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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2026

or

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

FOR THE TRANSITION PERIOD FROM TO

Commission file number: 001-38327

Cue Biopharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-3324577**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Chestnut Street, Suite 300 Somerville, Massachusetts	**02143**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CUE	Nasdaq Capital Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 13, 2026, the registrant had 8,359,523 shares of Common Stock ($0.001 par value per share) outstanding.

CUE BIOPHARMA, INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited) 6
Condensed Consolidated Balance Sheets 6
Condensed Consolidated Statements of Operations and Comprehensive Loss 7
Condensed Consolidated Statements of Stockholders' Equity 8
Condensed Consolidated Statements of Cash Flows 9
Notes to the Condensed Consolidated Financial Statements (Unaudited) 11
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 29
Item 3. Quantitative and Qualitative Disclosures about Market Risk 44
Item 4. Controls and Procedures 44

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 45
Item 1A. Risk Factors 45
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 91
Item 3. Defaults Upon Senior Securities 91
Item 4. Mine Safety Disclosures 91
Item 5. Other Information 91
Item 6. Exhibits 124

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

- the initiation, timing, progress and results of our ongoing and planned preclinical studies and any future 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, including our prioritization of our autoimmune programs, including CUE-221, CUE-401 and the CUE-500 series (excluding CUE-501, which has been licensed to Boehringer Ingelheim International GmbH);
- the timing of and our ability to submit applications for, and to 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, general economic and market conditions, inflation, and the imposition of new or revised global trade tariffs;
- our competitive position;
- developments relating to our competitors and our industry; and
- our ability to maintain and establish collaborations or obtain additional funding.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include the factors discussed below under the headings "Risk Factor Summary," and Part II. Item 1A. "Risk Factors," and the risk factors detailed further in Part I. Item 1A., "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 16, 2026.

This report includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates. All of the market data used in this report involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party

research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

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

RISK FACTOR SUMMARY

Investment in our securities involves risk. You should carefully consider the following summary of what we believe to be the principal risks facing our business, in addition to the risks described more fully in Part II. Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q, and Part I. Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 16, 2026 and other information included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations.

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

- We are a clinical-stage biopharmaceutical company, have no history of generating commercial revenue, have a history of operating losses and may never achieve or maintain profitability.
- We currently do not have, and may never develop, any FDA-approved or commercialized products.
- We are substantially dependent on the success of our lead product candidate, CUE-221, our lead autoimmune candidate, CUE-401, and our other product candidates, and significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our product candidates.
- We have no history of commercializing biologic products, which may make it difficult to evaluate the prospects for our future viability.
- Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.
- We have derived, and may in the future derive, results and data for CUE-221 from clinical trials conducted by UBI/Ascendant in China; our access to the clinical results and data may be limited and there is no assurance that the clinical data from any such trials will be accepted or considered by the FDA, or other comparable regulatory authorities.
- We plan to continue to seek collaborations or strategic alliances. However, we may not be able to establish such relationships, and relationships we have established may not provide the expected benefits.
- We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize the development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates.
- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to successfully complete development of, obtain regulatory approval for, or commercialize our product candidates and our business could be substantially harmed.
- We rely completely on third parties to manufacture our preclinical and clinical drug supplies for our product candidates.
- If we or our licensor(s) are unable to protect our or its intellectual property, then our financial condition, results of operations and the value of our technology and potential products could be adversely affected.
- Even if we, or any collaborators we may have, obtain marketing approvals for any of our product candidates, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

- We will need substantial additional financing to support our growth and ongoing operations. Additional capital may be difficult to obtain, restrict our operations, require us to relinquish rights to our technologies or product candidates, encumber our assets and result in ongoing debt service cost, or result in additional dilution to our stockholders.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,939	$ 27,136
Accounts receivable	5,132	5,546
Deposits, current portion	47	1,093
Prepaid expenses and other current assets	1,690	1,309
Foreign withholding tax receivable	1,899	1,899
Total current assets	66,707	36,983
Property and equipment, net	225	241
Operating lease right-of-use asset	—	4,074
Deposits	84	666
Restricted cash	154	154
Other long-term assets	85	94
Total assets	$ 67,255	$ 42,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,608	$ 3,948
Accrued expenses	15,190	1,611
Research and development contract liability, current portion	—	5,335
Operating lease liabilities, current	—	1,911
Other current payable	929	689
Total current liabilities	19,727	13,494
Operating lease liabilities, non-current	—	2,286
Top-up share obligation	9,130	—
Total liabilities	$ 28,857	$ 15,780
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 7,753,995 and 3,220,707 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	8	3
Additional paid in capital	615,117	394,895
Accumulated deficit	(576,727)	(368,466)
Total stockholders' equity	38,398	26,432
Total liabilities and stockholders' equity	$ 67,255	$ 42,212

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration revenue	$ 132	$ 2,149	$ 13,695	$ 5,524
Operating expenses:				
General and administrative	29,826	4,939	80,543	12,792
Research and development	17,015	4,754	72,919	21,211
Loss on fixed asset disposal	—	51	—	51
Gain on lease termination	(110)	—	(120)	—
Loss on write-off of lease security deposit	498	—	498	—
Total operating expenses	47,229	9,744	153,840	34,054
Loss from operations	(47,097)	(7,595)	(140,145)	(28,530)
Other income (expense):				
Interest income	483	222	819	649
Interest expense	(2)	(75)	(11)	(306)
Loss on issuance of liability-classified warrants and related issuance costs	—	—	(90,011)	—
Changes in fair value of financial instruments	(3,400)	—	21,087	—
Total other income (expense), net	(2,919)	147	(68,116)	343
Net loss	$ (50,016)	$ (7,448)	$ (208,261)	$ (28,187)
Unrealized gain from available-for-sale securities	—	1	—	1
Comprehensive loss	$ (50,016)	$ (7,447)	$ (208,261)	$ (28,186)
Net loss per common share – basic and diluted	$ (4.74)	$ (2.22)	$ (28.70)	$ (9.37)
Weighted average common shares outstanding – basic and diluted	10,561,814	3,362,311	7,255,392	3,009,035

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

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

For the three months ended September 30, 2026 and 2025:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, June 30, 2025	2,548,229	$ 3	$ 380,759	$ —	$ (362,603)	$ 18,159
Issuance of common stock from ATM offering, net of sales agent commissions and fees	44,495	—	1,001	—	—	1,001
Stock-based compensation	—	—	1,533	—	—	1,533
Unrealized gain from available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(7,448)	(7,448)
Balance, September 30, 2025	2,592,724	$ 3	$ 383,293	$ 1	$ (370,051)	$ 13,246
Balance, June 30, 2026	5,229,392	$ 5	$ 529,016	$ —	$ (526,711)	$ 2,310
Issuance of common stock upon vesting of restricted stock units	293,583	—	—	—	—	—
Issuance of common stock upon exercise of stock options	19,428	—	553	—	—	553
Issuance of common stock upon exercise of warrants and pre-funded warrants, net	993,521	1	241	—	—	242
Issuance of common stock, warrants, and pre-funded warrants, net of issuance costs	1,218,071	2	49,831	—	—	49,833
Stock-based compensation	—	—	35,476	—	—	35,476
Net loss	—	—	—	—	(50,016)	(50,016)
Balance, September 30, 2026	7,753,995	$ 8	$ 615,117	$ —	$ (576,727)	$ 38,398

For the nine months ended September 30, 2026 and 2025:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, December 31, 2024	2,060,636	$ 2	$ 359,361	$ —	$ (341,864)	$ 17,499
Issuance of common stock from ATM offering, net of sales agent commissions and fees	81,062	—	1,753	—	—	1,753
Issuance of common stock, warrants and pre-funded warrants, net of issuance costs	451,026	1	18,045	—	—	18,046
Stock-based compensation	—	—	4,134	—	—	4,134
Unrealized gain from available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(28,187)	(28,187)
Balance, September 30, 2025	2,592,724	$ 3	$ 383,293	$ 1	$ (370,051)	$ 13,246
Balance, December 31, 2025	3,220,707	$ 3	$ 394,895	$ —	$ (368,466)	$ 26,432
Issuance of common stock from ATM offering, net of sales agent commissions and fees	34,652	—	306	—	—	306
Issuance of common stock, warrants, and pre-funded warrants, net of issuance costs	1,218,071	1	157,292	—	—	157,293
Issuance of common stock upon vesting of restricted stock units	948,654	1	(1)	—	—	—
Issuance of common stock upon exercise of stock options	62,818	—	1,369	—	—	1,369
Issuance of common stock upon exercise of warrants and pre-funded warrants, net	2,269,093	3	1,894	—	—	1,897
Stock-based compensation	—	—	59,362	—	—	59,362
Net loss	—	—	—	—	(208,261)	(208,261)
Balance, September 30, 2026	7,753,995	$ 8	$ 615,117	$ —	$ (576,727)	$ 38,398

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

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

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (208,261)	$ (28,187)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	635	280
Stock-based compensation	59,362	4,134
Decrease in the carrying amount of right-of-use-assets	1,116	1,994
Loss on sale of property and equipment	—	51
Gain on lease termination	(120)	—
Issuance of Ascendant liability-classified pre-funded warrants and top-up share obligation	20,119	—
Loss on issuance of liability-classified warrants	87,559	—
Changes in fair value of financial instruments	(21,087)	—
Loss on write-off of lease security deposit	498	—
Amortization of premium/discount on purchased securities	—	(182)
Amortization of debt issuance costs	—	28
Accretion of final payment on term loans	—	98
Changes in operating assets and liabilities:		
Accounts receivable	414	558
Prepaid expenses and other current assets	(870)	(2,309)
Deposits	1,130	470
Foreign withholding tax receivable	—	(1,899)
Other payable	240	190
Accounts payable	(340)	(476)
Accrued expenses	16,031	(1,038)
Research and development contract liability	(5,335)	7,731
Operating lease liability	(1,119)	(2,054)
Net cash used in operating activities	(50,028)	(20,611)
Cash flows from investing activities		
Purchases of property and equipment	(121)	(177)
Cash received from the sale of property and equipment	—	20
Purchases of marketable securities	—	(16,288)
Redemptions of marketable securities	—	9,500
Net cash used in investing activities	(121)	(6,945)
Cash flows from financing activities		
Proceeds from ATM offering, net of sales agent commissions and fees	306	1,753
Proceeds from issuance of common stock, warrants and pre-funded warrants, net of transaction costs	77,380	18,046
Repayment of term loans	—	(3,000)
Proceeds from exercise of stock options	1,369	—
Proceeds from exercise of warrants and pre-funded warrants, net	1,897	—
Net cash provided by financing activities	80,952	16,799
Net increase (decrease) in cash, cash equivalents, and restricted cash	30,803	(10,757)
Cash, cash equivalents, and restricted cash at beginning of period	27,290	22,611
Cash, cash equivalents, and restricted cash at end of period	$ 58,093	$ 11,854
Supplemental disclosures of non-cash investing and financing activities:		
Cash paid for interest	$ —	$ 198
Reclassification of May 2026 warrants and pre-funded warrants to equity	$ (94,186)	$ —
Reclassification of Ascendant pre-funded warrants to equity	$ (13,275)	$ —
Lease liabilities arising from obtaining right-of-use assets	$ —	$ 2,226

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

1. Organization and Basis of Presentation

Cue Biopharma, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on advancing a portfolio of potentially transformative therapies aimed at enabling functional cures across immunological disorders. Its lead asset, CUE-221, is a novel humanized anti-IgE monoclonal antibody with a dual-mechanism of action that the Company is developing for allergic diseases. The Company has received topline results from a Phase 2 clinical trial of CUE-221 conducted in China by Genesis Life Sciences, a related company of Ascendant Health Ltd. ("Ascendant") in patients with chronic spontaneous urticaria ("CSU"). In addition, the Company has developed the Immuno-STAT® platform designed to engineer therapies that selectively target disease-specific T cells in vivo without broad immune modulation. The Company's lead candidate to treat autoimmune diseases, CUE-401, is designed to induce the development of regulatory T cell populations (Tregs) leading to Treg-mediated tolerance and control of autoimmunity. The Company initiated dosing in a Phase 1 clinical trial of CUE-401 in October 2026.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is in the clinical development and preclinical research and development stages and has incurred recurring losses and negative cash flows from operations since inception. During the nine months ended September 30, 2026, the Company had one-time cash outflows related to the license agreement with Ascendant totaling approximately $28 million, which consisted primarily of an upfront payment to Ascendant, and other one-time legal fees, consulting fees and employee related costs. As of September 30, 2026, the Company had cash and cash equivalents of $57.9 million. The Company believes that its cash and cash equivalents on hand as of September 30, 2026 will be sufficient to meet its projected operating needs at least through the next twelve months from the issuance date of these condensed consolidated financial statements included in this Quarterly Report. The Company has based its estimate as to how long it expects it will be able to fund its operating needs on assumptions that may prove to be wrong and the Company could use its available capital resources sooner than it currently expects.

The future viability of the Company is dependent on its ability to raise additional capital to finance its operations and fund research and development costs in order to seek approval for commercialization of its product candidates.

The Company continues to explore raising additional capital through a combination of equity offerings, collaborations, and other strategic alliances, and, depending on the availability and level of additional financings, potential cash expenditure reduction, but there is no guarantee that the Company will be successful in these mitigation efforts. The Company’s failure to access additional capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop and commercialize the Company’s product candidates in order to generate future revenue streams.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements as of September 30, 2026, and for the three and nine months ended September 30, 2026 and 2025, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the “SEC”) and generally accepted accounting principles in the United States (“U.S. GAAP”) for financial information, which prescribes elimination of all significant intercompany accounts and transactions in the accounts of the Company and its wholly owned subsidiary, Cue Biopharma Securities Corp., which was incorporated in the Commonwealth of Massachusetts in December 2018. In the opinion of management, these financial statements reflect all adjustments which are necessary for a fair statement of the Company’s financial position and results of its operations, as of and for the periods presented. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, 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 for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 16, 2026.

Interim results for the three and nine months ended September 30, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026, or any future periods.

Reverse Stock Split

The Company held its 2026 annual meeting of stockholders on April 13, 2026, where the Company's stockholders approved a reverse stock split at a ratio within a range of 1-for-30 and 1-for-50 and granted the Company's board of directors (the "Board") the discretion to determine the timing and ratio of the split within such range. On April 13, 2026, the Board determined to effect the reverse stock split of the common stock at a 1-for-30 ratio (the "Reverse Split") and approved the filing of a charter amendment to the Company's Certificate of Incorporation to effect the Reverse Split.

On April 22, 2026, the Company filed the charter amendment with the Delaware Secretary of State to effect the Reverse Split, effective at 5:00 P.M. Eastern Time on April 23, 2026 (the "Effective Time"). At the Effective Time, every 30 shares of issued and outstanding common stock automatically combined into one issued share of common stock, with no change in par value. No fractional shares were issued as a result of the Reverse Split. Stockholders of record who would otherwise hold fractional shares of the Company's common stock as a result of the Reverse Split were entitled to receive a cash payment (without interest and subject to applicable withholding taxes) in lieu of such fractional shares. The Reverse Split did not modify any voting rights or other terms of the common stock. The Company's common stock began trading on a Reverse Split-adjusted basis on The Nasdaq Capital Market on April 24, 2026.

Unless otherwise indicated, all issued and outstanding share and per share amounts contained in the accompanying condensed consolidated financial statements have been adjusted to reflect the Reverse Split for all prior periods presented. Proportionate adjustments for the Reverse Split were made to the exercise prices and number of shares issuable under the Company's equity incentive plans, and the number of shares underlying outstanding equity awards, as applicable. In connection with such proportionate adjustments, the number of shares of common stock issuable upon exercise of outstanding stock options and warrants was rounded down to the nearest whole share, and the exercise prices of outstanding stock options and warrants were rounded up to the nearest cent. Because the Reverse Split decreased the number of outstanding shares of the Company's common stock by a ratio of 1-for-30 but did not effect a decrease to the number of authorized shares of the Company's common stock, the Reverse Split resulted in a relative increase in the number of authorized and unissued shares of the Company's common stock.

Public Offerings and Private Placements

In October 2021, the Company entered into an open market sale agreement (the "ATM Sales Agreement") with Jefferies LLC ("Jefferies"), as agent, to sell shares of the Company's common stock for aggregate gross proceeds of up to $80 million, from time to time, through an at-the-market equity offering program. The ATM Sales Agreement will terminate upon the earlier of (a) the sale of $80 million of shares of the Company's common stock pursuant to the ATM Sales Agreement or (b) the termination of the ATM Sales Agreement by the Company or Jefferies.

During the three months ended September 30, 2026, there were no sales under the ATM Sales Agreement. During the nine months ended September 30, 2026, the Company sold 34,652 shares of common stock under the ATM Sales Agreement for proceeds of $0.3 million, net of commissions paid, but excluding transaction expenses. During the three and nine months ended September 30, 2025, the Company sold 44,495 and 81,062 shares of common stock under the ATM Sales Agreement for proceeds of $1.0 million and $1.8 million, net of commissions paid, but excluding transaction expenses. As of September 30, 2026, the Company had sold an aggregate of 450,866 shares of common stock under the ATM Sales Agreement for proceeds of $43.2 million, net of commissions paid, but excluding transaction expenses, since its inception.

On April 30, 2026, the Company entered into a securities purchase agreement with accredited investors (the "May 2026 Investors"), pursuant to which the Company agreed to issue and sell to the May 2026 Investors in a private placement (the "May 2026 Offering") prefunded warrants to purchase an aggregate of up to 2,727,272 shares of common stock (the "May 2026 Pre-Funded Warrants") and accompanying warrants (the "May 2026 Common Warrants" and together with the May 2026 Pre-Funded Warrants, the "May 2026 Warrants") to purchase an aggregate of up to 1,363,636 shares of common stock (or, in certain circumstances, May 2026 Pre-Funded Warrants to purchase common stock in lieu thereof) at a price of $11.00 per Pre-Funded Warrant and accompanying Warrant. The exercise price of the May 2026 Pre-Funded Warrants is $0.001 per share. The exercise price of the Warrants is $11.00 per share. The May 2026 Investors include the Company's President and Chief Executive Officer, Dr. Shao-Lee Lin. The May 2026 Offering closed on May 4, 2026 (the "May 2026 Offering Closing Date"). The Company received aggregate net proceeds from the May 2026 Offering of $27.6 million, after deducting placement agent fees and offering costs. The May 2026 Pre-Funded Warrants are cashless exercisable at any time. The Warrants are exercisable at any time prior to five years after the May 2026 Offering Closing Date. At September 30, 2026, the weighted average exercise price of the May 2026 Warrants was $11.00 and the weighted average contractual life was 4.59 years.

