 2.3-year remaining term.

The Company adopted ASC 842 as of January 1, 2019 using the effective date method, in which the Company did not restate prior periods. Upon adoption, the Company elected the package of practical expedients permitted under the transition guidance within ASC 842, which among other things, allowed it to carry forward the historical lease classification. The Company does not allocate consideration in its leases to lease and non-lease components and does not record leases on its balance sheets with terms of 12 months or less.

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of lease payments. The Company's incremental borrowing rate represents the rate of interest that it would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment.

The adoption of ASC 842 on January 1, 2019 resulted in the recognition of approximately \$9,692,000 of right-of-use asset and \$9,347,000 of lease liabilities on the Company's balance sheet. The adoption did not have a material net impact on the Company's consolidated statements of operations and comprehensive loss or accumulated deficit. The Company will review the classification of newly entered leases as either an operating or a finance lease and recognize a related right-of-use asset and lease liability on its balance sheet upon commencement.

On January 18, 2018, the Company entered into an operating lease agreement for its laboratory and office space in Cambridge, Massachusetts for the period from May 1, 2018 through April 30, 2021 (the "Laboratory and Office Lease"). The lease contains escalating payments during the lease period. Upon execution of this lease agreement, the Company prepaid three months of rent, two of which will be held in escrow and credited against future rent payments and the other of which was applied to the first month's rent. The Company also prepaid seven and one-half months' rent pursuant to an amendment to the lease agreement executed on June 18, 2018. These amounts were recorded to deposits and prepaid expenses, respectively, at December 31, 2018. On June 18, 2018, the Company entered into an amendment to the Laboratory and Office Lease that provided the Company with a reduction in rental fees for its office and laboratory space in exchange for prepayment of a portion of the fees. This amendment was effective beginning on May 15, 2018.

The monthly rent payment due under the Laboratory and Office Lease was \$330,550 until April 2021 and increased to \$375,174 for the remainder of the term.

On September 20, 2018, the Company entered into an operating lease for additional laboratory space at 21 Erie Street, Cambridge, Massachusetts for the period from October 15, 2018 through April 14, 2021 (the "Additional Laboratory Lease"). The lease contains escalating payments during the lease period. The monthly rental rate under the Additional Laboratory Lease was \$72,600 for the first 12 months and \$78,600 for the remainder of the term. Upon execution of this lease agreement, the Company prepaid 12 months' rent pursuant to the lease agreement executed on September 20, 2018.

On September 19, 2019, the Company entered into a second amendment to the Additional Laboratory Lease that removed one holding room from the additional laboratory space. The amendment was effective beginning on October 1, 2019. The monthly rental rate under the Additional Laboratory Lease decreased from \$78,600 to \$58,995 for the remainder of the lease term. The partial termination of the lease did not change the classification of the lease and remained accounted for as an operating lease. The weighted-average discount rate remained the same at 6%. The Company accounted for the lease modification under ASC 842 that removed one holding room by electing Approach 1, which remeasured the right-of-use asset on the basis of the amount of the liability change. The modification of the partial termination resulted in a reduction to right-of-use asset and lease liability of \$335,465 and \$327,079, respectively. The difference of \$8,386 was recorded as a loss to the right-of-use asset as of December 31, 2020.

On June 24, 2020, the Company entered into a second amendment to the Laboratory and Office Lease. Pursuant to the amendment (1) the term of the lease was extended to June 14, 2022 and (2) the monthly rental rate for the last 14 months of the lease term was increased to \$375,174. The Company determined that the amendment should be accounted for as a lease modification applicable under ASC 842, not as a separate contract, with an effective date of lease modification of May 14, 2020. At the effective date of modification, the Company recorded an adjustment to the right-of-use asset and lease liability in the amount of approximately \$4,826,000.

On July 20, 2020, the Company entered into a third amendment to the Additional Laboratory Lease. Pursuant to the amendment, the term of the lease was extended to June 14, 2022. The Company determined that the amendment should be accounted for as a lease modification applicable under ASC 842, not as a separate contract, with an effective date of lease modification of August 4, 2020, when the agreement was fully executed. At the effective date of modification, the Company recorded an adjustment to the right-of-use asset and lease liability in the amount of approximately \$813,000.

At March 31, 2021, the Company recorded approximately \$5,656,000 to operating right-of-use asset, and approximately \$4,989,000 and \$1,085,000 to short- and long-term operating lease liability, respectively. At March 31, 2021 the remaining lease term was 1.21 years for both leases. At December 31, 2020, the Company recorded approximately \$6,774,000 to operating right-of-use asset, and approximately \$4,777,000 and \$2,369,000 to short- and long-term operating lease liability, respectively. At December 31, 2020 the remaining lease term was 1.46 years for both leases. As of March 31, 2021 and December 31, 2020, a security deposit of approximately \$177,000 is included in deposits on the Company's balance sheet.

Future minimum lease payments under these leases at March 31, 2021 are as follows:

Year	(in thousands)
2021	3,905
2022	2,408
Total lease payment	\$ 6,313
Less: present value discount	(239)
Total	\$ 6,074

Total rent expense of approximately \$1,220,000 and \$1,080,000 was included in the consolidated statement of operations and other comprehensive loss for the three months ended March 31, 2021 and 2020, respectively. Other information pertaining to the Company's operating leases for the three months ended March 31, 2021 is summarized in the table below.