On July 9, 2026, the Company entered into a securities purchase agreement with accredited investors (the "July 2026 Investors"), including Cormorant Asset Management and Columbia Threadneedle Investments, pursuant to which the Company, in a private placement, agreed to issue and sell to the July 2026 Investors an aggregate of (i) 1,418,071 shares of the Company's common stock at a price per share of $33.21 and (ii) to certain July 2026 Investors, in lieu of shares of common stock, pre-funded warrants (the "July 2026 Pre-Funded Warrants") to purchase up to 87,500 shares of common stock at a price per Pre-Funded Warrant of $33.209 (the "July 2026 Private Placement"). The Company received net proceeds of approximately $49.8 million from the July 2026

Private Placement after deducting legal fees. Each July 2026 Pre-Funded Warrant has an exercise price of $0.001 per share and is cashless exercisable. The July 2026 Private Placement closed on July 13, 2026. Subsequent to closing, Cormorant Asset Management exchanged 200,000 shares of the Company's common stock for July 2026 Pre-Funded Warrants. At September 30, 2026, there were 287,500 outstanding July 2026 Pre-Funded Warrants with a weighted average exercise price of $0.001.

All common stock warrants and pre-funded warrants that have been issued are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the pre-funded warrants issued in 2024, April 2025 and December 2025, the May 2026 Pre-Funded Warrants, and July 2026 Pre-Funded Warrants do not provide any guarantee of value or return, and do not have an expiration date. As of September 30, 2026, warrants issued in 2022, 2024, April 2025 and December 2025, the May 2026 Warrants, and July 2026 Pre-Funded Warrants met the permanent equity criteria classification, and have been classified as a component of permanent equity in the Company's condensed consolidated financial statements.

Consolidation

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

Use of Estimates

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

Cash Concentrations

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

Cash and Cash Equivalents

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

Restricted Cash

The Company had $0.2 million in restricted cash deposited with a separate commercial bank to collateralize Company credit cards as of September 30, 2026 and December 31, 2025.

Top-up Share obligation

Pursuant to the securities purchase agreement with Ascendant (also referred to as the “Licensor”) (as described below), the Company may be required to issue additional shares of common stock (the "Top-Up Shares"), or, if stockholder approval is required for the issuance of such shares, pre-funded warrants (the "Top-Up Pre-Funded Warrants"), upon the achievement of specified clinical and financial milestones. The number of Top-Up Shares to be issued is variable and is designed to provide Ascendant with beneficial ownership of no less than 7.5% of the Company's outstanding common stock immediately following the achievement of the clinical and financial milestone, subject to the terms and conditions of the agreement. The foregoing obligation with Ascendant is referred to as the “Top-Up Obligation” in these unaudited condensed consolidated financial statements. For more information on the Top-Up Obligation, see Note 8.

The Company evaluated the Top-Up Shares and Top-Up Pre-Funded Warrants under Financial Accounting Standards Board (“FASB”) Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*, including the guidance in ASC 815-40, *Contracts in Entity's Own Equity*. Because the settlement amount is based on a variable number of shares necessary to achieve a specified

ownership percentage, the settlement provisions do not meet the fixed-for-fixed criterion and, therefore, are not considered indexed to the Company's own stock. Accordingly, the contingent obligation does not qualify for equity classification and is accounted for as a liability.

The contingent liability is initially recognized at fair value on the transaction date and subsequently remeasured at fair value at each reporting date until the contingency is resolved or the instrument is otherwise extinguished. Changes in the fair value of the liability are recognized in the accompanying condensed consolidated statements of operations and comprehensive loss within other income (expense), net.

If the issuance of Top-Up Shares would require stockholder approval, the Company is obligated to issue Top-Up Pre-Funded Warrants in lieu of such shares. The Company concluded that this alternative settlement mechanism does not change the accounting conclusion, as the underlying settlement amount remains based on a variable number of shares and therefore continues to fail the indexation requirements of ASC 815-40. Accordingly, the contingent obligation, including any potential issuance of Top-Up Pre-Funded Warrants, continues to be accounted for as a liability until settlement.

Equity Method Accounting

The Company applies the equity method of accounting for investments when it has significant influence, but no controlling interest in the investee. Judgment regarding the level of influence over each equity method investment includes key factors such as ownership interest, representation on the board of directors, participation in joint steering committees and material intercompany transactions. Upon investment, the Company evaluates any basis difference between the carrying value and fair value of the Company's proportionate share of the investee's net assets. Basis differences relating to in-process research and development (IPR&D) are expensed when the investee is not considered a business as defined in ASC Topic 805, *Business Combinations,* due to substantially all of the estimated fair value of the gross assets being concentrated in a group of similar IPR&D assets with no alternative future use. For the year ended December 31, 2025, the Company recognized $3.9 million in research and development expenses, for these basis adjustments related to IPR&D and reduced the equity method investment’s carrying value to zero, as the Company's proportionate share of the basis difference exceeded the carrying value. See Note 5 for further discussion.

Property and Equipment

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

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

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

Trademark

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

The Company has classified the trademark as a component of other long-term assets, having a useful life of 15 years. The Company evaluates the status of this intangible asset for amortization and impairment at each quarter end and year end reporting date. For each of the three and nine months ended September 30, 2026 and 2025, the Company recorded approximately $3,000 and $9,000, respectively, in amortization expense on a straight-line basis.

Debt Issuance Costs

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

Revenue Recognition

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

Research and Development Expenses

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

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

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

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

Patent Expenses

The Company is the exclusive 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 general and administrative expense as incurred.

Licensing Fees and Costs

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

Long-Lived Assets

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

Leases

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

Stock-Based Compensation

The Company periodically issues stock-based awards to officers, directors, employees, scientific and clinical advisory board members and consultants for services rendered. Such awards vest and expire according to terms established at the issuance date.

Stock-based compensation to officers, directors, employees, scientific and clinical advisory board members and consultants, including grants of employee stock options, is 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 valuation model. This valuation model takes into account the exercise price of the award, as well as a variety of significant assumptions. The assumptions used to estimate the fair value of stock options include the expected term, the expected volatility of the Company's stock over the expected term, the risk-free interest rate over the expected term, and the Company's expected annual dividend yield. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield is based on the current yield at the grant date; the Company has never declared or paid dividends and has no plans to do so for the foreseeable future. As permitted by Staff Accounting Bulletin No. 107, due to the Company’s limited trading history and option activity, management utilizes the simplified method to estimate the expected term of options at the date of grant. The exercise price is determined based on the fair value of 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 condensed consolidated statements of operations, 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 only other comprehensive income item in the periods reported were related to unrealized gains from marketable securities during the three and nine months ended September 30, 2025.

Variable Interest Entities

The Company reviews each legal entity in which it has a financial interest to determine whether or not the entity is a variable interest entity (“VIE”). A VIE is an entity in which equity investors lack the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. VIEs are consolidated by the primary beneficiary, which is the party (a) who has the power to direct the activities of a VIE that most significantly impact the entity’s economic performance and (b) who has an obligation to absorb losses of the entity or a right to

receive benefits from the entity that could potentially be significant to the entity. If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that VIE based on a number of factors, including (i) which party has the power to direct the activities that most significantly affect the VIE's economic performance, (ii) the parties' contractual rights and responsibilities pursuant to any contractual agreements and (iii) which party has the obligation to absorb losses or the right to receive benefits from the VIE. If the Company determines that it is the primary beneficiary of a VIE, it consolidates the financial statements of the VIE into its consolidated financial statements at the time that determination is made.

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.

The Company computes EPS in accordance with ASC Topic 260, Earnings Per Share ("ASC 260"). Per ASC 260-10-45-13, shares issuable for little to no consideration should be included in the number of outstanding shares used for basic EPS. The FASB proposed that warrants or options exercisable for little to no cost (sometimes referred to as "penny warrants") be included in the denominator of basic EPS (and therefore diluted EPS) once there were no further vesting conditions or contingencies associated with them. The Company included 3,058,963 and 796,827 pre-funded warrants in the denominator of basic EPS at September 30, 2026 and September 30, 2025, respectively.

At September 30, 2026 and 2025, the Company excluded the securities summarized below, which entitled the holders thereof to acquire shares of common stock, from its calculation of EPS, as their effect would have been anti-dilutive.

	September 30,	
	2026	2025
Common stock warrants	2,569,821	713,396
Common stock options	1,705,562	459,239
Total	4,275,383	1,172,635

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

Recent Accounting Pronouncements Adopted

ASU 2025-07 - Derivatives Scope Refinements

In September 2025, the FASB issued Accounting Standards Update ("ASU") 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract*. The guidance in ASU 2025-07 expands the scope of contracts that are excluded from derivative accounting and clarifies that an entity receiving share-based noncash consideration from a customer should apply the guidance on noncash consideration in ASC 606. The ASU will become effective in interim and annual periods for fiscal years beginning after December 15, 2026 and may be applied either on a prospective or modified retrospective basis. Early adoption is permitted for financial statements that have not yet been issued (or made available for issuance). Management determined to early adopt this ASU in the second quarter of 2026 on a prospective basis.

Recent Accounting Pronouncements Not Yet Adopted

ASU 2024-03 - Disaggregation of Income Statement Expense

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expense* ("ASU 2024-03"). The guidance in ASU 2024-03 requires additional disclosures about specific types of expenses included in the expense captions presented on the face of income statements as well as disclosures about selling expenses. The standard applies prospectively with the option to apply the standard retrospectively and is effective for calendar year-end public business entities in the 2027 annual period and in 2028 for interim periods with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its related 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 September 30, 2026 and December 31, 2025, and indicates the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2026 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 57,420	$ —	$ —	$ 57,420
Total current assets	$ 57,420	$ —	$ —	$ 57,420
Top-up Shares	$ —	$ —	$ 9,130	$ 9,130
Total current liabilities	$ —	$ —	$ 9,130	$ 9,130

	Fair Value Measurements as of December 31, 2025 (in thousands)			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 26,614	$ —	$ —	$ 26,614
Total	$ 26,614	$ —	$ —	$ 26,614

As of September 30, 2026, the Company had $57.4 million in cash equivalents, and did not hold any marketable securities. The Company measures the cash equivalents that are invested in money market funds using Level 1 inputs for identical securities. As of December 31, 2025, the Company had $26.6 million in cash equivalents, and did not hold any marketable securities. For each of the three and nine months ended September 30, 2026 and 2025, there were no transfers between Levels 1, 2 or 3.

The Top-Up Obligation with Ascendant is measured at fair value on a recurring basis and is classified as a Level 3 liability because the valuation incorporates significant unobservable inputs, including estimates regarding the probability and timing of achieving specified clinical and financial milestones and assumptions regarding the Company's future stock price. The initial fair value of the Top-Up Obligation was recognized as consideration for the acquired license and recorded within research and development license expense. The change in fair value of the Top-Up Obligation is recognized in other income (expense), net in the accompanying condensed consolidated statements of operations.

The Company estimates the fair value of the Top-Up Obligation using a Monte Carlo simulation model, which incorporates both observable market data and significant unobservable inputs. Changes in these assumptions could result in materially different fair value measurements. Significant assumptions used in the model include the following:

	Top-up Shares
Stock price	$25.87 - $31.56
Equity Volatility	110%
Probability of milestone achievement	20% - 50%
Time to exercise (years)	0.1 to 0.3

Nonrecurring Fair Value Measurements

In addition to assets and liabilities recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. In connection with the May 2026 securities purchase agreement and the License Agreement with Ascendant Health (as described below), the Company issued the May 2026 Pre-Funded Warrants, May 2026 Common Stock Warrants, and Ascendant Pre-Funded Warrants (as described below), each of which was initially classified as a liability and measured at fair value, as share settlement was contingent upon stockholder approval in accordance with the listing standards of the Nasdaq Stock Market (the "Issuance Stockholder Approval"), which was outside the Company's control. On June 1, 2026, the Issuance Stockholder Approval was obtained and the instruments were reclassified to permanent equity, after which they are no longer subject to remeasurement.

The initial fair value of the May 2026 Pre-Funded Warrants and May 2026 Warrants, and all subsequent changes in the fair value of the liability-classified instruments through the date of the Issuance Stockholder Approval, were recognized within other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss. The initial fair value of the Ascendant Pre-Funded Warrants was recognized as consideration for the acquired license and recorded within research and development license expense. The change in fair value of the Ascendant Pre-Funded Warrants is recognized in other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss.

The Company estimated the fair value of the May 2026 Pre-Funded Warrants and Ascendant Pre-Funded Warrants using the Company's publicly-traded stock price at the valuation date, which is a Level 1 input. The Company estimated the fair value of the May 2026 Warrants using the Black-Scholes option pricing model, which incorporates both observable market data and significant unobservable inputs. Changes in these assumptions could result in materially different fair value measurements. Significant assumptions include the following:

	May 2026 Warrants
Risk-free interest rate	4.04% - 4.13%
Expected dividend yield	0%
Expected volatility	110.00%
Expected term (yrs)	4.9 to 5.0

The following table shows the rollforward of the Top-up Share Obligation and liabilities associated with the Ascendant Pre-Funded Warrants, May 2026 Pre-Funded Warrants, and May 2026 Warrants:

(In thousands)	Ascendant Top-up Shares	Ascendant Pre-Funded Warrants	May 2026 Warrants and Pre-Funded Warrants	Total
Balance at January 1, 2026	$ —	$ —	$ —	$ —
Initial recognition of financial instrument	3,650	16,469	117,559	137,678
Changes in fair value recognized in earnings	5,480	(3,194)	(23,373)	(21,087)
Reclassification to equity	—	(13,275)	(94,186)	(107,461)
Balance at September 30, 2026	$ 9,130	$ —	$ —	$ 9,130

4. Property and Equipment, Net

Property and equipment, net as of September 30, 2026 and December 31, 2025 consisted of the following:

	September 30, 2026	December 31, 2025
	(in thousands)	
Laboratory equipment	$ 3,511	$ 3,511
Furniture and fixtures	68	68
Computer equipment	328	207
Leasehold improvements	—	118
Total property and equipment	3,907	3,904
Less: accumulated depreciation	(3,682)	(3,663)
Property and equipment, net	$ 225	$ 241

Depreciation expense for the three and nine months ended September 30, 2026 and 2025 was included in the condensed consolidated statements of operations and comprehensive loss as follows, and excludes trademark amortization of $3,000 and $9,000 for the three and nine months ended September 30, 2026 and 2025, respectively.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
General and administrative	$ 5	$ 8	$ 17	$ 16
Research and development	23	68	120	255
Depreciation total	$ 28	$ 76	$ 137	$ 271

5. Equity Method Investment

On November 6, 2025, ImmunoScape Pte. Ltd. ("IMSCP") exercised its option (the "Option") to obtain licenses to research, develop and commercialize molecules from the Company's CUE-100 series, including CUE-101 and CUE-102, subject to certain exclusions (the licensed series of molecules, the "Licensed Program"), for all oncology indications pursuant to a Collaboration and License Agreement, effective November 6, 2025, between the Company and IMSCP (as amended, the "IMSCP Collaboration and License Agreement"). Pursuant to the IMSCP Collaboration and License Agreement, the Company received equity of IMSCP equal to 40% of the issued and outstanding equity of IMSCP and is entitled to receive additional equity, in the form of warrants, upon certain dilution events in the future. As of the transaction date, the Company held 30% of IMSCP's common shares and warrants to purchase 10% of IMSCP's common shares at an exercise price of $0.01 per share. The warrants expire on November 5, 2035 or upon change in control of IMSCP.

As of the transaction date, the carrying value of the investment in IMSCP was $3.9 million, comprised of $2.9 million from common shares and $1.0 million from the warrants. The value of the warrants was included in the investment under equity method accounting as they are considered in-substance common stock. The contingent issuable warrants are accounted for as a derivative instrument and were prescribed no value at the inception of the IMSCP Collaboration and License Agreement and at December 31, 2025 as the probability of issuance was remote. There was no change in value from inception to September 30, 2026, and the inputs used to determine the fair value of the contingent issuable warrants are a Level 3 fair value measurement.

The Company has determined that its investment in IMSCP is an equity security, whereby such investment does not give the Company a controlling financial interest over the investee. Further, the Company assessed the accounting for its investment in IMSCP in accordance with ASC Topic 810-10, Consolidation—Overall. After determining that no scope exception applies under the guidance of ASC 810-10-15-12 and ASC 810-10-15-17, the Company concluded that it has a variable interest in IMSCP through its investment in IMSCP common stock. The Company concluded that IMSCP is a VIE in accordance with ASC 810-10-15-14(a) and is subject to potential consolidation under the VIE model. However, all activities that most significantly impact IMSCP and its subsidiary's economic performance are directed by the IMSCP board and the board approves decisions by a simple majority. Based on the board composition, the Company determined that no one party has control over the IMSCP board and power is not shared because the activities that most significantly affect IMSCP and its subsidiary's economic performance do not require the consent of all of the parties. Rather, all decisions are made by a simple majority vote of the IMSCP board. Therefore, while the Company has the ability to appoint one director of IMSCP, because that director represents a minority position of the IMSCP board, the Company cannot unilaterally direct any of the activities that most significantly impact IMSCP and its subsidiary's economic performance. Accordingly, the Company does not hold a controlling financial interest in IMSCP. Because both criteria (a) and (b) above have to be met for the application of the guidance in ASC 810-10-25-38A and criteria (a) has not been met, the Company concluded that it should not consolidate IMSCP under the VIE model.

The Company accounts for its investment in IMSCP as an equity method investment as it does not control but has significant influence over operating and financing policies of IMSCP. The initial fair value of the investment in IMSCP was determined by using the option pricing model to allocate the estimated equity value to each respective equity class. The equity value was determined by using the net asset value approach for the net assets of IMSCP and the cost replacement approach for the intellectual property related to the CUE-100 series licensed to IMSCP. The major assumptions used in the option pricing model include volatility of 120.0%, risk free rate of 3.7%, dividend yield of 0.0% and time to liquidity event of 5.0 years. The inputs used to determine the fair value of the investment in IMSCP are a Level 3 fair value measurement.

At the transaction date, a basis difference was identified between the carrying value of the Company's investment in IMSCP and the fair value of the Company's proportionate share of IMSCP's underlying net assets. The Company concluded that substantially all of the consideration transferred was attributable to in-process research and development activities. IMSCP was not deemed a business as defined in ASC 805 – Business Combinations, therefore the Company immediately expensed the basis difference attributable to the in-process research and development which has no alternative future use. The Company's proportionate share of the basis difference exceeded its carrying value of the equity method investment in IMSCP and the equity investment balance was reduced to zero on the transaction date. Since the Company has no obligation to provide financing support to IMSCP, the Company is not required to record further losses exceeding the carrying value of the investment. For the year ended December 31, 2025, the Company recognized $3.9 million in research and development expenses related to the basis difference in the Company's condensed consolidated statements of operations. The carrying value of the Company's investment in IMSCP was zero as of September 30, 2026.