Other information (in thousands)	Three Months Ended March 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 1,174
Operating lease cost	\$ 1,220
Weighted average discount rate	6.0%
Weighted average remaining lease term	1.21 years

## 11. Subsequent Events

In June 2020, the Company entered into the June 2020 ATM Agreement with Stifel to sell shares of the Company's common stock for aggregate gross proceeds of up to \$40.0 million, from time to time, through an ATM equity offering program. Subsequent to March 31, 2021, the Company sold 907,700 shares of common stock under the June 2020 ATM Agreement for proceeds of approximately \$10.4 million, net of commissions paid, but excluding estimated transaction expenses. As of May 3, 2021, aggregate sales under the June 2020 ATM Agreement totaled 2,099,700 shares of common stock sold for approximately \$32.7 million, net of commissions paid, but excluding estimated transaction expenses.

On April 30, 2021, LG Chem's option pursuant to the global license and collaboration agreement, as amended on November 5, 2020, whereby LG Chem had the option to elect one additional Immuno-STAT for an oncology target for a worldwide development and commercialization license, expired.

## 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, 2020 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 by us with the Securities and Exchange Commission, or SEC, on March 9, 2021, or the 2020 Annual Report.

### Overview

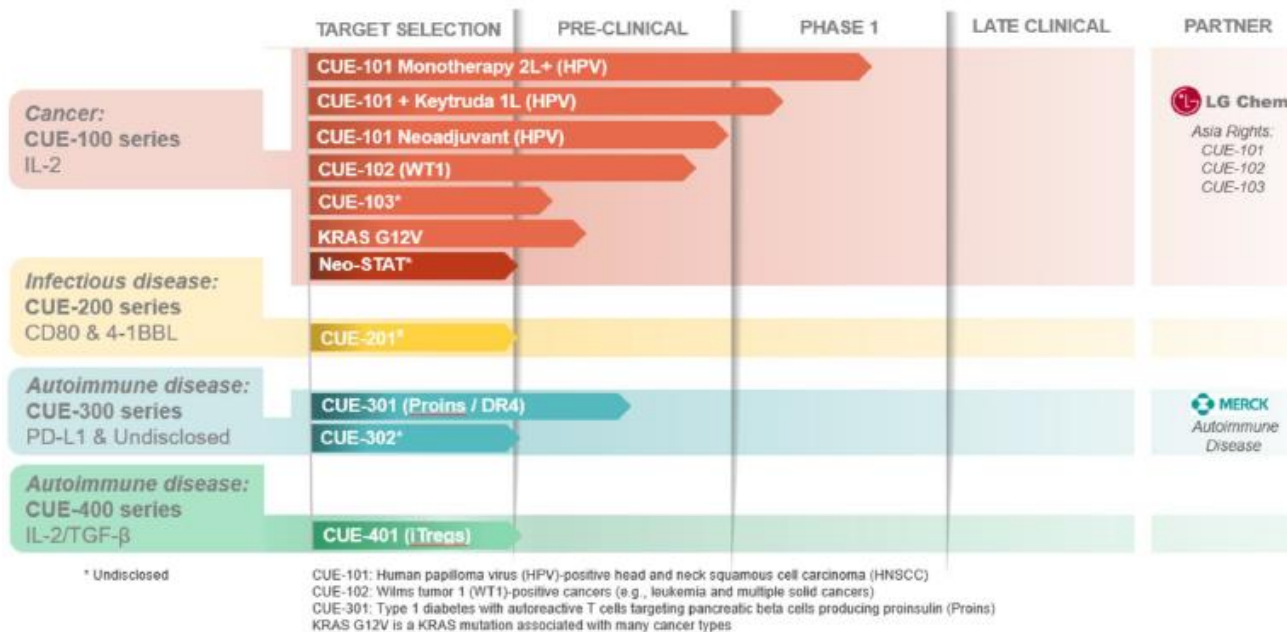
We are a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells within the patient’s body. We believe our proprietary Immuno-STAT (*Selective Targeting and Alteration of T Cells*) platform will allow us to harness the fullest potential of an individual’s intrinsic immune repertoire for restoring health while avoiding the deleterious side effects of broad immune activation (for immuno-oncology or infectious disease indications) or broad immune suppression (for autoimmunity and inflammation). In addition to the selective modulation of T cell activity, we believe Immuno-STATs offer several key points of potential differentiation over competing approaches, including modularity and versatility, providing broad disease coverage, manufacturability, and convenient administration.