6. Loan with First Citizens Bank (formerly with Silicon Valley Bank)

On February 15, 2022 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank, a division of First Citizens Bank & Trust Company, as lender ("SVB"). The Loan Agreement was amended

in April 2023 and October 2024. The Company drew $10,000,000 in term loans under the Loan Agreement (the "Term Loans") on the Closing Date. The Term Loans bore interest at a floating rate per annum equal to the greater of (A) the prime rate (as published in the money rates section of The Wall Street Journal) plus 2.25% and (B) 5.50%. The Term Loans were interest only from the Closing Date through June 30, 2023, after which the Company was required to pay 30 equal monthly installments of principal.

All outstanding principal and accrued and unpaid interest under the Term Loans and all other outstanding obligations with respect to the Term Loans were due and payable in full on December 1, 2025. Upon repayment in full of the Term Loans, the Company was required to pay a one-time final payment fee equal to 5.00% of the original principal amount of any funded Term Loans being repaid. This one-time final payment fee was recorded to interest expense using the effective interest method over the period of the Term Loans in the condensed consolidated statements of operations and comprehensive loss.

During the three and nine months ended September 30, 2025, the Company recognized interest expense related to the Term Loans of $0.03 million and $0.2 million, respectively, and interest expense related to accretion of the final payment of $33,000 and $98,000, respectively.

As of September 30, 2026, the Term Loans were fully paid off and there was no remaining balance related to the Term Loans.

Debt Issuance Costs

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

The Company incurred $142,000 in debt issuance costs related to the Loan Agreement at its onset. For the three and nine months ended September 30, 2025, the Company recorded $9,000 and $28,000, respectively, in amortization of debt issuance costs to interest expense in the condensed consolidated statements of operations and comprehensive loss. The Company did not record any amortization of debt issuance costs for the three and nine months ended September 30, 2026.

7. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	September 30, 2026	December 31, 2025
Employee and board compensation	$ 1,756	$ 757
Payroll tax liability	12,143	26
Contract research services	—	286
Contract manufacturing services	40	290
Professional services	1,251	252
Total	$ 15,190	$ 1,611

Payroll tax liability as of September 30, 2026 was primarily related to restricted stock units granted to certain executives.

8. License Agreements

Ascendant Health Sciences Ltd. License Agreement

On April 30, 2026, the Company entered into a License Agreement (as amended, the “License Agreement”) with Ascendant. Pursuant to the License Agreement and subject to certain rights retained by the Licensor, the Licensor granted the Company: (1) the exclusive and sublicensable rights to develop, manufacture, commercialize and otherwise exploit the Licensor’s anti-IgE monoclonal antibody known as Ascendant-221, which was formerly known as UB-221 (together with certain related molecules, the “Licensed Molecules”) and products containing a Licensed Molecule (collectively, the “Licensed Products”) throughout the world (except the mainland of China, Hong Kong, Macau and Taiwan (together, the “Ascendant Territory”)) (such territory of the Company, the “Cue Territory”) for any and all uses; and (2) the non-exclusive and sublicensable rights to manufacture the Licensed Molecules and Licensed Products in the Ascendant Territory (other than China) solely for the purposes of developing and commercializing the Licensed Molecules and Licensed Products in the Cue Territory.

As consideration for the rights granted to the Company by the Licensor, the Company paid the Licensor $15.0 million as the

upfront payment, and will pay up to an aggregate of $676.5 million in additional potential milestone payments, and tiered royalty payments (at percentages ranging from high single-digit to low double-digit) on future net sales of Licensed Products. The additional milestone payments include $5.0 million upon the completion of manufacturing technology transfer, $6.5 million upon the completion of data and know-how transfer, up to $205.0 million upon the achievement of specified development and regulatory milestone events, including upon receipt of threshold data from a specified Phase 2 clinical trial, and up to $460.0 million upon the achievement of specified commercial milestone events. In the event the Company grants a sublicense of its rights under the License Agreement within the first 18 months after the effective date of the License Agreement, certain sublicensing revenues received by the Company will be shared with Licensor at specified percentages between 20% and 40% for a period of up to 18 months after the effective date. In addition, in the event of a specified change of control transaction with respect to the Company within the first 18 months after the effective date of the License Agreement, certain milestone payments will accelerate, in an amount up to $215.0 million.

Under the License Agreement, royalty payments will be payable on a product-by-product and country-by-country basis outside of the Ascendant Territory during the period commencing on the first commercial sale and continuing until the later of: (a) the 10-year anniversary of the date of such first commercial sale; (b) the expiration of the relevant patent claims; and (c) the expiration of the relevant regulatory exclusivity. Subject to a certain floor, the Company's royalty payments will be reduced by specified percentages for patent expiration, biosimilar entry, payments for third party intellectual property, compulsory sublicenses or drug pricing programs. The Company's royalty payments are also subject to reduction in connection with royalty rates owed to an upstream academic licensor.

In connection with the execution of the License Agreement, on April 30, 2026, the Company and the Licensor also entered into a securities purchase agreement (the "Purchase Agreement"), pursuant to which the Company agreed to issue to the Licensor at an initial closing (the "Initial Closing") pre-funded warrants (the "Initial Closing Pre-Funded Warrants" or the "Ascendant Pre-Funded Warrants") to purchase up to 551,724 shares of common stock of the Company, as partial consideration for the license and rights granted under the License Agreement. The exercise price of the Initial Closing Pre-Funded Warrants is $0.001 per share. The Initial Closing occurred on May 4, 2026. Pursuant to the terms of the Purchase Agreement, and subject to and contingent upon the achievement of specified clinical and financial milestones (the "Top-Up Milestones"), the Company has agreed to issue to the Licensor at a second closing (the "Top-Up Closing") the Top-Up Shares such that, when combined with the shares of common stock issuable upon exercise of the Initial Closing Pre-Funded Warrants (the "Initial Closing Pre-Funded Warrant Shares"), the Licensor will beneficially own a number of shares of common stock (directly or indirectly) equal to no less than 7.5% of the Outstanding Capital Stock (as defined in the Purchase Agreement) immediately following achievement of the final Top-Up Milestone; provided that the aggregate value of all such securities issued to the Licensor under the Purchase Agreement (determined by multiplying (x) the sum of the Top-Up Shares and the Licensor Warrant Shares (as defined below) by (y) the closing price of the common stock on the Nasdaq Stock Market on the date of achievement of the final Top-Up Milestone) will be no less than $15.0 million (the "Value Threshold"). If the dollar value of such securities exceeds the Value Threshold, the Purchase Agreement provides that the Licensor will be entitled to be issued all such securities at the Top-Up Closing with no cap on the aggregate dollar value of the issuable securities, except that the Company will not issue any Top-Up Shares to the Licensor to extent that such issuance would require approval of the Company's stockholders in order to satisfy applicable listing rules of the Nasdaq Stock Market, including without limitation Nasdaq Listing Rule 5635, without first obtaining such stockholder approval (any such Top-Up Shares, the "Excess Shares") and, in such event, the Company will instead issue to the Licensor pre-funded warrants to purchase the number of shares of common stock equal to the Excess Shares (the "Top-Up Pre-Funded Warrants"), which Top-Up Pre-Funded Warrants will only be exercisable following receipt of approval by the Company's stockholders of the issuance of shares of common stock upon exercise of such Top-Up Pre-Funded Warrants (the "Top-Up Pre-Funded Warrant Shares") in accordance with the applicable listing rules of the Nasdaq Stock Market, including Nasdaq Listing Rule 5635. "Licensor Warrant Shares" means the Initial Pre-Funded Warrant Shares and the shares of common stock issuable upon exercise of the Top-Up Pre-Funded Warrant Shares (as discussed above).

The Company accounted for the License Agreement and Purchase Agreement as a combined contract. The licenses and rights granted to the Company all pertain to IPR&D assets as the underlying Licensed Products are still under development (in clinical trials). Since the acquired set does not meet the definition of a business, the purchase of the IPR&D assets was accounted for as an asset acquisition under ASC 805-50.

The initial cost of the IPR&D asset was equal to $35.1 million, which is comprised of the upfront cash payment of $15.0 million, the fair value of the Initial Closing Pre-Funded Warrants of $16.5 million, and the initial fair value of the contingently issuable Top-Up Shares of $3.65 million. As the IPR&D assets do not have alternative future uses, the initial cost of the IPR&D assets was expensed immediately.

As of September 30, 2026, the Company recognized a liability of $9.1 million related to the Top-Up Obligation, which is included in non-current liabilities in the accompanying condensed consolidated balance sheets. During the three and nine months ended September 30, 2026, the Company recognized a loss of $3.4 million and $5.5 million, respectively, from changes in the fair value of the Top-Up Obligation, which is included in other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss. See discussion of Top-Up Shares in Note 3.

As the contingent consideration settled in cash are not accounted for as derivatives under ASU 2025-07, the contingent consideration will be recognized when probable and reasonably estimable. Contingent consideration related to (i) development milestones will be expensed as incurred under ASC 730, (ii) regulatory milestones will be capitalized as intangible asset(s) under ASC 350, and (iii) commercial milestones and royalties will be expensed as cost of goods sold as the underlying net sales of the Licensed Products occur.

Einstein License Agreement

On January 14, 2015, the Company entered into a license agreement, as amended and restated on July 31, 2017 and as further amended on October 30, 2018, January 13, 2024, and April 10, 2025 (the "Einstein License"), with Albert Einstein College of Medicine ("Einstein") for certain patent rights relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides.

Pursuant to the April 2025 amendment, Einstein consented to the Company's entry into the Collaboration and License Agreement (the "BI Collaboration and License Agreement") with Boehringer Ingelheim International GmbH ("BI") and granted the Company the right to sublicense to BI. In addition, Einstein and the Company agreed to amend specified upstream payment obligations that may be owed to Einstein by the Company, solely in connection with the sublicense to BI.

Under the Einstein License, the Company holds an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the patents covered by the Einstein License, including certain technology received from Einstein relating thereto (the "Einstein Licensed Products"). Under the Einstein License, the Company is required to:

- Pay royalties and amounts based on a certain percentage of proceeds, as defined in the Einstein License, from sales of Einstein Licensed Products and sublicense agreements.
- Pay escalating annual maintenance fees, which are nonrefundable, but are creditable against the amount due to Einstein for royalties.
- Make significant payments based upon the achievement of certain milestones, as defined in the Einstein License. Payments made upon achievement of milestones are nonrefundable and are not creditable against any other payment due to Einstein. At September 30, 2026, the Company had made aggregate payments totaling $3.89 million since inception with respect to achievement of these milestones.
- Incur minimum product development costs until the first commercial sale of the first Einstein Licensed Product.

The Einstein License 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.

The Einstein License expires upon the expiration of the Company's last obligation to make royalty payments to Einstein which may be due with respect to certain Einstein Licensed Products, unless terminated earlier under the provisions thereof. The Einstein License includes certain termination provisions if the Company fails to meet its obligations thereunder. The Company was in compliance with its obligations under the Einstein License at September 30, 2026 and December 31, 2025.

Pursuant to the Einstein License, the Company issued to Einstein 22,385 shares of the Company's common stock in connection with the consummation of the initial public offering of its common stock on December 27, 2017.

The Company accounts for license fees incurred in connection with the Einstein License in accordance with ASC Topic 730, Research and Development. Please refer to Note 11 Collaboration Revenue.

9. Stock-Based Compensation

Stock Option Valuation

For stock options requiring an assessment of value during the nine months ended September 30, 2026 and 2025, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	September 30, 2026
Risk-free interest rate	3.85 - 4.86%
Expected dividend yield	0%
Expected volatility	88.60% - 105.55%
Expected life	5.50 to 6.25 years

	September 30, 2025
Risk-free interest rate	3.90% - 4.46%
Expected dividend yield	0%
Expected volatility	86.46% - 89.38%
Expected life	5.50 to 6.72 years

A summary of stock option activity for the nine months ended September 30, 2026 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2025	424,910	$ 116.68	6.79
Granted	1,491,075	29.93	—
Exercised	(62,818)	21.80	—
Forfeited	(120,380)	28.15	—
Expired	(27,225)	230.78	—
Stock options outstanding at September 30, 2026	1,705,562	48.76	8.95
Stock options exercisable at September 30, 2026	404,587	$ 108.21	6.90

The aggregate intrinsic value of exercisable but unexercised in-the-money stock options at September 30, 2026 was $0.1 million, with a weighted average remaining contractual term of 6.9 years. The aggregate intrinsic value of options is calculated as the difference of the market close price of $25.87 on September 30, 2026 and the exercise price.

During the three and nine months ended September 30, 2026, the Company recognized $2.1 million and $6.1 million, respectively, in stock-based compensation related to stock option activity. As of September 30, 2026, total unrecognized stock-based compensation expense was $30.7 million, which is expected to be recognized as an operating expense in the Company’s condensed consolidated statements of operations and comprehensive loss over the weighted average remaining period of 3.6 years.

During the three and nine months ended September 30, 2026, the Company granted stock options to purchase 0.2 million shares of common stock with a weighted average grant date fair value of $25.49 per share and stock options to purchase 1.5 million shares of common stock with a weighted average grant date fair value of $24.31 per share, respectively.

During the three and nine months ended September 30, 2025, the Company granted stock options to purchase 97.8 thousand shares of common stock with a weighted average grant date fair value of $21.60 per share and stock options to purchase 166.5 thousand shares of common stock with a weighted average grant date fair value of $24.60 per share, respectively.

Restricted Stock Units

The following table summarizes the RSU activity under the Company's equity plans for the nine months ended September 30, 2026:

Restricted Securities	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance at December 31, 2025	—	$ —
Granted	2,576,984	34.76
Vested/Released	(948,654)	32.30
Forfeited	(25,780)	36.51
Nonvested balance at September 30, 2026	1,602,550	$ 36.19

In July 2026, the Company granted employees performance-based RSUs that vest upon specified stock-price targets measured using a five-trading-day average before July 9, 2028, subject to applicable service conditions. The first tranche of performance-based RSUs of 292,586 shares had a grant date fair value of $36.51 per share and vested upon achieving a five-trading-day average closing price above $33.00 per share during the three months ended September 30, 2026. The second tranche of 292,586 shares had a grant date fair value of $35.98 per share and vests upon achieving a five-trading-day average closing price above $38.50 per share. The third tranche of 292,586 shares had a grant date fair value of $35.47 per share and vests upon achieving a five-trading-day average closing price above $44.00 per share. The Company used a Monte Carlo simulation to estimate the fair value at grant date for these performance-based RSUs, which totaled $31.2 million for all three tranches. The assumptions used in the Monte Carlo Simulation for the performance-based RSUs were a stock price on the date of grant of $36.51, expected volatility of 143.0%, and a cost of equity of 23.0%. Because the derived service periods for the second and third tranches were short, the Company recognized the full stock-based compensation for the performance-based RSUs during the quarter ended September 30, 2026.

The Company recognized $33.4 million and $53.3 million in stock-based compensation during the three and nine months ended September 30, 2026, respectively, related to RSU activity. As of September 30, 2026, total unrecognized stock-based compensation expense was $35.3 million, which is expected to be recognized as an operating expense in the Company's condensed consolidated statements of operations and comprehensive loss over the weighted average remaining period of 3.0 years.

Stock-based Compensation

Stock-based compensation for the three and nine months ended September 30, 2026 and 2025 was included in the Company's condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
General and administrative	$ 25,757	$ 1,104	$ 46,112	$ 2,379
Research and development	9,719	429	13,250	1,755
Total stock-based compensation	$ 35,476	$ 1,533	$ 59,362	$ 4,134

Stock-based compensation for the three and nine months ended September 30, 2026 and 2025 by type was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Stock options	$ 2,072	$ 1,533	$ 6,064	$ 4,134
RSUs	33,404	—	53,298	—
Total stock-based compensation	$ 35,476	$ 1,533	$ 59,362	$ 4,134

10. Warrants

Information with respect to the Company's outstanding warrants as of September 30, 2026 is as follows:

	Warrants Issued November 2022	Warrants Issued September 2024	Warrants Issued April 2025	Warrants Issued December 2025	Warrants Issued May 2026	Warrants Issued to Ascendant in 2026	Warrants Issued July 2026
Outstanding common stock warrants	306,280	196,962	200,416	526,839	1,339,324	—	—
Outstanding pre-funded warrants	—	315,706	337,552	428,325	1,138,156	551,724	287,500
Weighted average exercise price of common stock warrants	$ 117.90	$ 15.00	$ 23.70	$ 9.00	$ 11.00	$ —	$ —
Weighted average exercise price of pre-funded warrants	$ —	$ 0.030	$ 0.030	$ 0.030	$ 0.001	$ 0.001	$ 0.001
Weighted average contract remaining life (in years)	1.12	3.00	3.55	4.22	4.59	9.60	N/A

In connection with the May 2026 securities purchase agreement and the Ascendant License Agreement, the Company issued the May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants, each of which was initially classified as a liability and measured at fair value, as share settlement was contingent upon the Issuance Stockholder Approval, which was outside the Company's control. The Company's stock price increased from $14.74 on the April 30, 2026 pricing date to $29.85 on the May 2026 Offering Closing Date, causing the aggregate fair value of the instruments to exceed the proceeds received and resulting in a loss upon issuance of $90.0 million, which included issuance costs of $2.5 million. The fair value of these instruments declined through June 1, 2026, when the Issuance Stockholder Approval was obtained and the instruments were reclassified to permanent equity, after which they are no longer subject to remeasurement. See Note 3 for the initial fair value and change in fair value of the May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants.

The initial fair value of the Ascendant Pre-Funded Warrants, together with the initial fair value of the contingent obligation to issue the Top-Up Shares, was recognized as consideration for the acquired license and recorded within research and development license expense. The initial fair value of the May 2026 Pre-Funded Warrants and May 2026 Warrants in excess of the proceeds received under the May 2026 Offering, and all subsequent changes in the fair value of the liability-classified instruments through the date of the Issuance Stockholder Approval, were recognized within other income (expense). See Note 3 for the initial fair value and change in fair value of the May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants.

11. Collaboration Revenue

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

The terms of the Company's arrangements with customers typically include the payment of one or more of the following: (i) non-refundable, up-front payment, and pass through costs related to research activities, (ii) development, regulatory and commercial milestone payments, (iii) future options and (iv) royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of pass-through costs and milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "expected value method" 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 judgment to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenues, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

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

Collaboration revenue for the three and nine months ended September 30, 2026 and 2025 was as follows:

(In thousands)	Three months ended September 30, 2026	Three months ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Collaboration revenue	$ 132	$ 2,149	$ 13,695	$ 5,524

Revenue for the three and nine months ended September 30, 2026 and September 30, 2025 was recognized over time.

Collaboration and Option Agreement with Ono

In February 2023, the Company entered into a strategic collaboration agreement (the "Ono Collaboration and Option Agreement") with Ono Pharmaceutical Co., Ltd. ("Ono") to further develop CUE-401. In March 2025, the Company and Ono agreed to terminate the Ono Collaboration and Option Agreement effective as of March 6, 2025. At such time, the Ono Collaboration and Option Agreement had no further force or effect with the exception of certain customary provisions which are intended to survive termination and expiration of the Ono Collaboration and Option Agreement. The Company retained all rights to CUE-401.

As of September 30, 2026, both Ono and the Company have satisfied all of their performance obligations and made all outstanding payments required under the agreement. For the three months ended September 30, 2025 and the three and nine months ended September 30, 2026, the Company did not recognize any revenue related to the Ono Collaboration and Option Agreement. For the nine months ended September 30, 2025, the Company recognized revenue of $0.4 million related to the Ono Collaboration and Option Agreement. The Company did not record short or long-term research and development liabilities on its condensed consolidated balance sheets dated September 30, 2026 and December 31, 2025, as the performance obligation has been met and completed.

BI Collaboration and License Agreement

On April 10, 2025, the Company entered into the BI Collaboration and License Agreement to research, develop and commercialize differentiated B cell depletion molecules, including CUE-501.

Under the terms of the BI Collaboration and License Agreement, the Company and BI will conduct collaborative research focused on CUE-501 during a four-year period or, if earlier, the completion of activities under the research plan (the “BI Research Term"). In addition to, or instead of, CUE-501, BI may elect, at its sole discretion, to include additional or alternative compounds targeted at B cell depletion. BI will have an exclusive, royalty-bearing, worldwide, sublicensable license, under the Company's applicable patents and know-how, to develop, manufacture and commercialize such compounds and their derivatives (the "BI Licensed Products") for all uses, and BI shall be responsible for all further research, preclinical and clinical development, manufacturing, regulatory approvals, and commercialization of BI Licensed Products at its expense. During the BI Research Term, the Company is prohibited from developing or commercializing any molecule for applications in B cell depletion.

Pursuant to the terms of the BI Collaboration and License Agreement, the Company received an upfront payment of $10.1 million in cash in the second quarter of 2025, which is net of $1.9 million of German withholding taxes that the Company expects to be refunded in the fourth quarter of 2026. The withholding has been recorded as a foreign withholding tax receivable at September 30, 2026 and December 31, 2025 on the Company's condensed consolidated balance sheets. The Company will also be eligible to receive up to an aggregate of approximately $345.0 million in success-based research, development and commercial milestone payments, beginning with two preclinical development milestones, as well as royalty payments on net sales. The royalty payments will be subject to reduction due to patent expiration, payments made under certain licenses for third-party intellectual property and generic competition. BI has agreed to reimburse the Company for agreed upon costs incurred in conducting research during the BI Research Term, including certain pass through costs from third party contractors and full-time employee salaries.

The BI Collaboration and License Agreement will continue, on a product-by-product and country-by-country basis, until the expiration of the applicable royalty term, unless earlier terminated. BI has the right to terminate the BI Collaboration and License Agreement for any reason after a specified notice period. Each party has the right to terminate the BI Collaboration and License Agreement on account of the other party’s bankruptcy or material, uncured breach. In connection with the Company's entry into the BI Collaboration and License Agreement, the Company entered into an amendment to the Company's Einstein License whereby Einstein consented to the Company's entry into the BI Collaboration and License Agreement and

granted the Company the right to sublicense to BI. In addition, the Company and Einstein agreed to amend specified upstream payment obligations that may be owed to Einstein by the Company, solely in connection with the sublicense to BI.

The Company determined that the research activities and the exclusive license granted under the BI Collaboration and License Agreement is considered as a single performance obligation, and therefore, the transaction price was allocated entirely to the single performance obligation. The Company recognizes revenue related to the single performance obligation over time as the underlying services are performed and/or external costs are incurred during the research term. The Company has constrained the variable consideration associated with the future research, development and commercial milestones and royalty payments and excluded them from the transaction price.

On April 1, 2026, the Company received notice from BI that BI had approved selection of its first compound for lead optimization under the BI Collaboration and License Agreement. This preclinical milestone event triggered a $7.5 million payment to the Company, which was received in May 2026.

For the three and nine months ended September 30, 2026, the Company recognized revenue of $0.1 million and $13.4 million, respectively, related to the BI Collaboration and License Agreement. For the three and nine months ended September 30, 2025, the Company recognized revenue of $2.1 million and $5.1 million, respectively, related to the BI Collaboration and License Agreement. The Company recorded accounts receivable of $0.1 million and $0.5 million on its condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025, respectively. The Company did not record short or long-term research and development liabilities on its condensed consolidated balance sheets dated September 30, 2026, as the research term is substantially completed. The Company recorded short-term research and development liabilities of $5.3 million on its condensed consolidated balance sheets as of December 31, 2025.

The Company considered the capitalization of contract costs under the guidance in ASC Topic 340-40, Other Assets and Deferred Costs: Contracts with Customers, as it relates to the BI Collaboration and License Agreement. The Company capitalized license expenses of approximately $1.1 million, paid to Einstein pursuant to the Einstein License 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. As of December 31, 2025, $0.5 million was included in prepaid expenses and other short-term assets related to the BI Collaboration and License Agreement. This amount is comprised of approximately $1.1 million of capitalized license expenses related to the up-front payment received from BI in May 2025, net of accumulated amortization of approximately $0.6 million. As of September 30, 2026, the capitalized license expenses were fully amortized as the performance obligation had been met and was completed. The Company also accrued $0.2 million to be paid when the German withholding tax refund is received in other current payable on its condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025.

ImmunoScape Collaboration and License Agreement

On November 6, 2025, IMSCP exercised its option to obtain licenses to research, develop and commercialize molecules from the Company's CUE-100 series, including CUE-101 and CUE-102, subject to certain exclusions, for all oncology indications pursuant to the IMSCP Collaboration and License Agreement, effective November 6, 2025, between the Company and IMSCP. The licenses provided pursuant to the IMSCP Collaboration and License Agreement include a co-exclusive development license for five years or, if longer, for so long as IMSCP has a specified number of CUE-100 series molecules under active development and, pursuant to which, the Company retains non-exclusive research rights to support its other programs. The Company also retained its rights to the CUE-100 series, including CUE-101 and CUE-102, for use in any manner other than as a component of a cell therapy product for 18 months past the effective date of the IMSCP Collaboration and License Agreement. The licenses include an exclusive commercial license to IMSCP for any CUE-100 series molecule that IMSCP advances to IND-enabling studies while the co-exclusive development license is in effect. The licensed series of molecules will be further developed and potentially commercialized by IMSCP. The Option was exercised pursuant to an Option Agreement between the Company and IMSCP, dated October 22, 2025. In connection with entry into the Option Agreement and IMSCP's exercise of the Option, the Company received an aggregate of $9.5 million, net of withholding taxes, in the fourth quarter of 2025 and was entitled to receive an additional $5.0 million before the first anniversary of the effective date of the IMSCP Collaboration and License Agreement.

On November 6, 2026, the Company and IMSCP entered into a Second Amendment to the IMSCP Collaboration and License Agreement (the "Second Amendment"), pursuant to which, among other things, the Company's right to receive the additional $5.0 million payment was amended such that the Company is entitled to receive a $5.5 million payment from IMSCP as follows: (a) $3.0 million on or before November 27, 2026, (b) $1.5 million on or before July 30, 2027, and (c) $1.0 million on or before November 27, 2027.

Accordingly and pursuant to the IMSCP Collaboration and License Agreement (after giving effect to the Second Amendment), the Company (a) received equity of IMSCP equal to 40% of the issued and outstanding equity of IMSCP and is entitled to receive additional equity, in the form of warrants, upon certain dilution events in the future, (b) received time-based payments of $10.0 million in the fourth quarter of 2025, (c) is entitled to receive an additional time-based payment of $5.5 million, payable as described above and (d) is entitled to receive high single-digit royalties on global net sales and low- to mid-double digit royalties from sublicensing royalties and income. The IMSCP Collaboration and License Agreement includes customary termination provisions, including IMSCP's ability to terminate the agreement in its entirety on 60 days' advanced written notice to the Company.

The Company accounted for the Option Agreement and IMSCP Collaboration and License Agreement as a combined contract. The transaction price includes the upfront payments of $15.0 million and the $3.9 million fair value of equity interest in IMSCP received. The Company concluded there is one combined performance obligation for the licenses as the Company does not have material performance obligations beyond the issuance of the licenses. The Company recognized revenue for the licenses at a point in time when the licenses were granted and there was a right to payment, the exclusive rights were transferred, and significant risks and rewards of ownership of the rights to use the licensed IP were transferred. The sales-based royalties resulting from sales made under the IMSCP Collaboration and License Agreement will only be included in the transaction price upon occurrence of the underlying sales in the future.

For the three and nine months ended September 30, 2026, the Company recognized revenue of less than $0.1 million and $0.3 million related to the IMSCP Collaboration and License Agreement. The Company recorded accounts receivable from IMSCP of $5.1 million and $5.0 million on its condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025, respectively.

The Einstein License 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. The Company incurred $1.5 million of license expense during the year ended December 31, 2025 upon entering the IMSCP Collaboration and License Agreement, of which $1.0 million was paid in the first quarter of 2026.

12. Commitments and Contingencies

Einstein License Agreement

In 2015, the Company entered into the Einstein License with Einstein for certain patent rights relating to the Company's core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides. The Company entered into an amended and restated license agreement on July 31, 2017, as amended on October 2018, which modified certain obligations of the parties under the Einstein License. The Einstein License was further amended on January 13, 2024 and April 10, 2025.

The Company pays $0.1 million in annual maintenance license fees to Einstein, which are amortized equally throughout the year. The Company incurred less than $0.1 million in annual maintenance fees for each of the three and nine months ended September 30, 2026 and 2025.

The Company's remaining commitments with respect to the Einstein License are based on the attainment of future milestones. The aggregate amount of milestone payments made under the Einstein License may equal up to $1.85 million for each Einstein Licensed Product, and up to $1.85 million for each new indication of an Einstein Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Einstein Licensed Products may equal up to $5.75 million. The Company is also party to a service agreement with Einstein to support the Company's ongoing research and development activities.

Ascendant License Agreement

The Company's remaining commitments with respect to the Ascendant License Agreement are based on the attainment of future milestones. The aggregate amount of milestone payments made under the Ascendant License Agreement may equal up to $676.5 million in additional potential milestone payments, and tiered royalty payments (at percentages ranging

from high single-digit to low double-digit) on future net sales of Licensed Products. In the event the Company grants a sublicense of its rights under the License Agreement within the first 18 months after the effective date of the License Agreement, certain sublicensing revenues received by the Company will be shared with Licensor at specified percentages between 20% and 40% for a period of up to 18 months after the effective date. In addition, in the event of a specified change of control transaction with respect to the Company within the first 18 months after the effective date of the License Agreement, certain milestone payments will accelerate, in an amount up to $215.0 million. See discussion of the Ascendant License Agreement in Note 8.

Pursuant to the Purchase Agreement with Ascendant, the Company may be required to issue Top-Up Shares, or, if stockholder approval is required for the issuance of such shares, the Top-Up Pre-Funded Warrants, upon the achievement of specified clinical and financial milestones. The number of Top-Up Shares to be issued is variable and is designed to provide Ascendant with beneficial ownership of no less than 7.5% of the Company's outstanding common stock immediately following the achievement of the final milestone, subject to the terms and conditions of the agreement.

Collaboration and Option Agreement with Ono

See discussion of the Ono Collaboration and Option Agreement in Note 11.

Collaboration and License Agreement with BI

See discussion of the BI Collaboration and License Agreement in Note 11.

Collaboration and License Agreement with IMSCP

See discussion of the IMSCP Collaboration and License Agreement in Note 11.

Contingencies

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

The Company may be subject to various legal proceedings from time to time as part of its business. As of September 30, 2026, 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.

13. Leases

On March 28, 2022, the Company entered into a License Agreement (the “License”) with MIL 40G, LLC (the “Licensor”), pursuant to which the Company leased approximately 13,000 square feet of office, research and development and laboratory space located at 40 Guest Street, Boston, Massachusetts 02135 (the “Office and Laboratory Space”). On July 7, 2022, the Company entered into an operating lease for additional laboratory space (the “Additional Laboratory Space”) at 40 Guest Street for the period from December 1, 2022 through December 1, 2024 (the “40G Additional Laboratory Lease”).
The License and the 40G Additional Laboratory Lease was modified at various times from inception through 2024.

On June 30, 2025, the Company entered into the Second Amendment to the License with the Licensor. Pursuant to the Second Amendment, effective June 30, 2025, the monthly rental rate for the Office and Laboratory Space decreased from $235,884 to $147,546, subject to a 4% increase on April 15, 2027, and the term of the License was extended from April 14, 2026 to April 14, 2028. In addition, the Licensor agreed to provide the Company a partial credit of $44,169 for rent the Company had paid at the new monthly rental rate for the month of June 2025.

On January 10, 2026, the Company entered into the Third Amendment to the License with the Licensor. Pursuant to the Third Amendment, effective January 10, 2026, the Company terminated the 40G Additional Laboratory Lease. As a result, the Company derecognized the corresponding right-of-use asset of $0.4 million and lease liability of $0.4 million, with the difference of $9,842 recognized as a gain in the condensed consolidated statement of operations. In addition, the Licensor agreed to provide the Company a partial credit of $59,379 for the security deposit the Company had paid, to be applied in four equal monthly installments. Under the Third Amendment, the Company continued to have access to the shared laboratory spaces and would recognize the associated fees as incurred.

On September 18, 2026, the Licensor made an Assignment for the Benefit of Creditors under Delaware law. As a result, the Company terminated the License with the Licensor and vacated all office, research and development and laboratory space effective September 30, 2026. The Company is in the process of leasing a new space.

Upon the termination of the License, the Company recorded a gain of approximately $0.1 million during the three months ended September 30, 2026, which includes writing off the remaining balances of the right-of-use asset of $2.6 million and the corresponding lease liability of $2.7 million. As of September 30, 2026, the Company had no operating lease right-of-use assets or corresponding operating lease liabilities on its condensed consolidated balance sheets.

The Company also determined that the security deposits related to the 40G Additional Laboratory Lease were not recoverable and recognized a loss on security deposit of $0.5 million in the three months ended September 30, 2026. As of December 31, 2025, security deposits of $0.5 million related to the 40G Additional Laboratory Lease were included in deposits on the Company’s condensed consolidated balance sheets.

For the three months ended September 30, 2026 and 2025, the Company recorded $0.1 million in interest expense to the lease liability. For the nine months ended September 30, 2026 and 2025, the Company recorded $0.2 million in interest expense to the lease liability.

Rent expense of $0.5 million and $1.4 million was included in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026, respectively. Rent expense of $0.6 million and $2.3 million was included in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2025, respectively.

The weighted average remaining lease term and discount rate related to the Company's leases as of December 31, 2025 were as follows:

	December 31, 2025
Weighted average remaining lease term (years)	2.12
Weighted average discount rate	9.77%

14. Subsequent Events

On November 6, 2026, the Company and IMSCP entered into a Second Amendment to the IMSCP Collaboration and License Agreement. See Note 11 for further discussion.

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, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 16, 2026, or the 2025 Annual Report.

Overview

We are a clinical-stage biopharmaceutical company focused on advancing a portfolio of potentially transformative therapies aimed at enabling functional cures across immunological disorders. Our lead asset, CUE-221, is a novel humanized anti-IgE monoclonal antibody designed with a dual-mechanism of action that we are developing for allergic diseases. We have received topline results from a Phase 2 clinical trial of CUE-221 conducted in China by Genesis Life Sciences, a related company of Ascendant Health Ltd. (Ascendant), in patients with chronic spontaneous urticaria, or CSU. In addition, we have developed the Immuno-STAT® platform designed to engineer therapies that selectively target disease-specific T cells in vivo without broad immune modulation. Our lead candidate to treat autoimmune diseases, CUE-401 was designed to induce the development of regulatory T cell populations (Tregs) leading to Treg-mediated tolerance and control of autoimmunity. In the fourth quarter of 2026, we initiated dosing of human subjects in our Phase 1 clinical trial of CUE-401.

Our Lead Programs

- CUE-221 (Ascendant-221, UB-221) is a humanized anti-IgE IgG1 monoclonal antibody designed with a precision engineered dual mechanism of action. CUE-221 binds to IgE at sites that are distinct from the binding sites for XOLAIR® or other similar anti-IgE monoclonal antibodies. In doing so, it maintains the capacity of total IgE to bind the CD23 receptor at the surface of B cells, resulting in reduced IgE synthesis. Therefore, CUE-221 is a functionally distinct novel anti-IgE antibody designed to not only neutralize free IgE with high potency, but also to prevent the synthesis of new IgE with the possibility to achieve b-cell quiescence through crosslinking of CD23, which could ultimately result in sustained disease control beyond drug exposure. The CUE-221 Phase 2 clinical trial in CSU produced positive topline results and clinical evidence providing initial validation of the clinical potential of a precision engineered anti-IgE dual mechanism of action. The study also demonstrated fundamental biological differences compared to XOLAIR®.
- CUE-401 is a bispecific fusion protein of 2 human cytokines: IL-2 and TGFβ, each engineered in an attenuated form so as to decrease their affinity for their respective cognate receptor to limit the potential for broader off-target or adverse immunomodulatory effects. The design of CUE-401 stemmed from the Nobel Prize winning discovery of the role of regulatory T cells (Tregs) in autoimmunity, granted in 2025, and the recognition that the cytokines IL-2 and TGF-beta, when acting in concert are essential components in establishing immune tolerance by fostering the development of Tregs.

Partnered Programs

CUE-500 Series

The CUE-500 series is designed to selectively target and deplete disease-causing cells by redirecting existing anti-viral memory T cells toward pathogenic cell populations, including autoreactive B cells implicated in autoimmune diseases. We believe this approach may enable targeted immune modulation while potentially reducing the broader immune effects associated with certain existing therapies. CUE-501, which is being developed through our collaboration and license agreement with Boehringer Ingelheim, or BI, is focused on the treatment of autoimmune diseases driven by pathogenic B cells. We believe the modular design of the CUE-500 series may support development across multiple disease areas by incorporating different cell-targeting domains into the platform framework.