Through rational protein engineering, we leverage the modular and versatile nature of the Immuno-STAT platform to design drug product candidates for selective immune modulation in cancer, chronic infectious disease, and autoimmune disease. To address the needs of these clinical indications, we have developed four biologic series within the Immuno-STAT platform: CUE-100, CUE-200, CUE-300 and CUE-400, each specifically designed through rational protein engineering to possess distinct signaling modules for desired biological mechanisms that may be applied across many diseases. The CUE-100 series exploits rationally engineered IL-2 in context of the core Immuno-STAT framework for selective activation of targeted tumor-specific T cells, while the CUE-200 series is focused on cell surface receptors including CD80 and/ or 4-1BBL to address T cell exhaustion associated with chronic infections. The CUE-300 series, being developed for autoimmune diseases, incorporates the inhibitory PD-L1 co-modulator for selective inhibition of the autoreactive T cell repertoire. This approach is pertinent for autoimmune diseases with known, well characterized, limited or few autoantigens, such as type 1 diabetes. The CUE-400 series, for autoimmune diseases with diverse or unknown autoantigens, represents a novel class of bispecific molecules that can selectively and effectively expand induced regulatory T cells, or iTregs. We categorize these molecules as “pathway-specific modulators,” or PSM. The first candidate, CUE-401, incorporates the two key biological signals that are necessary for generation of iTregs, namely IL-2 and TGF-beta. Based on structure-based rational protein engineering, both IL-2 and TGF-beta have been affinity tuned (i.e. the binding strength has been optimized) to maintain on-target engagement while minimizing systemic toxicities.

Our drug product candidates are in various stages of clinical and preclinical development, and while we believe that these candidates hold potential value, our activities are subject to significant risks and uncertainties. We have not yet commenced any commercial revenue-generating operations, have limited cash flows from operations, and will need to raise additional capital to fund our growth and ongoing business operations.

### Our Immuno-STAT Platform Pipeline

The pipeline below details our current portfolio assets and their stages of development. CUE-101 is our most advanced clinical stage asset, currently being dosed in a Phase 1 monotherapy trial for human papilloma virus (HPV)-driven recurrent/metastatic(R/M) head and neck cancer, as well as in a first line Phase 1 combination trial with KEYTRUDA® (pembrolizumab) in the same indication. CUE-102 focuses on Wilm’s tumor-1 (WT1) as the tumor antigen.



We have made significant progress advancing the IL-2-based CUE-100 series for oncology. We dosed the first patient in September 2019 in a monotherapy Phase 1 dose escalation clinical trial of CUE-101 for the treatment of HPV16-driven R/M head and neck squamous cell carcinoma, or HNSCC, in late-stage treatment-refractory patients with R/M-HNSCC who have received and failed several prior lines of systemic therapy including checkpoint inhibitors such as KEYTRUDA, already approved for first-line, or 1L, HPV+R/M HNSCC. To date, CUE-101 has demonstrated a favorable tolerability profile in the monotherapy trial and continues to generate encouraging emerging data pertaining to its pharmacokinetic, or PK, and pharmacodynamic, or PD, profile, as well as anti-tumor clinical activity as evidenced by a confirmed partial response, or PR, as well as several confirmed stable diseases, or SDs, in the dose escalation phase of the clinical trial.

During the fourth quarter of 2020, we initiated a Phase 1 clinical trial into the first-line R/M HNSCC setting to evaluate the combination of CUE-101 with Merck Sharp & Dohme Corp.'s, or Merck's, anti-PD-1 therapy KEYTRUDA®. The first patient in this combination study was dosed in the first quarter of 2021. The potential synergy with KEYTRUDA is due to CUE-101's design and protein engineering to selectively activate and expand tumor-targeted T cells directly in the patient's body. We believe the potential of CUE-101 to synergize with and enhance the clinical activity of KEYTRUDA is mechanistically attractive since the presence of expanded tumor-specific T cells are a pre-requisite for and an obligatory target of anti-PD-1. In preclinical studies, we have observed activation and expansion of the targeted T cells circulating in the peripheral blood, as well as a significant expansion of tumor infiltrating lymphocytes. In addition to the Phase 1 monotherapy and combination trial with KEYTRUDA, we also intend to initiate a neoadjuvant study in locally advanced HPV+ HNSCC patients in the second half of 2021, which is expected to provide further mechanistic evidence and insights into the activation and effector function of T cells resident in tumor tissue and their impact on tumor viability.

CUE-101 is the most advanced candidate from our IL-2 based CUE-100 series and is exemplary of the union of the rational protein engineering underscoring the Immuno-STAT platform and key immunological targets, or activity nodes, to selectively enhance anti-tumor immunity. Data relating to this work were recently published in a peer-reviewed journal (Quayle et al., Clinical Cancer Research 2020, <https://clincancerres.aacrjournals.org/content/early/2020/01/15/1078-0432.CCR-19-3354>). Importantly, we believe that the totality of clinical data with CUE-101, underscored by the recent confirmed PR and SDs from the ongoing Phase 1 monotherapy study of CUE-101, effectively reduces the risk profile of the IL-2 based CUE-100 series due to the fact that the core framework of the CUE-100 series remains essentially the same for each drug candidate, except for the targeting peptide epitope within the major histocompatibility complex, or MHC, pocket or the human leukocyte antigen, or HLA, in humans. Therefore, with the exception of some protein engineering modifications to ensure stability and manufacturability the core IL-2 scaffold is a shared molecular feature of all molecules generated within this series (including CUE-102, and the next-gen platform, Neo-STAT™, as described below).