CUE-100 Series

Historically, we primarily focused our resources on the development of our CUE-100 series for oncology, namely the CUE-101 and CUE-102 product candidates, which are representative of our approach to selectively activate targeted CD8+ T cells against cancer, both of which have been licensed to ImmunoScape Pte. Ltd., or IMSCP, to advance a novel in vivo approach to cell therapy for the treatment of solid tumors. Through our Collaboration and License Agreement with IMSCP,

IMSCP is developing a novel Seed-and-Boost immunotherapy that combines our clinically validated Immuno-STAT T-cell engagers, the CUE-100 series, with IMSCP's proprietary tumor-specific T cell receptors, or TCRs. The combination therapy is designed to overcome core limitations of existing cell therapies and to potentially establish a new standard of care with superior anti-tumor activity, durable T cell persistence and product scalability.

Plan of Operation

As a clinical stage company, the majority of our business activities to date have been, and our planned future activities will be, devoted to furthering research and development of our product candidates. We intend that the majority of our business activities will be devoted to furthering the development of our two lead assets: CUE-221 and CUE-401. We also plan to continue to support our collaborations across our pipeline, such as our strategic collaboration and license agreements with BI for the development of CUE-501, and ImmunoScape Pte. Ltd. for the development of our CUE-100 series.

Liquidity

We have incurred significant losses since our inception and have never generated revenue or profit from product sales, and it is possible we will never generate revenue or profit from product sales. During the nine months ended September 30, 2026, we had one-time cash outflows related to the license agreement with Ascendant totaling approximately $28 million, which consisted primarily of a $15 million upfront payment to Ascendant and other one-time legal fees, consulting fees and employee related costs. As of September 30, 2026 we had cash and cash equivalents of $57.9 million. Based on our current operating plans, we believe that our cash and cash equivalents as of September 30, 2026 will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance date of our condensed consolidated financial statements included in this Quarterly Report. We have based our estimate as to how long we expect we will be able to fund our obligations on assumptions that may prove to be wrong and we may use our available capital resources sooner than we currently expect. Beyond that, we will need to raise substantial additional capital to fund our future operations. We expect to finance our future cash needs through a combination of equity offerings, collaborations, and other strategic alliances. Volatility in capital markets and general economic conditions in the U.S. may be a significant obstacle to raising the required funds and, as a result, we may be unable to secure the necessary funding on acceptable terms, if at all. To the extent that we raise additional capital through future equity offerings, the ownership interest of common stockholders will be diluted, which dilution may be significant. We cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us. In the event that we are unable to obtain any or sufficient additional funding, we may be forced to delay, reduce or discontinue our product development programs or consider other various strategic alternatives, including the sale or disposition of our rights or assets or our dissolution and liquidation with little or no return to investors. Any such change in our product development programs or strategic alternatives may have a material adverse effect on the price per share of our common stock.

Critical Accounting Estimates and Significant Judgments

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

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our 2025 Annual Report may have the greatest potential impact on our financial statements, so we consider those estimates, assumptions and judgments to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during nine months ended September 30, 2026.

Recent Accounting Pronouncements and Adopted Standards

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

Reverse Stock Split

We held our 2026 annual meeting of stockholders on April 13, 2026, where our stockholders approved a reverse stock split at a ratio within a range of 1-for-30 and 1-for-50 and granted our board of directors, or the Board, the discretion to determine the timing and ratio of the split within such range. On April 13, 2026, our Board determined to effect the reverse stock split of the common stock at a 1-for-30 ratio, or the Reverse Split, and approved the filing of a charter amendment to our Certificate of Incorporation to effect the Reverse Split. On April 22, 2026, we filed the charter amendment with the Delaware Secretary of State to effect the Reverse Split at 5:00 P.M. Eastern Time on April 23, 2026, or the Effective Time. At the Effective Time, every 30 shares of issued and outstanding common stock were automatically combined into one issued share of common stock, with no change in par value. No fractional shares were issued as a result of the Reverse Split. Stockholders of record who would otherwise hold fractional shares of our common stock as a result of the Reverse Split were entitled to receive a cash payment in lieu of such fractional shares. The Reverse Split did not modify any voting rights or other terms of the common stock. Our common stock began trading on a Reverse Split-adjusted basis on The Nasdaq Capital Market on April 24, 2026. The Reverse Split was implemented for the purpose of regaining compliance with the minimum bid price requirement for continued listing of our common stock on the Nasdaq Capital Market. The Reverse Split did not proportionately reduce the total number of shares of our capital stock and common stock that we are authorized to issue. Unless otherwise indicated, all issued, and outstanding stock and per share amounts have been adjusted to reflect the Reverse Split for all prior periods presented. Proportionate adjustments for the Reverse Split were made to the exercise prices and number of shares issuable under our equity incentive plans, and the number of shares underlying outstanding equity awards, as applicable. In connection with such proportionate adjustments, the number of shares of common stock issuable upon exercise of outstanding stock options and warrants was rounded down to the nearest whole share, and the exercise prices of outstanding stock options and warrants were rounded up to the nearest cent. On May 8, 2026, we received notification from The Nasdaq Stock Market that, since the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days, from April 24 through May 7, 2026, we regained compliance with the minimum bid price requirement for continued listing, and this matter is now closed.

Significant Contracts and Agreements Related to Research and Development Activities

Einstein License Agreement

On January 14, 2015, we entered into a license agreement, as amended and restated on July 31, 2017, and as further amended on October 30, 2018, January 13, 2024 and April 10, 2025, or the Einstein License, with Albert Einstein College of Medicine, or Einstein, for certain patent rights, or the Patents, relating to our core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides.

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

- Pay royalties and amounts based on a certain percentage of proceeds, as defined in the Einstein License, from sales of Einstein Licensed Products and sublicense agreements.
- Pay escalating annual maintenance fees, which are non-refundable, but are creditable against the amount due to Einstein for royalties.
- Make significant payments based upon the achievement of certain milestones, as defined in the Einstein License. As of September 30, 2026, two of these milestones had been achieved, as we had filed an IND application in 2019, and initiated an investigator sponsored Phase 1b neoadjuvant clinical trial for CUE-101 in locally advanced head and neck squamous cell carcinoma in 2021.
- Incur minimum product development costs per year and meet certain diligence obligations until the first commercial sale of the first Einstein Licensed Product.

The Einstein License requires us to pay a percentage of sublicenses related to our patent rights for components of our core technology that is licensed from Einstein. On April 10, 2025, we entered into an amendment to the Einstein License. Pursuant to the amendment, Einstein consented to our entry into the BI Collaboration and License Agreement and granted us the right to sublicense to BI. In addition, we and Einstein agreed to amend specified upstream payment obligations that may be owed to Einstein by us, solely in connection with the sublicense to BI. In the second quarter of 2025, we paid Einstein $0.9 million in fees in relation to the amendment to this license with Einstein.

As of September 30, 2026, we were in compliance with our obligations under the Einstein License.

We account for the costs incurred in connection with the Einstein License in accordance with Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

We pay $0.1 million in annual maintenance license fees to Einstein, which are amortized equally throughout the year. We incurred less than $0.1 million in annual maintenance fees for each of three and nine months ended September 30, 2026 and 2025. Such costs are included in research and development costs in our condensed consolidated statements of operations and comprehensive loss.

Pursuant to the Einstein License, we issued to Einstein 22,385 shares of our common stock in connection with the consummation of the initial public offering of our common stock on December 27, 2017.

See Note 8 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the Einstein License.

Collaboration and Option Agreement with Ono

In February 2023, we entered into a strategic collaboration agreement, or the Ono Collaboration and Option Agreement, with Ono Pharmaceutical Co., Ltd., or Ono, to further develop CUE-401. In March 2025, we and Ono agreed to terminate the Ono Collaboration and Option Agreement, effective as of March 6, 2025. At such time, the Ono Collaboration and Option Agreement had no further force or effect with the exception of certain customary provisions which are intended to survive termination and expiration of the Ono Collaboration and Option Agreement. We retained all rights to CUE-401.

Both we and Ono have satisfied all of our respective performance obligations and made all outstanding payments under the agreement as of September 30, 2026. For the three months ended September 30, 2025 and the three and nine months ended September 30, 2026, we did not recognize any revenue related to the Ono Collaboration and Option Agreement. For the nine months ended September 30, 2025, we recognized revenue of $0.4 million related to the Ono Collaboration and Option Agreement. As of September 30, 2026, we had recorded $14.8 million in collaboration revenue related to this agreement since the agreement was entered into.

See Note 11 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the Ono Collaboration and Option Agreement.

BI Collaboration and License Agreement

On April 10, 2025, we entered into the BI Collaboration and License Agreement, to research, develop and commercialize differentiated B cell depletion molecules, including CUE-501.

Under the terms of the BI Collaboration and License Agreement, we and BI will conduct collaborative research focused on CUE-501 during a four-year period or, if earlier, the completion of activities under the research plans, or the BI Research Term. In addition to, or instead of, CUE-501, BI may elect, at its sole discretion, to include additional or alternative compounds targeted at B cell depletion. BI will have an exclusive, royalty-bearing, worldwide, sublicensable license, under our applicable patents and know-how, to develop, manufacture and commercialize such compounds and their derivatives, or BI Licensed Products, for all uses, and BI shall be responsible for all further research, preclinical and clinical development, manufacturing, regulatory approvals, and commercialization of BI Licensed Products at its expense. During the BI Research Term, we are prohibited from developing or commercializing any molecule for applications in B cell depletion.

Pursuant to the terms of the BI Collaboration and License Agreement, we received an upfront payment of $10.1 million in cash in the second quarter of 2025, which is net of $1.9 million of German withholding taxes that we expect to be refunded in the fourth quarter of 2026. We will also be eligible to receive up to an aggregate of approximately $345.0 million in success-based research, development and commercial milestone payments, beginning with two preclinical development milestones, as well as royalty payments on net sales. The royalty payments will be subject to reduction due to patent expiration, payments made under certain licenses for third-party intellectual property and generic competition. BI has agreed to reimburse us for agreed upon costs incurred in conducting research during the BI Research term, including certain pass-through costs from third party contractors and full-time employee salaries.

The BI Collaboration and License Agreement will continue, on a product-by-product and country-by-country basis, until the expiration of the applicable royalty term, unless earlier terminated. BI has the right to terminate the BI Collaboration and License Agreement for any reason after a specified notice period. Each party has the right to terminate the BI Collaboration and License Agreement on account of the other party's bankruptcy or material, uncured breach. In connection with our entry into the BI Collaboration and License Agreement, we entered into an amendment to our Einstein License whereby Einstein consented to our entry into the BI Collaboration and License Agreement and granted us the right to sublicense to BI. In addition, we and Einstein agreed to amend specified upstream payment obligations that may be owed to Einstein by us, solely in connection with the sublicense to BI.

On April 1, 2026, we received notice from BI that BI had approved selection of its first compound for lead optimization under the BI Collaboration and License Agreement. This preclinical milestone event triggered a $7.5 million payment to us, which was received in May 2026.

For the three and nine months ended September 30, 2026, we recognized revenue of $0.1 million and $13.4 million related to the BI Collaboration and License Agreement, respectively. For the three and nine months ended September 30, 2025, we recognized revenue of $2.1 million and $5.1 million, respectively, related to the BI Collaboration and License Agreement. We recorded accounts receivable of $0.1 million and $0.5 million on our condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025, respectively. We did not record short or long-term research and development liabilities on our condensed consolidated balance sheets dated September 30, 2026, as the research term is substantially completed. We recorded short-term research and development liabilities of $5.3 million on our condensed consolidated balance sheets as of December 31, 2025.

See Note 11 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the BI Collaboration and License Agreement.

ImmunoScape Collaboration and License Agreement

On November 6, 2025, IMSCP exercised its option, or Option, to obtain licenses to research, develop and commercialize molecules from our CUE-100 series, including CUE-101 and CUE-102, subject to certain exclusions, for all oncology indications pursuant to a Collaboration and License Agreement, effective November 6, 2025, between us and IMSCP, or, as amended, the IMSCP Collaboration and License Agreement. The licenses provided pursuant to the IMSCP Collaboration and License Agreement include a co-exclusive development license for five years or, if longer, for so long as IMSCP has a specified number of CUE-100 series molecules under active development and, pursuant to which, we retain non-exclusive research rights to support our other programs. We also retained our rights to the CUE-100 series, including CUE-101 and CUE-102, for use in any manner other than as a component of a cell therapy product for 18 months past the effective date of the IMSCP Collaboration and License Agreement. The licenses include an exclusive commercial license to IMSCP for any CUE-100 series molecule that IMSCP advances to IND-enabling studies while the co-exclusive development license is in effect. The licensed series of molecules will be further developed and potentially commercialized by IMSCP. The Option was exercised pursuant to an Option Agreement between us and IMSCP, dated October 22, 2025, or Option Agreement. In

connection with entry into the Option Agreement and IMSCP's exercise of the Option, we received an aggregate of $9.5 million, net of withholding taxes, in the fourth quarter of 2025 and was entitled to receive an additional $5.0 million before the first anniversary of the effective date of the IMSCP Collaboration and License Agreement. On November 6, 2026, we entered into a Second Amendment to the IMSCP Collaboration and License Agreement, or the Second Amendment, with IMSCP, pursuant to which, among other things, our right to receive the additional $5.0 million payment was amended such that we are entitled to receive a $5.5 million payment from IMSCP as follows: (a) $3.0 million on or before November 27, 2026, (b) $1.5 million on or before July 30, 2027, and (c) $1.0 million on or before November 27, 2027.

Pursuant to the IMSCP Collaboration and License Agreement (after giving effect to the Second Amendment), we (a) received equity of IMSCP equal to 40% of the issued and outstanding equity of IMSCP and are entitled to receive additional equity, in the form of warrants, upon certain dilution events in the future, (b) received time-based payments of $10.0 million in the fourth quarter of 2025, (c) are entitled to receive an additional time-based payment of $5.5 million, payable as described above and (d) are entitled to receive high single-digit royalties on global net sales and low- to mid-double digit royalties from sublicensing royalties and income. The IMSCP Collaboration and License Agreement includes customary termination provisions, including IMSCP's ability to terminate the agreement in its entirety on 60 days' advanced written notice to us.

For the three and nine months ended September 30, 2026, we recognized revenue of less than $0.1 million and $0.3 million, respectively, related to the IMSCP Collaboration and License Agreement. We recorded accounts receivable from IMSCP of $5.1 million and $5.0 million on our condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025, respectively.

See Note 11 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the IMSCP Collaboration and License Agreement.

Ascendant License Agreement

On April 30, 2026, we entered into a License Agreement, or the License Agreement, with Ascendant Health, or the Licensor. Pursuant to the License Agreement and subject to certain rights retained by the Licensor, the Licensor granted us: (1) the exclusive and sublicensable rights to develop, manufacture, commercialize and otherwise exploit the Licensor's anti-IgE monoclonal antibody known as Ascendant-221, which was formerly known as UB-221 (together with certain related molecules, or the Licensed Molecules) and products containing a Licensed Molecule (or, collectively, the Licensed Products) throughout the world (except the mainland of China, Hong Kong, Macau and Taiwan (or, together, the Ascendant Territory)) (such territory of the Company, the Cue Territory) for any and all uses; and (2) the non-exclusive and sublicensable rights to manufacture the Licensed Molecules and Licensed Products in the Ascendant Territory (other than China) solely for the purposes of developing and commercializing the Licensed Molecules and Licensed Products in the Cue Territory.

As consideration for the rights granted to us by the Licensor, we paid the Licensor $15.0 million as the upfront payment, and will pay up to an aggregate of $676.5 million in additional potential milestone payments, and tiered royalty payments (at percentages ranging from high single-digit to low double-digit) on future net sales of Licensed Products. The additional milestone payments include $5.0 million upon the completion of manufacturing technology transfer, $6.5 million upon the completion of data and know-how transfer, up to $205.0 million upon the achievement of specified development and regulatory milestone events, including upon receipt of threshold data from a specified Phase 2 clinical trial, and up to $460.0 million upon the achievement of specified commercial milestone events. In the event we grant a sublicense of its rights under the License Agreement within the first 18 months after the effective date of the License Agreement, certain sublicensing revenues received by us will be shared with Licensor at specified percentages between 20% and 40% for a period of up to 18 months after the effective date. In addition, in the event of a specified change of control transaction with respect to us within the first 18 months after the effective date of the License Agreement, certain milestone payments will accelerate, in an amount up to $215.0 million.

See Note 8 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the Ascendant Health License Agreement.

Components of Results of Operations

Collaboration Revenue

We have not yet generated commercial revenue from product sales. To date, we have generated revenue from collaboration agreements with BI, IMSCP, LG Chem, Ono (which terminated in March 2025), and Merck Sharp & Dohme Corp. (which terminated in December 2022). Our collaboration revenue may vary from period to period depending on the progress of our work in connection with our collaboration agreements.

Research and Development Expenses

Research and development expenses consist primarily of compensation costs, license fees, 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 our product candidates. We utilize our employee and infrastructure resources across multiple research and development programs, and do not track these costs by project. We believe the attempted allocation of these costs by project would be arbitrary and not meaningful.

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. We evaluate whether we expect the services to be rendered at each quarter end and year end reporting date. If we do not expect the services to be rendered, the advance payment is recorded as 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.

We evaluate the status of our 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 adjust the carrying amounts and their classification on the balance sheet as appropriate.

The following table summarizes our research and development expenses by category for the three months ended September 30, 2026 and 2025 (in millions):

	September 30,	
	2026	**2025**
Employee compensation	$ 11.9	$ 2.2
License fees	—	—
Clinical trial costs	2.5	0.3
Facilities and overhead	0.8	1.3
Contract manufacturing costs	0.9	0.2
Lab costs	0.1	0.1
Professional fees	0.8	0.7
Total	$ 17.0	$ 4.8

Employee compensation in the table above includes $9.7 million of non-cash equity based compensation expense.

The following table summarizes our research and development expenses by category for the nine months ended September 30, 2026 and 2025 (in millions):

	September 30,	
	2026	**2025**
Employee compensation	$ 22.7	$ 7.7
License fees	35.9	—
Clinical trial costs	3.9	3.1
Facilities and overhead	2.6	3.8
Contract manufacturing costs	3.9	3.9
Lab costs	0.5	0.6
Professional fees	3.4	2.1
Total	$ 72.9	$ 21.2

Employee compensation in the table above includes $13.2 million of non-cash equity based compensation expense.

General and Administrative Expenses

General and administrative expenses consist of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as professional fees, insurance costs, and other general corporate expenses. We expect general and administrative expenses to remain consistent in future periods as we continue to incur expenses related to our operation as a public company, which requires our ongoing compliance with certain laws and regulations.

Interest Income

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

Interest Expense

We incurred interest expense from borrowings under our Loan and Security Agreement, as amended, or the Loan Agreement, with Silicon Valley Bank, a division of First Citizens Bank & Trust Company, or SVB. As of September 30, 2026, the loan principal balance was fully paid off. Beginning in 2026, we incurred interest expense from the financing of insurance payments.