We are also advancing a pipeline of additional promising preclinical candidates that we believe hold the potential to treat multiple cancers. Data from our second product candidate of the CUE-100 series, CUE-102 (WT1) were recently presented at the New York Academy of Science, or NYAS, Frontiers in Cancer Immunotherapy meeting and at the Society for Immunotherapy of Cancer, or SITC, meeting in November 2020. These data support early evidence of selective T cell expansion, along with polyfunctional effector function including killing of target cells. We are continuing to develop CUE-102 toward an investigational new drug



application, or IND, through enabling studies, and we anticipate filing an IND for this product candidate in the first half of 2022. We have also generated foundational data with Immuno-STATs targeting the mutated G12V KRAS T cell epitope including demonstration of activation and expansion of T cells expressing G12V-specific T cell receptors, or TCRs. These data were presented at the SITC meeting in November 2020 and more recently at the Immuno-Oncology conference, IO-360, in February 2021.

Importantly, through rational protein engineering, we have expanded the reach of the Immuno-STAT platform to potentially address the heterogeneity and diversity of many cancers by developing a derivative scaffold from the CUE-100 series that contains stable “peptide-less” or “empty” MHC pocket or human leukocyte antigen, or HLA, molecules, to which peptides of interest may be covalently attached. We refer to this derivative scaffold as Neo-STAT™. Neo-STAT is designed to provide greater flexibility for targeting multiple tumor epitopes, enhance production efficiencies, decrease time and cost to manufacture and potentially lend itself to personalized neo-antigen strategies in cancer immunotherapy as an off-the-shelf approach.

In addition, in an effort to address tumor escape mechanisms of HLA loss and related components of antigen presentation, we have engineered a bi-specific RDI-STAT (**Re-Directed Immuno-STAT**) platform that harnesses virally directed Immuno-STATs linked with tumor-targeting molecules to bind to the cancer cell and make them appear like virally infected cells. This allows us to exploit and re-purpose the pre-existing protective anti-viral T cell repertoire to kill cancers, including those that have lost expression of HLA or have defects in antigen-presenting pathways. Like CUE-101 and our other CUE-100 Series drug candidates, these innovative platforms potentially avoid systemic T cell activation and related cytokine release syndrome to provide significant differentiation over other approaches, including IL-2 variants and other bi-specific molecules, that rely on global T cell activation.

We have also made recent advances in the application of our protein engineering platform to autoimmune disease, where our core strategy has centered on two major themes: (i) modulating antigen-specific T cells with Immuno-STATs in diseases with restricted or known autoantigens (e.g., type 1 diabetes), and (ii) exploiting a pathway-specific approach via modalities focused on regulatory T cells and other mechanisms that could be broadly applied to autoimmune disease with unknown or diverse autoantigens. In the first instance we have made significant advances with the CUE-300 series for targeting antigen-specific T cells in autoimmune disorders, including progress made in our collaboration with Merck which was recently extended and further supported through 2021. To date, we have generated proof of concept data demonstrating the potential for targeting autoreactive T cells in type 1 diabetes; <https://www.cuebiopharma.com/wp-content/uploads/2020/03/CUE-Merck-Autoimmune-Data.pdf>. Based upon the promising progress we have made through our Merck collaboration to date, we expect to further develop a growing pipeline of autoimmune product candidates throughout 2021.

Additionally, we have expanded our reach into chronic autoimmune diseases with diverse and/or uncharacterized antigens by focusing on activating and increasing regulatory T cells for re-setting immune balance. Our first candidate from this effort, CUE-401, incorporates two key signals, namely IL-2 and TGF-beta, for differentiation and expansion of iTregs.

Furthermore, we are assessing the potential of developing programs from the Immuno-STAT platform for treating chronic infectious disease with the CUE-200 series through research being conducted by Dr. Steven Almo, a co-founder of the Company and Chair of Biochemistry at The Albert Einstein College of Medicine. Data supporting these applications were recently presented at the SITC meeting in November 2020; <https://www.cuebiopharma.com/wp-content/uploads/2020/11/Immuno-STAT-SITC-2020-Poster.pdf>.

#### Coronavirus (“COVID-19”) Pandemic

The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to issue “stay-at-home” or similar orders, and enact restrictions on the performance of “non-essential” services, public gatherings and travel. Beginning in March 2020, we undertook precautionary measures intended to help minimize the risk of virus transmission to our employees, including the establishment of remote working standards, pausing all non-essential travel worldwide for our employees, and limiting employee attendance at industry events and in-person work-related meetings, to the extent those events and meetings are continuing. We also established policies and procedures for all personnel who enter our company premises. The policies and procedures we implemented are consistent with the rules and guidelines recommended by the Centers for Disease Control and Prevention, the Commonwealth of Massachusetts and the City of Cambridge. To date, we do not believe these actions have had a significant impact on our productivity or our operations. However, these actions or additional measures we may undertake may ultimately delay progress of our developmental goals or otherwise negatively affect our business. In addition, third-party actions taken to contain the spread of the novel coronavirus, SARS-CoV-2, and mitigate public health effects may negatively affect our business.