Results of Operations

Three Months Ended September 30, 2026 and 2025

Our condensed consolidated statements of operations and comprehensive loss for the three months ended September 30, 2026 and 2025, as discussed herein, are presented below in thousands.

	Three Months Ended September 30,	
	2026	2025
Collaboration revenue	$ 132	$ 2,149
Operating expenses:		
General and administrative	29,826	4,939
Research and development	17,015	4,754
Loss on fixed asset disposal	—	51
Gain on lease termination	(110)	—
Loss on write-off of lease security deposit	498	—
Total operating expenses	47,229	9,744
Loss from operations	(47,097)	(7,595)
Other income (expense):		
Interest income	483	222
Interest expense	(2)	(75)
Changes in fair value of financial instruments	(3,400)	—
Total other income (expense), net	(2,919)	147
Net loss	$ (50,016)	$ (7,448)
Unrealized gain from available-for-sale securities	—	1
Comprehensive loss	$ (50,016)	$ (7,447)

Collaboration Revenue

Collaboration revenue decreased by $2.0 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The decrease was primarily attributable to less revenue recognized under our BI Collaboration and License Agreement during the three months ended September 30, 2026, compared to the same period in 2025, reflecting the planned progression of activities under the agreement.

General and Administrative Expenses

General and administrative expenses increased by $24.9 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily due to an increase of $24.9 million in employee compensation related to the transition to a new management team in 2026, and is comprised of a $24.7 million increase in stock-based compensation expense, primarily related to restricted stock unit awards granted in July 2026, and a $0.2 million increase in salary expense.

Research and Development Expenses

Research and development expenses increased by $12.2 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily due to an increase in compensation expense of $9.7 million, which comprised of a $9.3 million increase in stock-based compensation expense, primarily related to restricted stock unit awards granted in July 2026, and an increase in salary expense of $0.4 million. In addition, clinical trial costs increased by $2.2 million, contract manufacturing costs increased by $0.7 million, and professional fees increased by $0.1 million. These were partially offset by a $0.5 million decrease in facility costs.

Gain on Lease Termination

Upon the termination of our license agreement with MIL 40G, LLC in September 2026, we wrote off the remaining right-of-use asset and the corresponding lease liability balances during the three months ended September 30, 2026, which resulted in a gain of $0.1 million.

Loss on Security Deposit

We determined that security deposits related to our license agreement with MIL 40G, LLC, which was terminated in September 2026, were not recoverable and recognized a loss of $0.5 million during the three months ended September 30, 2026.

Interest Income

Interest income increased by $0.3 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase was primarily due to higher interest earned on cash and cash equivalents.

Interest Expense

Interest expense decreased by less than $0.1 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025. Interest expense incurred during the three months ended September 30, 2026 consisted of interest related to the financing of insurance payments. Interest expense incurred during the three months ended September 30, 2025 consisted of interest incurred from borrowings under our Loan Agreement with SVB, which was repaid in full in December 2025.

Changes in Fair Value of Financial Instruments

The May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants were all initially classified as liabilities measured at fair value. All subsequent changes in the fair value of the liability-classified instruments through the date of stockholder approval in accordance with the listing standards of the Nasdaq Stock Market of the issuance of shares of common stock upon exercise of the warrants, or the Issuance Stockholder Approval, were recognized within other income (expense). The related top-up share obligation remains classified as a liability and is remeasured at fair value at each reporting date, with the changes in fair value recognized within other income (expense). We recognized a net loss of $3.4 million from changes in the fair value of financial instruments during the three months ended September 30, 2026, compared to no such gain or loss during the same period in 2025. See Note 3 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants.

Nine Months Ended September 30, 2026 and 2025

Our condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2026 and 2025, as discussed herein, are presented below in thousands.

	Nine Months Ended September 30,	
	2026	2025
Collaboration revenue	$ 13,695	$ 5,524
Operating expenses:		
General and administrative	80,543	12,792
Research and development	72,919	21,211
Loss on fixed asset disposal	—	51
Gain on lease termination	(120)	—
Loss on write-off of lease security deposit	498	—
Total operating expenses	153,840	34,054
Loss from operations	(140,145)	(28,530)
Other income (expense):		
Interest income	819	649
Interest expense	(11)	(306)
Loss on issuance of liability-classified warrants and related issuance costs	(90,011)	—
Changes in fair value of financial instruments	21,087	—
Total other income (expense), net	(68,116)	343
Net loss	$ (208,261)	$ (28,187)
Unrealized gain from available-for-sale securities	—	1
Comprehensive loss	$ (208,261)	$ (28,186)

Collaboration Revenue

Collaboration revenue increased by $8.2 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily due to more revenue earned during the nine months ended September 30, 2026 compared to revenue earned during the nine months ended September 30, 2025 from our BI Collaboration and License Agreement due to the timing of activities and a preclinical milestone event triggered in the second quarter of 2026.

General and Administrative Expenses

General and administrative expenses increased by $67.8 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily due to an increase of $65.1 million in employee compensation related to the transition to a new management team in 2026, and is comprised of a $43.7 million increase in stock-based compensation expense, primarily related to restricted stock unit awards granted in July 2026, and a $19.3 million increase in payroll tax expense related to one-time restricted stock units granted in the second quarter of 2026, a $1.3 million increase in salary expense, and a $0.8 million increase in severance expense. In addition, professional fees increased by $2.4 million due to higher legal fees incurred related to the private placement in the second quarter of 2026, the License Agreement with Ascendant, and related SEC filings, and facilities costs increased by $0.3 million.

Research and Development Expenses

Research and development expenses increased by $51.7 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily due to expenses totaling $35.1 million associated with the License Agreement with Ascendant. These comprised a one-time $15.0 million upfront cash payment and non-cash items comprising of $20.1 million related recognition of initial fair value of the Ascendant Pre-Funded Warrants as well as the related top-up share obligation. In addition, the increase also included an increase in employee compensation expense of $15.0 million, which comprised a $11.5 million increase in stock-based compensation expense, primarily related to restricted stock unit awards granted in July 2026, and a $3.5 million increase in payroll tax expense related to restricted stock units granted in the second quarter of 2026. There were also increases in professional fees of $1.3 million related to the private placement in the second quarter of 2026 and the License Agreement with Ascendant, in license fees of $0.8 million associated with the Einstein License Agreement, as well as in clinical trial costs of $0.8 million, partially offset by a decrease in facilities costs of $1.2 million and a decrease in manufacturing costs of $0.1 million.

Gain on Lease Termination

Upon the termination of our license agreement with MIL 40G, LLC in September 2026, we wrote off the remaining right-of-use asset and the corresponding lease liability balances during the three months ended September 30, 2026, which resulted in a gain of $0.1 million.

Loss on Security Deposit

We determined that the security deposits related to our license agreement with MIL 40G, LLC, which was terminated in September 2026, were not recoverable and recognized a loss of $0.5 million during the three months ended September 30, 2026.

Interest Income

Interest income increased by $0.2 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase was primarily due to higher interest earned on cash and cash equivalents.

Interest Expense

Interest expense decreased by $0.3 million for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. Interest expense incurred during the nine months ended September 30, 2026 consisted of interest related to the financing of insurance payments. Interest expense incurred during the nine months ended September 30, 2025 consisted of interest incurred from borrowings under our Loan Agreement with SVB which was paid in full in December of 2025.

Loss on Issuance of Liability-Classified Warrants and related Issuance Costs

In May 2026, we issued the May 2026 Pre-Funded Warrants and May 2026 Warrants as part of the May 2026 Offering, and pre-funded warrants to Ascendant in connection with our entry into the Ascendant License Agreement, each of which was initially classified as a liability and measured at fair value. Due to our stock price increasing from the April 30, 2026 pricing date to the closing date of the May 2026 Offering, the aggregate fair value of the instruments exceeded the proceeds received, resulting in a loss upon issuance and related issuance costs of $90.0 million in the second quarter of 2026.

Changes in Fair Value of Financial Instruments

The May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants were all initially classified as liabilities measured at fair value. All subsequent changes in the fair value of the liability-classified instruments through the date of the Issuance Stockholder Approval, were recognized within other income (expense). The related top-up share obligation remains classified as a liability and is remeasured at fair value at each reporting date, with the changes in fair value recognized within other income (expense). We recognized a net gain of $21.1 million from changes in the fair value of financial instruments during the nine months ended September 30, 2026, compared to no such gain or loss during the same period in 2025. See Note 3 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional discussion of the May 2026 Pre-Funded Warrants, May 2026 Warrants, and Ascendant Pre-Funded Warrants.

Liquidity and Capital Resources

We have financed our working capital requirements primarily through private and public offerings of equity securities, cash received under collaboration agreements, and borrowings under the Loan Agreement. At September 30, 2026, we had cash and cash equivalents totaling $57.9 million available to fund our ongoing business activities. Additional information concerning our financial condition and results of operations is provided in the financial statements included in this Quarterly Report on Form 10-Q.

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

On May 9, 2023, we filed a registration statement on Form S-3, which was declared effective on May 26, 2023 (File No. 333-271786), to register for sale from time to time up to $300 million of our common stock, preferred stock, debt securities, warrants, subscription rights and/or units in one or more offerings. In anticipation of the expiration of this registration statement, on March 16, 2026, we filed a new registration statement on Form S-3, which was declared effective on March 31, 2026 (File No. 333-294366), to register for sale from time to time up to $300 million of our common stock, preferred stock, debt securities, warrants, subscription rights, and/or units in one or more offerings.

In October 2021, we entered into an open market sale agreement, or the ATM Sales Agreement, with Jefferies LLC, or Jefferies, to sell shares of our common stock for aggregate gross proceeds of up to $80.0 million, from time to time, through an "at-the-market" equity offering program under which Jefferies acts as sales agent. The ATM Sales Agreement will terminate upon the earliest of (a) the sale of $80.0 million of shares of our common stock pursuant to the ATM Sales Agreement or (b) the termination of the ATM Sales Agreement by us or Jefferies. During the three months ended September 30, 2026, there were no sales under the ATM Sales Agreement. During the nine months ended September 30, 2026, we sold 34,652 shares of common stock under the ATM Sales Agreement for proceeds of $0.3 million, net of commissions paid, but excluding transaction expenses. During the three and nine months ended September 30, 2025, we sold 44,495 and 81,062 shares of common stock under the ATM Sales Agreement for proceeds of $1.0 million and $1.8 million, net of commissions paid, but excluding transaction expenses. As of September 30, 2026, we had sold an aggregate of 450,866 shares of common stock under the ATM Sales Agreement for proceeds of $43.2 million, net of commissions paid, but excluding transaction expenses, since its inception.

On April 30, 2026, we entered into a securities purchase agreement with accredited investors, pursuant to which we agreed to issue and sell to the investors in a private placement, or the May 2026 Offering, pre-funded warrants to purchase an aggregate of up to 2,727,272 shares of common stock, or the May 2026 Pre-Funded Warrants, and accompanying warrants, or the May 2026 Warrants, to purchase an aggregate of up to 1,363,636 shares of common stock (or, in certain circumstances, May 2026 Pre-Funded Warrants to purchase common stock in lieu thereof) at a price of $11.00 per May 2026 Pre-Funded Warrant and accompanying May 2026 Warrant. The exercise price of the May 2026 Pre-Funded Warrants is $0.001 per share. The exercise price of the May 2026 Warrants is $11.00 per share. The May 2026 Offering closed on May 4, 2026. We received net proceeds from the May 2026 Offering of approximately $27.6 million, after deducting placement agent fees and offering expenses. The May 2026 Pre-Funded Warrants are cashless exercisable. The May 2026 Warrants are exercisable at any time prior to five years after the closing date of the May 2026 Offering.

On July 9, 2026, we entered into a securities purchase agreement with accredited investors, including Cormorant Asset Management and Columbia Threadneedle Investments, pursuant to which we, in a private placement, agreed to issue and sell to the investors an aggregate of (i) 1,418,071 shares of common stock at a price per share of $33.21 and (ii) to certain investors, in lieu of shares of common stock, pre-funded warrants (the “July 2026 Pre-Funded Warrants”) to purchase up to 87,500 shares of common stock at a price per July 2026 Pre-Funded Warrant of $33.209 (the “July 2026 Private Placement”), for net proceeds of approximately $49.8 million. Each July 2026 Pre-Funded Warrant has an exercise price of $0.001 per share and is cashless exercisable. The July 2026 Private Placement closed on July 13, 2026.

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

Cash Flows

Based on our current plans and forecasted expenses, we believe our existing cash and cash equivalents as of September 30, 2026 will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance date of our condensed consolidated financial statements included in this Quarterly Report. We have based our estimate as to how long we expect we will be able to fund our obligations on assumptions that may prove to be wrong and we may use our available capital resources sooner than we currently expect. However, we will need to raise substantial additional capital to fund our future operations. We expect to finance our future cash needs through a combination of equity offerings, collaborations, and other strategic alliances. Volatility in capital markets and general economic conditions in the United States

may be a significant obstacle to raising the required funds and, as a result, we may be unable to secure the necessary funding on acceptable terms.

The following table summarizes our changes in cash, cash equivalents, and restricted cash for the nine months ended September 30, 2026 and 2025 in thousands:

	Nine Months Ended September 30,	
	2026	2025
Net cash provided by (used in):		
Operating activities	$ (50,028)	$ (20,611)
Investing activities	(121)	(6,945)
Financing activities	80,952	16,799
Net change in cash, cash equivalents, and restricted cash	$ 30,803	$ (10,757)

Operating Activities

Net cash used in operating activities totaled $50.0 million for the nine months ended September 30, 2026 compared to $20.6 million for the nine months ended September 30, 2025. The increase in cash used in operating activities of $29.4 million was primarily due to an increase in net loss adjusted for non-cash expenses and a decrease in cash flows from changes in research and development contract liability, partially offset by an increase in cashflows from changes in accrued expenses and other current assets.

Investing Activities

Net cash used in investing activities totaled $0.1 million for the nine months ended September 30, 2026 compared to net cash used in investing activities of $6.9 million during the nine months ended September 30, 2025. The decrease of $6.8 million in cash used was primarily due to purchases of marketable securities during the nine months ended September 30, 2025.

Financing Activities

Net cash provided by financing activities totaled $81.0 million for the nine months ended September 30, 2026 compared to $16.8 million for the nine months ended September 30, 2025. The increase of $64.2 million was primarily due to higher proceeds received from the May 2026 Offering and July 2026 Private Placement.

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 and continue ongoing and initiate new clinical trials of and seek marketing approval for our product candidates. In addition, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- continue the clinical development of CUE-221 and CUE-401 and preclinical development of the CUE-500 series (excluding CUE-501, which has been licensed to BI);
- continue to assess maturing clinical data of CUE-221 and of our CUE-100 series, including CUE-101 and CUE-102, which we have deprioritized and which have been licensed to IMSCP for development in oncology indications;
- leverage our autoimmune and cancer programs to advance our other product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates for which we 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;

- expand our manufacturing, quality, operational, financial and management systems, including personnel to support these functions;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating as a public company.

We currently believe that our existing cash and cash equivalents as of September 30, 2026 will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance date of our condensed consolidated financial statements included in this Quarterly Report. We have based our estimate as to how long we expect we will be able to fund our obligations on assumptions that may prove to be wrong and we may use our available capital resources sooner than we currently expect.

We will need to raise additional capital or incur additional indebtedness to continue to fund our operations in the near term. 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 ongoing, planned and any 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 existing collaborations, licensing or other arrangements or any potential future collaborations, licensing or other arrangements that we may establish, including the payment of any milestones thereunder;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- the impact of government laws and regulations, general economic and market conditions, inflation, and the imposition of new or revised global trade tariffs;
- any disputes which may occur between us and our employees, collaborators, including Ascendant, Einstein, LG Chem, BI, IMSCP, 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. New investors may demand rights, preferences or privileges senior to those of existing holders of our common stock. If we issue debt securities, we may be required to grant security interests in our assets, could have substantial debt service obligations, and lenders may have a senior position (compared to stockholders) in any potential future bankruptcy or liquidation. 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. 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.

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 operations and financial condition, including the possibility that a lack of funds could cause our business to fail, dissolve and liquidate with little or no return to investors.

Principal Commitments

Except as set forth below, there have been no material changes to our contractual obligations and commitments as described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our 2025 Annual Report.

On September 18, 2026, we terminated our License Agreement with MIL 40G and vacated all office, research and development and laboratory space effective September 30, 2026. Additional information regarding the termination of our License Agreement with MIL 40G, as well as the Ascendant Health License Agreement, BI Collaboration and License Agreement, and the amendment to our Einstein License may be found in Notes 8, 11, 12 and 13 to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

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 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 principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures were effective as of September 30, 2026, the end of the period covered by this report.

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2026 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 following risks, the information included in this Quarterly Report on Form 10-Q and in other documents we file with the SEC.

Risks Related to Our Financial Position, Our Need for Additional Capital and Our Business

We are a clinical-stage biopharmaceutical company and have no history of generating commercial revenue. We have a history of operating losses, and we anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company. We have a limited operating history, have never generated revenue from product sales, and have a history of losses from operations. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment in development or commercialization.

We have incurred, and expect to continue to incur, significant operating losses related to the development of our product candidates and ongoing operations. As of September 30, 2026, we had an accumulated deficit of $576.7 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development activities related to our Immuno-STAT platform and continue ongoing and initiate new clinical trials of, and seek marketing approvals for, CUE-221, CUE-401, CUE-501 and our other product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company.

Our expenses will also increase if, and as, we:

- continue the clinical development of CUE-221 and CUE-401 and preclinical development of the CUE-500 series (excluding CUE-501, which has been licensed to Boehringer Ingelheim International GmbH, or BI);
- continue to assess maturing clinical data of CUE-221 and of our CUE-100 series, including CUE-101 and CUE-102, which we have deprioritized and which have been licensed to ImmunoScape Pte. Ltd., or IMSCP, for development in oncology indications;
- leverage our autoimmune and cancer programs to advance our other product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates for which we 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;
- expand our manufacturing, quality, operational, financial and management systems, including personnel to support these functions;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we expect to incur substantial expenditures to develop and market additional product candidates.

Our ability to achieve commercial revenue-generating operations and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive regulatory approval of our product candidates, successfully commercialize our product candidates and/or find and/or maintain strategic collaborations that can incorporate our product candidates into new or existing drugs which can be successfully commercialized together. There can be no assurance that we will ever generate commercial revenues or achieve or maintain profitability.

We will need substantial additional financing to support our growth and ongoing operations. Additional capital may be difficult to obtain, restrict our operations, require us to relinquish rights to our technologies or product candidates, encumber our assets and result in ongoing debt service cost, or result in additional dilution to our stockholders.