In January 2021, we were notified by our contract manufacturing organization, or CMO, that the manufacture of our cGMP material for the CUE-102 drug candidate would be delayed by approximately six weeks due to the invocation of the Defense Production Act, or DPA, which gives priority to the manufacture of vaccines and other drug products used to prevent or treat COVID-19. The delay in the manufacturing of our CUE-102 cGMP batch has impacted the expected filing date of the CUE-102 IND that was

planned for the fourth quarter of 2021. The CUE-102 IND is now expected to be filed in the first quarter of 2022 based on the revised CUE-102 cGMP manufacturing date provided by our CMO.

### **Plan of Operation**

Our technology is in the development phase. We believe that our licensed platforms have the potential for creating a diverse pipeline of promising drug candidates addressing multiple medical indications. We intend to maximize the value and probability of commercialization of our Immuno-STAT 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 and our planned future activities will be devoted to furthering research and development.

A fundamental part of our corporate development strategy is to establish one or more strategic partnerships with leading pharmaceutical or biotechnology organizations that will allow us to more fully exploit the potential of our technology platform, such as those described below under the headings “Collaboration Agreement with Merck” and “Collaboration with LG Chem”.

### **Critical Accounting Policies and Significant Judgements and Estimates**

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the estimates, assumptions and judgments involved in the accounting policies described in Management’s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020, have the greatest potential impact on our financial statements, so we consider the 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, 2021.

### **Recent Accounting Pronouncements and Adopted Standards**

A discussion of recent accounting pronouncements is included in Note 2 to the 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, or the Einstein License, with Albert Einstein College of Medicine, or Einstein, for certain patent rights relating to our core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory drug 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 covered by the Einstein License, including certain technology received from Einstein related thereto, or the Licensed Products. Under the Einstein License, we are required to:

- Pay royalties and amounts based on 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. For the three months ended March 31, 2021, none of these milestones had been achieved by us.
- Incur minimum product development costs per year until the first commercial sale of the first Licensed Product.

As of March 31, 2021, 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 if we fail to meet our obligations thereunder.

We account for the costs incurred in connection with the Einstein License in accordance with Accounting Standards Codification, or ASC 730, *Research and Development*. For each of the three months ended March 31, 2021 and 2020, costs incurred with respect to the Einstein License aggregate \$18,750. Such costs are included in research and development costs in the consolidated statement of operations and other comprehensive loss.

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

### ***Collaboration Agreement with Merck***

On November 14, 2017, we entered into an Exclusive Patent License and Research Collaboration Agreement, or the Merck Collaboration Agreement, with Merck for a partnership to research and develop certain of our proprietary biologics that target certain autoimmune disease indications, or the Initial Indications. We view the Merck Collaboration Agreement as a component of our development strategy since it will allow us to advance our autoimmune programs in partnership with a world class pharmaceutical company, while also continuing our focus on our more advanced cancer programs. The research program outlined in the Merck Collaboration Agreement entails (1) our research, discovery and development of certain Immuno-STAT drug candidates up to the point of demonstration of certain biologically relevant effects, or Proof of Mechanism, and (2) the further development by Merck of the Immuno-STAT drug candidates that have demonstrated Proof of Mechanism, or the Proposed Product Candidates, up to the point of demonstration of all or substantially all of the properties outlined in such Proposed Product Candidates' profiles as described in the Merck Collaboration Agreement.

For the purposes of this collaboration, we granted to Merck under the Merck Collaboration Agreement an exclusive license under certain of our patent rights, including a sublicense of patent rights licensed from Einstein, to the extent applicable to the specific Immuno-STAT that are elected to be developed by Merck. So long as Merck continues product development on a Proposed Product Candidate, we are restricted from conducting any development activities within the Initial Indication covered by such Proposed Product Candidate other than pursuant to the Merck Collaboration Agreement.

In exchange for the licenses and other rights granted to Merck under the Merck Collaboration Agreement, Merck paid to us a \$2.5 million nonrefundable up-front payment. Additionally, we may be eligible to receive funding in developmental milestone payments, as well as tiered royalties, if all research, development, regulatory and commercial milestones agreed upon by both parties are successfully achieved. Excluding the \$2.5 million up-front payment described above, we are eligible to earn up to \$101.0 million for the achievement of certain research and development milestones, \$120.0 million for the achievement of certain regulatory milestones and \$150.0 million for the achievement of certain commercial milestones, in addition to tiered royalties on sales, if all pre-specified milestones associated with multiple products across the primary disease indication areas are achieved. The Merck Collaboration Agreement requires us to use the first \$2.5 million of milestone payments we receive under the agreement to fund contract research. The amount of the royalty payments is a percentage of product sales ranging in the single digits based on the amount of such sales. For the three months ended March 31, 2021 and 2020, we recorded approximately \$765,000 and \$55,000, respectively, in collaboration revenue related to the Merck Collaboration Agreement.

The term of the Merck Collaboration Agreement extends until the expiration of all royalty obligations following a product candidate's receipt of marketing authorization, at which point Merck's licenses and sublicenses granted under the agreement shall become fully paid-up, perpetual licenses and sublicenses, as applicable. Royalties on each product subject to the Merck Collaboration Agreement shall continue on a country-by-country basis until the expiration of the later of: (1) the last-to-expire patent claiming the compound on which such product is based and (2) a period of ten years after the first commercial sale of such product in such country.