As of September 30, 2026, we had cash and cash equivalents of $57.9 million. Based on our current operating plans, we believe that our existing cash and cash equivalents will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance date of our condensed consolidated financial statements included in this Quarterly Report. We have based our estimate as to how long we expect we will be able to fund our obligations on assumptions that may prove to be wrong and we may use our available capital resources sooner than we currently expect.

We will need to raise substantial additional capital or incur additional indebtedness to continue to fund our operations in the near term. 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 ongoing, planned and any 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 existing collaborations, licensing or other arrangements or any potential future collaborations, licensing or other arrangements that we may establish, including the payment of any milestones thereunder;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments;
- the impact of government laws and regulations, general economic, market and geopolitical conditions, inflation, and the imposition of new or revised global trade tariffs;
- any disputes which may occur between us and our employees, collaborators, including Ascendant, Einstein, LG Chem, BI, IMSCP, 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. New investors may demand rights, preferences or privileges senior to those of existing holders of our common stock. If we issue debt securities, we may be required to grant security interests in our assets, could have substantial debt service obligations, and lenders may have a senior position (compared to stockholders) in any potential future bankruptcy or liquidation. 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. Additionally, 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.

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 operations 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.

We currently do not have, and may never develop, any FDA-approved or commercialized products.

We currently do not have any products approved by the FDA or any other regulatory agency or any commercialized products and thus have never generated commercial revenue from product sales. We have not yet sought to obtain any regulatory approvals for any product candidates in the United States or any foreign market. Therefore, any estimated timing for our product candidates to be commercialized would be highly speculative.

To date, we have invested substantial resources in an exclusive license with Einstein that forms the foundation for certain of our product candidates and potential applications and in April 2026, we entered into an exclusive license agreement with Ascendant to develop, manufacture and commercialize CUE-221 worldwide (except in mainland China, Hong Kong, Macau and Taiwan). In addition, in April 2025, we licensed differentiated B cell depletion molecules, including CUE-501, to BI for research, development and commercialization and in November 2025, we licensed molecules from our CUE-100 series, including CUE-101 and CUE-102, to IMSCP for research, development and commercialization in oncology indications.

For us to develop any products that might ultimately be commercialized, we will have to invest further time and capital in research and product development, regulatory compliance and market development. We and our licensors, prospective business partners and other collaborators may never develop any products that can be commercialized. All of our development efforts will require substantial additional funding, none of which may result in any commercial revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we and our licensors, prospective business partners and other collaborators may not be able to complete research regarding, and nonclinical and clinical development of, our product candidates;
- regulatory approvals and marketing authorizations may not be achieved for our product candidates, or the scope of the approved indication may be narrower than sought;
- we and our licensors, prospective business partners and other collaborators may experience delays in our development programs, clinical trials and the regulatory approval process;
- our product candidates may not prove to be safe and effective in clinical trials or preclinical studies and our product candidates may have adverse side effects which outweigh any potential benefit to patients;
- we may not be able to identify suitable collaborators to complete development or commercialization of our potential products;

- we may not be able to maintain, protect or expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- any future products that are ultimately approved by the FDA or other regulatory bodies may not be commercially accepted in the marketplace by physicians or patients;
- any future products that are ultimately approved by the FDA or other regulatory bodies may not be able to be manufactured in commercial quantities or at an acceptable cost;
- physicians may not receive any reimbursement from third-party payors, or the level of reimbursement may be insufficient to support widespread adoption of any of our future products once approved by the FDA or other regulatory bodies; and
- rapid technological change may make our technology and product candidates obsolete.

There can be no assurances that any of our programs covered by our existing or any future collaborations or licenses will be developed further or reach commercialization. We plan to continue to seek third party support through partnerships and collaborations, or alternative funding structures and there is no guarantee that we will be able to do so on favorable terms or at all.

We are substantially dependent on the success of our lead product candidate, CUE-221, our lead autoimmune candidate, CUE-401, and our other product candidates. Significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our product candidates.

Our lead product candidate, CUE-221, our lead autoimmune candidate, CUE-401, and our other product candidates, including CUE-501, are in various stages of clinical and preclinical development. We expect significant additional research and development activity and clinical testing will be required before we and our collaborators will have a chance to achieve a commercially viable product from CUE-221, CUE-401, CUE-501 or our other product candidates.

Our research and development efforts remain subject to all of the risks associated with the development of new biopharmaceutical products and treatments based on immune modulation. Development of the underlying technology may be affected by unanticipated technical or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of these product candidates. Safety, regulatory and efficacy issues, clinical hurdles or other challenges may result in delays and cause us to incur additional expenses that would increase our losses. If we and our collaborators cannot complete, or if we experience significant delays in developing, our potential product candidates or products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

We have limited experience in conducting clinical trials and no history of commercializing biologic products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our company, conducting research and developing our core technologies, and identifying and optimizing our lead product candidates. Additionally, we have conducted limited clinical testing of two of our product candidates. Although we have recruited a team that has experience with clinical trials in the United States, as a company, we have limited experience conducting clinical trials and have not had previous experience commercializing product candidates or submitting a Biologic License Application, or BLA, to the FDA or similar submissions to obtain marketing authorization to foreign regulatory authorities. In July 2026, we submitted an Investigational New Drug, or IND, application to the FDA to expand development of CUE-221 into food allergy, but have not yet conducted any clinical trials of CUE-221 ourselves. In October 2026, we initiated dosing in a Phase 1 clinical trial of CUE-401 following FDA clearance of our IND for the clinical trial. We cannot be certain that our current or any future clinical trials will begin or be completed on time, if at all, or that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations, or CROs, contract manufacturing organization, or CMOs, consultants and collaborators. Relying on third-party clinical investigators, CROs, CMOs or collaborators may result in delays that are outside of our control.

Furthermore, we may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- negative or inconclusive results from our IND-enabling studies, clinical trials or the clinical trials of other product candidates similar to ours, leading to a decision or requirement to conduct additional nonclinical testing or clinical trials or abandon a program;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or a foreign regulatory authority regarding the number, scope or design of our clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate supply or quality of clinical trial materials or other supplies necessary to conduct our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness or unacceptable side effects of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or the inability to gain access to facilities or documentation to complete required inspections of clinical sites;
- difficulty in establishing or managing relationships with CROs, CMOs, and clinical investigators;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and foreign regulatory authorities.

In addition, policies of the FDA and other regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted, any of which could delay or hinder our ability to successfully conduct clinical trials. For example, the regulatory landscape related to clinical trials in the EU has evolved. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. In addition, the FDA recently signaled increased scrutiny of foreign clinical trial data submitted in support of marketing applications, indicating plans for increased foreign site inspections and increased transparency of inspection results.

We have derived, and may in the future derive, results and data for CUE-221 from clinical trials conducted by Ascendant in China. Our access to the clinical results and data, or our access to clinical trial support services or clinical supply, may be limited and there is no assurance that the clinical data from any such trials will be accepted or considered by the FDA or other comparable regulatory authorities.

Ascendant is developing CUE-221 in China in chronic spontaneous urticaria, or CSU, and we recently announced topline data from Ascendant's Phase 2 clinical trial of CUE-221 in CSU. While this trial may provide us with clinical data that can inform our future development strategy, we did not have control over the protocols, administration, or conduct of the trial or its compliance with regulatory requirements. In addition, our access to the full suite of clinical data from this and any future clinical trials of CUE-221 in China may be limited or delayed due to, among other things, regulatory requirements related to the export of data. Moreover, there is no assurance that the clinical data from any such clinical trial will be accepted or considered by the FDA or other comparable regulatory authorities. Additionally, if the FDA requires an onsite inspection of the clinical trial sites in China to validate the data and access GCP compliance, there could be site or documentation access delays or restrictions that could adversely affect the FDA's ability to accept those foreign data in consideration of future submissions or marketing applications. We have no control over the conduct and timing of, and communications with the National Medical Products Administration, or NMPA, or other foreign regulatory agencies in Greater China with respect to, any trial that

Ascendant has conducted or may in the future conduct for CUE-221. Any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our product candidates.

In connection with the development of CUE-221 or any of our other product candidates, we may rely upon one or more companies located in China, or that are owned or operated by Chinese companies, to provide non-clinical or clinical trial support services or clinical supply. If so, the process of changing these vendors could have an adverse impact on our current clinical development programs if they were no longer permitted to provide services or products due to geopolitical pressures, including legislative activities or executive orders aimed at prohibiting certain Chinese or Chinese-owned biotechnology companies from engaging in biotechnology or biopharmaceutical research activities. We are unable to predict whether or when any such proposed legislative or executive actions would be effective, and whether such changes would materially and adversely affect our liquidity, access to capital and our ability to conduct our clinical development programs or other business operations, and any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop or manufacture our product candidates. If such legislative or execution actions become effective, we could experience delays in finding suitable replacement service providers located outside China or not otherwise owned by or associated with Chinese companies, which could have a material adverse effect on our development activities and our business.

We are dependent on third parties accurately generating and reporting data related to our product candidates, and their conduct could adversely affect our business.

We have and may in the future acquire or in-license our product candidates at various stages of development. For example, we in-licensed CUE-221 from Ascendant in April 2026. Our assumptions about the potential of CUE-221 are partially based on data generated from nonclinical studies, preclinical studies and clinical trials conducted by Ascendant. We are dependent on Ascendant having conducted its research and development in accordance with the applicable protocols, informed consent, legal and regulatory requirements, and scientific standards, having accurately reported the results of all studies conducted, and having correctly collected the data from these studies. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of CUE-221 will be adversely affected.

Additionally, in cases where third parties conduct clinical trials using our product candidates through partnership or licensing agreements, we face additional risks related to the conduct and outcome of those trials that are outside of our direct control. For example, issues such as poor data integrity, safety concerns, protocol violations, or failure to meet endpoints in these third-party trials could adversely impact the development timeline and regulatory approval process for those product candidates in other indications or territories, require additional studies, create negative market perception affecting future commercial potential, impact our ability to pursue strategic alternatives for such product candidates, or result in increased regulatory scrutiny across our programs.

Our current or any future clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our nonclinical or preclinical studies and may result in a safety profile that could inhibit or prevent regulatory approval or market acceptance of any of our product candidates.

In order to obtain marketing approval for any of our biologic product candidates, we must demonstrate the safety, purity, and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in nonclinical or preclinical studies or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Ascendant has completed a Phase 1 and Phase 2 clinical trial for CUE-221, and we recently initiated dosing in a Phase 1 clinical trial of CUE-401, but otherwise we have not conducted any other clinical trials for CUE-221, CUE-401, or CUE-501. We have conducted various nonclinical and preclinical studies of our product candidates, but we do not know the predictive value of these studies for humans, and we cannot guarantee that any positive results in nonclinical or preclinical studies will successfully translate to human patients. It is not uncommon to observe results in human clinical trials that are unexpected based on nonclinical or preclinical testing, and many product candidates fail in clinical trials despite promising nonclinical or preclinical results. Moreover, nonclinical, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical, preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Human patients in clinical trials may suffer significant adverse events or other side effects not observed in our nonclinical or preclinical studies, including, but not limited to, immunogenic responses, organ toxicities such as liver, heart or kidney or

other tolerability issues or possibly even death. The observed potency and kinetics of our product candidates in nonclinical or preclinical studies may not be observed in human clinical trials. If clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an Institutional Review Board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the pharmaceutical and biotechnology industries that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability as compared to other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies, preclinical studies or clinical testing. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more subject data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, we may report preliminary analyses of only certain endpoints rather than all endpoints. As a result, the interim, topline or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data becomes available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular program, product candidate or our business.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to further develop, obtain marketing approval for and/or commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Clinical development is a lengthy, expensive and uncertain process. Success in nonclinical studies or early clinical trials may not be indicative of results obtained in later trials. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs is extremely risky. Only a small percentage of programs that enter the clinical development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies, and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Results from nonclinical studies or early clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Further, success in nonclinical studies and early clinical trials of CUE-221 conducted by Ascendant does not ensure that later clinical trials conducted by us will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in nonclinical studies or having successfully advanced through initial clinical trials or preliminary stages of clinical trials. There can be no assurance that the results seen in nonclinical studies for any of our product candidates ultimately will result in success in clinical trials or that results seen in Phase 1 or 2 trials will be replicated in Phase 3 trials.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical testing and earlier-stage clinical trials. Data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy or requirements during the period of our product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

We plan to continue to seek collaborations or strategic alliances. However, we may not be able to establish such relationships, and relationships we have established may not provide the expected benefits.

On November 6, 2018, we entered into a Collaboration, License and Option Agreement, as amended from time to time, or the LG Chem Collaboration Agreement, with LG Chem for the development of CUE-101 and CUE-102 Immuno-STATs. Pursuant to the LG Chem Collaboration Agreement, we granted certain exclusive license rights to LG Chem in Australia and in certain countries in Asia and LG Chem agreed to provide certain services to us and to make payments to us that include licensing fees, milestone payments and sales royalties. This agreement does not commit LG Chem to a long-term relationship, and LG Chem may disengage with us at any time.

In furtherance of pursuing strategic options pertaining to CUE-101, on March 11, 2025, we regained our rights to the LG Chem Territory for the CUE-101 program, which had previously been licensed to LG Chem, and LG Chem terminated all of its rights to the same program. We also agreed to make future payments to LG Chem, if and when one or more potential scenarios related to the CUE-101 program occur, up to a predetermined aggregate amount.

LG Chem continues to maintain its interest and rights in the CUE-102 program, targeting WT1 expressing cancers, pursuant to the LG Chem Collaboration Agreement. On April 13, 2026, LG Chem sent us a notice of termination of the LG Chem Collaboration Agreement with respect to the CUE-102 Program targeting WT1 expressing cancers and the CUE-103 Program (which was never initiated), effective sixty (60) days from the date of the notice of termination. We and LG Chem are currently negotiating a final amendment relating to certain LG Chem rights in the LG Chem Territory.

On February 22, 2023, we entered into the Ono Collaboration and Option Agreement with Ono to further develop CUE-401 and provide dedicated resources and capabilities to help advance CUE-401 toward the clinic. On March 11, 2025, we and Ono agreed to terminate the Ono Collaboration and Option Agreement, effective as of March 6, 2025. Effective upon termination, we regained worldwide development and commercialization rights for CUE-401 from Ono. At such time, the agreement had no further force or effect with the exception of certain customary provisions which were intended to survive termination and expiration of the agreement.

On April 10, 2025, we entered into the BI Collaboration and License Agreement with BI to research, develop and commercialize differentiated B cell depletion molecules, including CUE-501. Under the terms of the BI Collaboration and License Agreement, we and BI will conduct collaborative research focused on CUE-501 during a four-year period or, if earlier, the completion of activities under the research plans, or the BI Research Term. In addition to, or instead of, CUE-501, BI may elect, at its sole discretion, to include additional or alternative compounds targeted at B cell depletion. BI will have an exclusive, royalty-bearing, worldwide, sublicensable license, under our applicable patents and know-how, to develop, manufacture and commercialize such compounds and their derivatives, or BI Licensed Products, for all uses, and BI shall be responsible for all further research, preclinical and clinical development, manufacturing, regulatory approvals, and commercialization of BI Licensed Products at its expense. During the BI Research Term, we are prohibited from developing or commercializing any molecule for applications in B cell depletion. On May 29, 2026, we executed an amendment to the BI Collaboration and License Agreement under which we will perform additional research activities for BI to advance the development of CUE-501.

On November 6, 2025, IMSCP exercised its option to obtain licenses to research, develop and commercialize molecules from the CUE-100 series, including CUE-101 and CUE-102, subject to certain exclusions, for all oncology indications pursuant to the IMSCP Collaboration and License Agreement. The licenses provided pursuant to the IMSCP Collaboration and License Agreement include a co-exclusive development license for five years or, if longer, for so long as IMSCP has a specified number of CUE-100 series molecules under active development and, pursuant to which, we retain non-exclusive research rights to support our other programs, or the co-exclusive development license. We also retained our rights to the CUE-100 series, including CUE-101 and CUE-102, for use in any manner other than as a component of a cell therapy product for 18 months past the effective date of the IMSCP Collaboration and License Agreement. The licenses include an exclusive commercial license to IMSCP for any CUE-100 series molecule that IMSCP advances to IND-enabling studies while the co-exclusive development license is in effect. The licensed series of molecules will be further developed and potentially commercialized by IMSCP.

On April 30, 2026, we entered the License Agreement with Ascendant for the exclusive license to develop, manufacture and commercialize CUE-221. Under the terms of the Ascendant License Agreement, as amended, Ascendant granted us (i) the exclusive and sublicensable rights to develop, manufacture, commercialize and otherwise exploit CUE-221, or products containing CUE-221 throughout the world (except mainland China, Hong Kong, Macau and Taiwan), for any and all such uses, and (ii) the non-exclusive and sublicensable rights to manufacture CUE-221 and products containing CUE-221 in the Ascendant Territory (other than mainland China) for the sole purpose of developing and commercializing CUE-221 and products containing CUE-221 in the Cue Territory. We have agreed to pay Ascendant potential milestone payments and tiered royalty payments (at percentages ranging from high single-digit to low double-digit) on future new sales of CUE-221.

We plan to continue to seek additional strategic alliances or collaborations with other third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In addition, we currently do not have sales, marketing, manufacturing or distribution capabilities or arrangements. In order to commercialize our potential products, we plan to seek development and marketing partners or sublicensees to obtain necessary marketing, manufacturing and distribution capabilities.

Any of these relationships 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. Moreover, we may not be successful in our efforts to establish additional strategic partnerships or collaborations for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite clinical and/or commercial potential based on current or future demonstrated safety, purity, and efficacy. If we are unable to maintain existing strategic partnerships or collaborations, or establish additional strategic partnerships or collaborations, to develop our product candidates, the costs for us to independently develop our product candidates may be higher than we currently anticipate, which could materially harm our business prospects, financial condition and results of operation.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will apply to our collaboration as compared to their other then-existing collaborations;
- our collaborators may not pursue development and commercialization of our product candidates or may not elect to continue or renew development or commercialization of our programs based on clinical trial results, changes in

their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- our collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of each of our potential products;
- our collaborators may not properly maintain or defend our intellectual property rights in accordance with the terms of our contractual arrangements with them or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to other potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts our management's attention and our other resources;
- collaborations have been, and in the future, additional collaborations may be, terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- our collaborators may own or co-own intellectual property covering our potential products that results from our collaboration with them, and in such case, we would not have the exclusive right to commercialize such intellectual property without our collaborators' involvement and consent.