Notwithstanding the foregoing, Merck may terminate the Merck Collaboration Agreement at any time upon 30 days' notice to us. The Merck Collaboration Agreement may also be terminated by either party if the other party is in breach of its obligations thereunder and fails to cure such breach within 90 days after notice or by either party if the other party files for bankruptcy or other similar insolvency proceedings.

### ***Collaboration Agreement with LG Chem***

Effective November 6, 2018, we entered into a collaboration agreement with LG Chem Life Sciences, or LG Chem, which we refer to as the LG Chem Collaboration Agreement, 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 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. On December 20, 2018, we reported the selection of Wilm's Tumor 1, or WT1, as the first target antigen for a Product Candidate under the LG Chem Collaboration Agreement. 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 Product Candidates. The LG Chem Collaboration Agreement provided LG Chem with 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 but generally does not become effective unless and until LG Chem exercises 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, as amended on November 5, 2020, expired. We will retain an option to co-develop and co-commercialize the additional program worldwide.

Under the terms of the LG Chem Collaboration Agreement, LG Chem paid us a \$5.0 million non-refundable, non-creditable up-front payment and purchased approximately \$5.0 million of shares of our common stock at a price per share equal to a twenty percent (20%) premium to the volume weighted-average closing price per share over the thirty (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 approximately \$400.0 million if certain research, development, regulatory and commercial milestones are successfully achieved. On May 16, 2019, we earned a \$2.5 million milestone payment for the U.S. Food and Drug Administration's, or FDA's, acceptance of the IND for our lead drug 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 pre-clinical candidate pursuant to the LG Chem Collaboration Agreement. In addition, the LG Chem Collaboration Agreement also provides that LG Chem will pay us tiered single-digit royalties on net sales of commercialized 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 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 royalty payments on the sales of Collaboration Products sold in all countries outside the LG Chem Territory. The amount of fees and milestone payments, as well as whether we receive royalty payments, will depend on the number of alleles selected by LG Chem and whether we exercise our option to co-develop and co-commercialize the additional program worldwide, in which case we would share costs and profits instead of receiving royalties and post-option-exercise milestones. For the three months ended March 31, 2021 and 2020, we recognized approximately \$788,000 and \$844,000, respectively, in collaboration revenue related to the LG Chem Collaboration agreement.

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 in the event we undergo a change of control 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.

## Results of Operations

### Collaboration Revenue

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

### Operating Expenses

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

General and administrative expenses consist of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as professional fees, insurance costs, and other general corporate expenses. Management expects general and administrative expenses to increase in future periods as we add personnel and incur additional expenses related to an expansion of our research and development activities, including higher legal, accounting, insurance, compliance, compensation and other expenses.

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 product candidates. We charge research and development expenses to operations as they are incurred. Management expects research and development expenses to increase in the future as we increase our efforts to develop technology for potential future products based on our technology and research.

### Three Months Ended March 31, 2021 and 2020

Our consolidated statements of operations and other comprehensive loss for the three months ended March 31, 2021 and 2020, as discussed herein, are presented below.

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
<b>Collaboration revenue</b>	\$ 1,553	\$ 900
<b>Operating expenses:</b>		
General and administrative	4,255	3,989
Research and development	9,816	9,906
<b>Total operating expenses</b>	<b>14,071</b>	<b>13,895</b>
<b>Loss from operations</b>	<b>(12,518)</b>	<b>(12,995)</b>
<b>Other income:</b>		
Interest income	13	177
<b>Total other income</b>	<b>13</b>	<b>177</b>
<b>Net Loss</b>	<b>\$ (12,505)</b>	<b>\$ (12,818)</b>
Unrealized (loss) gain from available-for-sale securities	(7)	259
<b>Comprehensive loss</b>	<b>\$ (12,512)</b>	<b>\$ (12,559)</b>
Net loss per common share – basic and diluted	<b>\$ (0.41)</b>	<b>\$ (0.48)</b>
Weighted average common shares outstanding – basic and diluted	30,434,525	26,569,681

### Collaboration Revenue

Collaboration revenue was \$1,553,000 and \$900,000 for the three months ended March 31, 2021 and 2020, respectively. All collaboration revenue recognized was related to the performance of services under our collaboration agreements with Merck and LG Chem.

## **General and Administrative**

General and administrative expenses totaled approximately \$4,255,000 and \$3,989,000 for the three months ended March 31, 2021 and 2020, respectively. This increase of approximately \$266,000 during the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was due primarily to stock-based compensation related to executive management and legal fees offset by a decrease in travel expenses as the COVID-19 pandemic continued to hamper business travel through the first quarter of 2021. We expect our general and administrative expenses to increase as we continue to expand our operations.

General and administrative expenses for the three months ended March 31, 2021 included expenses related to employee and director compensation of approximately \$1,114,000, stock-based compensation expense of \$1,114,000, professional and consulting fees of \$1,399,000, rent of \$270,000, insurance expense of \$85,000, depreciation and amortization of \$30,000, travel of \$1,000, investor relations expense of \$2,000 and other expenses of \$240,000. General and administrative expenses for the three months ended March 31, 2020 included expenses related to employee and director compensation of approximately \$1,045,000, stock-based compensation expense of \$1,017,000, professional and consulting fees of \$1,323,000, rent of \$257,000, insurance expense of \$63,000, depreciation and amortization of \$24,000, travel of \$26,000, investor relations expense of \$45,000 and other expenses of \$189,000.

## **Research and Development**

Research and development expenses totaled approximately \$9,816,000 and \$9,906,000 for the three months ended March 31, 2021 and 2020, respectively. This decrease of approximately \$90,000 during the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was due primarily to the decrease in laboratory and drug substance manufacturing costs and clinical expenses and reduced travel expenses, offset by an increase in stock-based compensation expense and the completed eligibility for a research related payroll tax credit. We expect our research and development expenses to increase as we expand our clinical development activities.

Research and development expenses for the three months ended March 31, 2021 included expenses related to employee and Scientific and Clinical Advisory Board member compensation of approximately \$2,535,000, stock-based compensation expense of \$1,322,000, depreciation and amortization of \$289,000, research and laboratory expenses of \$2,669,000, clinical expenses of \$1,062,000, rent of \$952,000, other professional fees of \$513,000, licensing fees of \$23,000, insurance expense of \$241,000, travel of \$3,000, and other expenses of \$207,000. Research and development expenses for the three months ended March 31, 2020 included expenses related to employee and Scientific and Clinical Advisory Board member compensation of approximately \$2,046,000, stock-based compensation of \$2,158,000, depreciation and amortization of \$239,000, research and laboratory expenses of \$3,031,000, clinical expenses of \$995,000, rent of \$823,000, other professional fees of \$120,000, licensing fees of \$26,000, insurance expense of \$160,000, travel of \$24,000, and other expenses of \$284,000.

## **Interest Income**

Interest income was approximately \$13,000 and \$177,000 for the three months ended March 31, 2021 and 2020, respectively. This decrease of approximately \$164,000 was due to reduced investment of our cash in cash equivalents and marketable securities during 2021.

## **Liquidity and Capital Resources**

We have financed our working capital requirements primarily through private and public offerings of equity securities and cash received from Merck and LG Chem under the respective collaboration agreements. At March 31, 2021, we had unrestricted cash, cash equivalents, and marketable securities totaling approximately \$73,257,000 available to fund our ongoing business activities. Additional information concerning our financial condition and results of operations is provided in the financial statements included in this Quarterly Report on Form 10-Q.

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

On January 4, 2019, we filed a universal shelf registration statement on Form S-3 with the SEC, or the 2019 Shelf, to register for sale from time to time up to \$150.0 million of our common stock, preferred stock, debt securities, warrants and/or units in one of more offerings (File No. 333-229140). The 2019 Shelf became effective on February 3, 2019.

In March 2020, we entered into an at-the-market, or ATM, equity offering sales agreement, or the March 2020 Sales Agreement, with Stifel to sell shares of our common stock for aggregate gross proceeds of up to \$35.0 million, from time to time, through an "at-the-market" equity offering program under which Stifel acts as sales agent. As of March 31, 2021, we sold a total of 1,824,901 shares of common stock under the March 2020 Sales Agreement for proceeds of approximately \$34.3 million, net of commissions paid, but excluding estimated transaction expenses. Due to the issuance and sale of all the shares of common stock subject thereto, the March 2020 Sales Agreement terminated in accordance with its terms.

The shares of common stock sold under the March 2020 Sales Agreement were made pursuant to the 2019 Shelf.

On June 22, 2020, we filed a registration statement on Form S-3ASR, which became automatically effective upon filing with the SEC (File No. 333-239357), or the 2020 Shelf, to register for sale from time to time up to \$300.0 million of our common stock, preferred stock, debt securities, warrants, rights and/or units in one or more offerings.

In June 2020, we entered into an ATM equity offering sales agreement, or the June 2020 Sales Agreement, with Stifel to sell shares of our common stock for aggregate gross proceeds of up to \$40.0 million, from time to time, through an “at-the-market” equity offering program under which Stifel acts as sales agent. The sales agreement will terminate upon the earliest of (a) the sale of \$40.0 million of shares of our common stock or (b) the termination of the June 2020 Sales Agreement by us or Stifel. As of March 31, 2021, we sold 1,192,000 shares of common stock under the June 2020 Sales Agreement for proceeds of approximately \$22.4 million, net of commissions paid, but excluding estimated transaction expenses. The shares of common stock sold under the June 2020 Sales Agreement are made pursuant to the 2020 Shelf.

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 its assets, could have substantial debt service obligations, and lenders may have a senior position (compared to stockholders) in any potential future bankruptcy or liquidation. Additionally, corporate collaboration and licensing arrangements may require us to incur non-recurring and other charges, give up certain rights relating to our intellectual property and research and development activities, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, issue debt which may require liens on our assets and which will increase our monthly expense obligations, or disrupt our management and business.

### Cash Flows

The following table summarizes our changes in cash, cash equivalents, and restricted cash for the three months ended March 31, 2021 and 2020:

	Three Months Ended	
	March 31,	
	2021	2020
<i>(in thousands)</i>		
Net cash provided by (used in):		
Operating activities	\$ (11,795)	\$ (10,944)
Investing activities	9,352	(9,950)
Financing activities	834	36
Net decrease in cash, cash equivalents, and restricted cash	<u>\$ (1,609)</u>	<u>\$ (20,858)</u>

### Operating Activities

During the three months ended March 31, 2021 and 2020, we used cash of \$11,795,000 and \$10,944,000, respectively, in operating activities. This increase of \$851,000 was primarily due to an increase in deposits for laboratory and drug substance manufacturing costs. Cash used in operating activities during the three months ended March 31, 2021 consisted primarily of our net loss of \$12,505,000, and increases of \$1,590,000 in prepaid expenses, and decreases of \$811,000 in accrued expenses, \$139,000 in research and development contract liabilities, \$1,072,000 in operating lease liability and \$7,000 in other non-cash items. Cash used was partially offset by a decrease in \$4,000 in accounts receivable and \$250,000 in other assets and increases of \$203,000 in accounts payable, as well as non-cash charges of approximately \$318,000 in depreciation and amortization, \$2,436,000 in stock-based compensation expense, and \$1,118,000 in change in operating lease right-of-use asset.

Cash used in operating activities during the three months ended March 31, 2020 consisted primarily of our net loss of approximately \$12,818,000, and increases of approximately \$994,000 in prepaid expenses and decreases in \$1,083,000 in accrued expenses, \$295,000 in research and development contract liabilities and \$1,087,000 in operating lease liability. Cash used was partially offset by increases of approximately \$150,000 in accounts receivable, \$717,000 in accounts payable, and, as well as non-cash charges of approximately \$263,000 in depreciation and amortization, \$3,175,000 in stock-based compensation expense, \$998,000 in change in operating lease right-of-use asset and \$30,000 in other non-cash items.



### ***Investing Activities***

During the three months ended March 31, 2021 and 2020, our cash provided by (used in) investing activities was \$9,352,000 and \$(9,950,000), respectively. This increase of cash provided of \$19,302,000 was primarily due to the redemption of our entire short-term investment in marketable securities. Cash provided by investing activities during the three months ended March 31, 2021 consisted primarily of \$10,000,000 for the redemption of short-term investments, offset by the purchase of property and equipment of \$648,000. Cash used in investing activities during the three months ended March 31, 2020 consisted primarily of \$10,000,000 for the purchase of short-term investments, offset by a discount on securities purchased of \$50,000.

### ***Financing Activities***

During the three months ended March 31, 2021 and 2020, we generated cash from financing activities of \$834,000 and \$36,000, respectively. This increase of \$798,000 was primarily due to cash proceeds from the exercise of common stock options. Cash from financing activities during the three months ended March 31, 2021, consisted of cash proceeds from the exercise of common stock options of \$919,000, offset by cash used for restricted stock buy-back at vesting of \$85,000. Cash from financing activities during the three months ended March 31, 2020, consisted of cash proceeds from the exercise of common stock options.

### ***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 product candidates. Our expenses will also increase if, and as, we:

- continue the clinical development of CUE-101;
- leverage our programs to advance our other product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to discover and develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, quality control and scientific personnel;
- expand our manufacturing, 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; and
- acquire or in-license other product candidates and technologies.

We believe that our existing cash and cash equivalents as of March 31, 2021 will enable us to fund our operating requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We will need to raise additional capital or incur 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 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 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 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 product candidates that we may in-license and develop;
- our ability to successfully commercialize our product candidates, if approved;
- the amount of sales and other revenues from 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 product candidates;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- any disputes which may occur between us and Einstein, employees, collaborators or other prospective business partners; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that 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 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.

#### **Contractual Obligations and Commitments**

During the three months ended March 31, 2021, there were no material changes to our contractual obligations and commitments as of December 31, 2020 described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2020 Annual Report.

#### **Off-balance Sheet Arrangements**

At March 31, 2021, we did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

### **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, 2021, 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, 2021 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 Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit	Filing Date	Registration/File No.
<a href="#">31.1</a>	<a href="#">Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934</a>	X				
<a href="#">31.2</a>	<a href="#">Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934</a>	X				
<a href="#">32.1</a>	<a href="#">Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	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, 2021, has been formatted in Inline XBRL.	X				

**SIGNATURES**

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

Cue Biopharma, Inc.

Dated: May 10, 2021

By: /s/ Daniel R. Passeri  
Daniel R. Passeri  
Chief Executive Officer and Director  
(Principal Executive Officer)

Dated: May 10, 2021

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

**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 10, 2021

/s/ Daniel R. Passeri

Name: Daniel R. Passeri

Title: Chief Executive Officer

(Principal Executive Officer)

**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 10, 2021

/s/ Kerri-Ann Millar

Name: Kerri-Ann Millar

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)



**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, 2021 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.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Daniel R. Passeri

\_\_\_\_\_  
Name: Daniel R. Passeri  
Title: Chief Executive Officer  
(Principal Executive Officer)

Date: May 10, 2021

/s/ Kerri-Ann Millar

\_\_\_\_\_  
Name: Kerri-Ann Millar  
Title: Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

Date: May 10, 2021