As a result, we may not be able to realize the benefit of collaboration agreements, strategic partnerships or licenses of our technology or potential products, which could delay our product development timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve sufficient revenue, net income or other benefits to justify such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

Our collaboration agreement with BI contains exclusivity provisions that restrict our research and development activities.

We have granted to BI under the BI Collaboration and License Agreement an exclusive, royalty-bearing, worldwide, sublicensable license, under our applicable patents and know-how, to develop, manufacture and commercialize CUE-501, and any additional or alternative compounds targeted at B cell depletion compounds and their derivatives, for all uses. As such, during the BI Research Term, we are prohibited from developing or commercializing any molecule for applications in B cell depletion.

This restriction on our development, manufacturing, and commercialization activities could impact our ability to successfully develop certain product candidates, which could harm our future business prospects for commercializing drugs for those product candidates.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize the development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. For example, in July 2024, we decided to strategically focus on our autoimmune programs, including CUE-401 and CUE-501. As noted above, we subsequently out-licensed our CUE-501 program to BI and in April 2026, we entered into a license agreement with Ascendant related to the development, manufacture and commercialization of CUE-221. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success.

Although we may explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, our resource allocation may cause us to fail to identify successful product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources, whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- our key platform technology, Immuno-STAT Biologics™, may not adequately enable us to design, discover and validate product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If the market opportunities for our current and potential future product candidates are smaller than we believe they are, our ability to generate product revenue may be adversely affected and our business may suffer.

Our understanding of the number of people who suffer from certain diseases that our current or potential future product candidates may have the potential to treat is based on estimates. These estimates may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for our product candidates may be further reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from such product candidates.

Further, there are several factors that could contribute to making the actual number of patients who receive our current or potential future product candidates less than the potentially addressable market, including limited reimbursement for new therapies in many markets.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates. Our competitors may include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources than we have, such as a larger research and development staff and experienced marketing and manufacturing organizations, established relationships with CROs and other collaborators, as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less

costly than our product candidates or may develop proprietary technologies or secure patent protection and, in turn, exclude us from technologies that we may need for the development of our technologies and potential products.

CUE-221 is a humanized anti-IgE IgG1 monoclonal antibody intended to treat allergic diseases, including food allergy and CSU. If approved for food allergy, we could face branded competition from omalizumab (XOLAIR®). In addition, OMLYCLO®(Celltrion, Inc.) is an omalizumab biosimilar approved by FDA and it is likely that other omalizumab biosimilars will become available before CUE-221 is approved. There are several companies developing anti-IgE treatments that may be approved for food allergy and CSU, including GSK plc and LongBio Pharma. Additionally, some food allergen specific immunotherapies are currently in development and may be approved. If approved for CSU, we could face branded competition from omalizumab, as well as biosimilars. There are several large and specialty pharmaceutical companies, as well as biotechnology companies, with products in late-stage clinical development for CSU, including Sanofi, Novartis, Otsuka, and Celldex.

We also compete with other companies working to develop cytokines to restore immune balance, as well as those developing other therapeutic modalities, including monoclonal antibodies, bi-specific antibodies, cell therapies, and vaccines with application in treating patients living with autoimmune disease. Potential competitors in the cytokine-based therapy space include Amgen, Bristol-Myers Squibb, Merck, Nektar Therapeutics, Sanofi S.A., TRex Bio and RegCell. In the regulatory T cell therapies space, potential competitors include Coya Therapeutics, Quell Therapeutics, EVOQ Therapeutics, and Sonoma Biotherapeutics.

Many of our competitors have greater financial and other resources than we currently have. Additionally, many competitors have greater experience in product discovery and development, obtaining FDA and other regulatory approvals, and commercialization capabilities, which may provide them with a competitive advantage. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we obtain regulatory approval of any of our product candidates, we may not be the first to market, and that may negatively affect the price or demand for our product candidates. Additionally, we may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Furthermore, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, we may be prevented from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances, and we may be subject to similar restrictions under non-U.S. regulations.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our management team, including Shao-Lee Lin, our President and Chief Executive Officer, and other members of our scientific and clinical advisory team. The loss of any current or future team member could impair our ability to design, identify, and develop new intellectual property and product candidates and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the development of our product candidates and the implementation of our business plan and plan of operations and diversion of our management's attention. We can give no assurance that we could find satisfactory replacements for our current and future key scientific and management employees on terms that would not be unduly expensive or burdensome to us.

To induce valuable personnel to remain at our company, in addition to salary and cash incentives, we have granted stock options and restricted stock units that vest over time. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that these employees could leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to

continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

Our internal computer systems, or those used by third-party CROs, manufacturers, collaborators, other contractors or consultants, may fail or suffer security breaches.

In the ordinary course of our business, we and the third parties with whom we work, process, collect, receive, store, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, trade secrets and business plans, transactions, financial information, and other confidential business information (collectively, sensitive information). Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, manufacturers, collaborators, other contractors and consultants, and other third parties with whom we work are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions, online and offline fraud, loss of funds or information from phishing or other fraudulent schemes, denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), foreign governments, nation-state supported actors and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, clinical trials, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats may in the future cause a security incident or other interruption that may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. Further, applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information (such as individually identifiable health information), we may suffer material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms, and we could incur significant liabilities and the further development and commercialization of our product candidates could be delayed.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company or third parties could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnels', or vendors' use of generative AI technologies.

In addition, the foreign, federal and state regulatory environment surrounding information security and privacy is increasingly demanding, with frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and standards may result in significant expense due to increased investment in technology and the development of new operational processes.

Changes in and uncertainty surrounding U.S. and international trade policies may adversely impact our business and operating results.

In the spring of 2025, the U.S. government initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, an executive order announced a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Then, on July 31, 2025, the United States administration issued an executive order detailing new reciprocal tariffs rates for individual countries that took effect on August 7, 2025. The reciprocal tariffs were imposed pursuant to the International Emergency Economic Powers Act, or IEEPA.

In February 2026, the U.S. Supreme Court held that the IEEPA does not authorize the president to impose tariffs, invalidating both the "reciprocal" tariffs and certain country-specific tariffs previously imposed by executive orders. Following this decision, the U.S. Customs and Border Protection began refunding previously collected IEEPA duties through a phased administrative process, but the timing, scope and ultimate amount of any such refunds remain uncertain and subject to ongoing litigation.

The U.S. government subsequently invoked Section 122 of the Trade Act of 1974 to impose a 10% tariff, which could be raised to 15%, on nearly all foreign imports, or the Section 122 tariffs. The Section 122 tariffs expired in July 2026. In addition, the U.S. Trade Representative has conducted two investigations under Section 301 of the Trade Act of 1974, which have resulted in additional tariffs, or the Section 301 tariffs. In July 2026, in one such investigation, it imposed additional tariffs of 10% to 12.5% on products of 60 economies determined to have failed to impose and effectively enforce a prohibition on the importation of goods produced with forced labor. The second investigation into structural excess capacity and production in manufacturing sectors remains ongoing. In July 2026, the U.S. government also invoked Section 338 of the Trade Expansion Act of 1962 to impose a 50% tariff on certain Canadian imports, effective August 19, 2026, or the Section 338 tariffs. As was the case under the IEEPA tariffs, pharmaceuticals and pharmaceutical ingredients were among the products exempt from the Section 122 tariffs, the Section 301 tariffs related to forced labor, and the Section 338 tariffs.

Separately, in April 2025, the Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items.

Then, on April 2, 2026, the U.S. government issued a Proclamation invoking Section 232 of the Trade Expansion Act of 1962 to impose tariffs on imports of patented pharmaceuticals, biologics, and associated ingredients into the United States, or the Section 232 tariffs. The action affects pharmaceutical manufacturers, importers, and supply chain participants. Specifically, beginning for companies like ours that are not listed in the annexes to the Proclamation (i.e., those that have not concluded onshoring plans and MFN pharmaceutical pricing agreements with the U.S. government), beginning September 29, 2026, a 100% tariff will apply to pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations or are listed in the FDA's Lists of Licensed Biological Products. The 100% tariff also applies to active pharmaceutical ingredients and key starting materials for such articles. Preferential tariff rates are provided for imports of covered pharmaceuticals from Japan, the European Union, Korea, Switzerland, Lichtenstein and the UK. Certain categories of products are exempt from these tariffs, including, but not limited to, generic pharmaceuticals and biosimilars; specified U.S.-origin pharmaceutical products, active pharmaceutical ingredients and key starting materials; products classified in certain 10-digit tariff codes, listed in Annex IV of the Proclamation. Also likely to be exempt from the Section 232 tariffs are drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act; drugs for certain specific uses, including nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological, and nuclear threats; animal health; and other specialty pharmaceutical products to be later identified by the Secretary of Commerce.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the research, development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Further, some of our collaborators and suppliers are located in China. Trade tensions and conflicts between the United States and China have been escalated in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions.

For example, in December 2025, as part of the Fiscal Year 2026 National Defense Authorization Act, President Trump signed into law the BIOSECURE Act. Under the Act, US government agencies cannot (1) buy or obtain biotechnology equipment or services provided by biotechnology companies of concern, or BCCs; (2) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or (3) expend loan or grant funds for biotechnology equipment or services provided by a BCC, whether directly or through a loan or grant recipient. The Act does not name specific companies as BCCs but treats any company on the Department of Defense 1260H list of "Chinese military companies" as a BCC.

On December 18, 2025, the Chairs of multiple Senate and House committees, including the House Select Committee on China, sent a letter to the Department of Defense recommending that WuXi AppTec, WuXi Biologics, and WuXi XDC be added to the 1260H list, which would make all of those entities BCCs. On June 8, 2026, the Department of Defense published an updated 1260H list that included WuXi AppTec (not WuXi Biologics or WuXi XDC) as a "Chinese military company" based on alleged indirect ownership by a Chinese state entity and indirect affiliation with the People's Liberation Army. WuXi AppTec has publicly disputed the designation and, on June 11, 2026, filed suit against the Department of Defense in the U.S. District Court for the District of Columbia. On August 7, 2026, the court granted WuXi AppTec's motion for a preliminary injunction barring the Department of Defense from enforcing or giving effect to the designation while the litigation proceeds. The injunction is preliminary, not a final resolution, and the designation (and its implications for WuXi AppTec's potential BIOSECURE Act "biotechnology company of concern" status and for our current or future business relationships with WuXi AppTec) remains subject to the outcome of that litigation and to further Department of Defense or OMB action, including the initial BCC list due from OMB by December 18, 2026. Notwithstanding the injunction, OMB could still include WuXi AppTec on that initial BCC list. More broadly, because the BIOSECURE Act's implementing regulations, the BCC-designation process, and the scope of covered "biotechnology equipment or services" have not yet been finalized, the full impact of the Act on our business and on the biotechnology industry generally remains uncertain..

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, and cash tax obligations. For example, the Inflation Reduction Act, or IRA, was signed into law in August 2022, and the One Big Beautiful Bill Act, or OBBBA, was signed into law in July 2025. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules, and the international tax framework. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation.

War, terrorism, other acts of violence, or natural or manmade disasters may affect the markets in which we operate, our patients and resources required in our research and development activities.

Our business may be adversely affected by political instability, disruption or destruction in a geographic region in which we operate, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest, and natural or manmade disasters, including famine, flood, fire, earthquake, storm or pandemic events and spread of disease, and geopolitical conflicts. Such events may affect our business by increasing prices for resources required in our research and development activities or limiting our access to patients for our clinical trials which may delay our progress on one or more of our clinical or preclinical product candidates.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to successfully complete development of, obtain regulatory approval for, or commercialize our product candidates and our business could be substantially harmed.

We rely upon and plan to continue to rely upon third-party CROs for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, for all of our products in clinical development. Comparable requirements apply abroad. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and

trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or GMP, regulations. While we work closely with our CMOs on the manufacturing process for our product candidates, including quality audits, we have limited control over the implementation of the manufacturing process of, and are dependent on, our CMOs for compliance with GMP regulatory requirements and for manufacture of both active drug substances and finished drug products. In addition, portions of the clinical trials for our product candidates may be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate for any reason, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies for our product candidates.

We rely completely on third parties to manufacture clinical drug supplies for our product candidates. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience disruptions in supply or delays, suspensions or terminations of clinical trials or regulatory submissions. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our product candidates must obtain and maintain approval by the FDA. Comparable approvals will apply to any facilities located abroad. While we work closely with our third-party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally have limited control over the implementation of the manufacturing process of, and are dependent on, our contract manufacturers or other third-party manufacturers for compliance with GMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other comparable foreign regulatory authorities, as applicable, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities and we may not have sufficient access to supplies, which could significantly and adversely affect our operations.

In addition, we have limited control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve, or withdraws approval for, these facilities for the manufacture of our products and product candidates, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercialize, develop, or obtain or maintain regulatory approval for our products, if approved, and product candidates.

We also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture

our product candidates, or any products if approved, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials. We have limited control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Reliance on third-party manufacturers entails additional risks, including the possible breach of manufacturing agreements by the third party, the possible misappropriation of our proprietary information and the possible termination or non-renewal of an agreement by a third party at a time that is costly or inconvenient for us.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. We may, however, be unable to enter into agreements or do so on commercially reasonable terms for potential future product candidates, which could have a material adverse impact upon our business.

We rely on certain sole or limited sources of supply for our product candidates and disruptions in the chain of supply have in the past, and may in the future, cause delays in developing, obtaining approval for, and commercializing our product candidates.

The manufacturing processes for CUE-221, CUE-401 and our other product candidates are complex, and it may be difficult or impossible to finalize appropriate processes for the scaled manufacture of the product candidates. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of any of our product candidates; cause us to incur higher costs; or prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required clinical or commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed.

Risks Related to Intellectual Property and Other Legal Matters

We are highly dependent on intellectual property licensed from third parties and termination of these licenses could result in the loss of significant rights, which would harm our business.

In January 2015, we entered into a 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 product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides. In April 2026, we entered into a license agreement with Ascendant for an exclusive license to develop, manufacture and commercialize CUE-221 worldwide, except in the Ascendant Territory and a non-exclusive license to manufacture CUE-221 in the Ascendant Territory (other than mainland China) solely for the purpose of developing and commercializing CUE-221 in the Cue Territory.

We are dependent on the patents, know-how and proprietary technology licensed from these counterparties. Any termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Of note, the patent rights that we in-licensed under the Einstein license agreement do not cover either CUE-221 or CUE-401, and thus the termination of the Einstein license agreement would have no legal effect on our ability to develop and commercialize either CUE-401 or CUE-221.

The license agreements with Einstein and Ascendant impose certain obligations on us, and non-compliance with such obligations may result in termination of the applicable license agreement or in legal and financial consequences. If these counterparties terminate the applicable license agreement, we may not be able to develop, commercialize or sell our product candidates. Such an occurrence could materially adversely affect the value of product candidates being developed under the agreement or using rights granted under such agreement. Termination of our license agreements or reduction or elimination of our rights thereunder may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop, commercialize or sell the affected product candidate or may cause us to lose our rights under the applicable agreement. As noted above, however, the termination of the Einstein license agreement would have no legal effect on our ability to develop and commercialize either CUE-221 or CUE-401.

In addition, our licensors may make decisions in prosecuting, maintaining, enforcing and defending any licensed intellectual property rights, for example, any licensed patents or patent applications, that may not be in our best interest. Moreover, if our licensors take any action with respect to any licensed intellectual property rights, for example, any licensed patents or patent applications, that results in a successful challenge to the licensed intellectual property by a third party, such patents may be invalidated or held to be unenforceable, and we may lose our rights under such patents, which could materially harm our business.

Further, license agreements under which we license intellectual property from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution and enforcement of the licensed patents and our licensors' overall patent prosecution and enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and any future partners or collaborators; and
- the amounts of royalties, milestones or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates.

If we or any of our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our licensor(s) are unable to protect our or its intellectual property, then our financial condition, results of operations and the value of our technology and potential products could be adversely affected.

Patents and other proprietary rights are essential to our business, and our ability to compete effectively is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of ourselves and our licensor(s) to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for its intellectual property, particularly those patent applications and other intellectual property to which we have secured exclusive rights. We and our licensor(s) may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of pending patent applications, we or our licensor(s) may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would. Without adequate protection for the intellectual property that we own or license, others may be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be

challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of the term of patent protection that we may have for our potential products.

Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength than do those in the United States. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many U.S.-based companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and potential products could be adversely affected.

In addition to our licensed technology, we rely, and will continue to rely, upon, among other things, unpatented proprietary technology, processes, trade secrets, trademarks, and know-how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their former employee's therapeutic development activities for us. Any dispute involving such employees may result in liabilities to us.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.

We hold an exclusive license from Einstein to intellectual property relating to certain patent rights, relating to our core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides and an exclusive license from Ascendant to develop, manufacture and commercialize CUE-221. These licenses impose various developmental and commercial milestone obligations on us. If we fail to comply with any obligations under the license agreements and fail to cure such noncompliance, the counterparties will have the right to terminate the applicable agreement and our license. The existing patent applications or future patents to which we have rights based on our license agreements may be too specific and narrowly construed to prevent third parties from developing or designing around

the protection provided by these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of termination of the license agreement. There is no assurance that we will be successful in meeting all of the milestones in the future on a timely basis or that either of these license agreements will not be terminated for other reasons, depriving us of significant rights. The termination of either of these license agreements would have a material adverse effect on our financial condition, results of operations, and prospects.

If we are unable to patent and protect the intellectual property used in our potential products, others may be able to copy our innovations, which may impair our ability to compete effectively in our markets.

The strength of our anticipated patents will involve complex legal and scientific matters and can be uncertain. We own or license a number of pending patent applications. Our anticipated patents may be challenged or fail to result in issued patents and anticipated patents may be too specific and narrowly construed to prevent third parties from developing or designing around the protections provided by our intellectual property and in that event we may lose competitive advantage and our business may suffer. Further, the patent and patent applications that we license or have filed may fail to result in issued patents or the claims may need to be amended. Even after amendment, a patent may not issue. In that event, we may not obtain the exclusive use of the intellectual property that we seek, and we may lose competitive advantage, which could result in harm to our business.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our anticipated patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by third parties asserting that our potential products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business.

If successful, those claims could result in our having to pay substantial damages or could prevent us from developing one or more product candidates. Further, if a patent infringement suit is brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If we or our collaborators experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into license agreements on acceptable terms or at all. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, and even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their greater financial and human resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement, the biotechnology and pharmaceutical industries are characterized by many suits regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe upon their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our potential products, by preventing the patentability of one or more aspects of our potential products or those of our licensor or by covering the same or similar technologies that may affect our ability to market our potential products. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for

U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers. In this regard, we note that neither CUE-221 nor CUE-401 was discovered through U.S. government-funded programs.

The intellectual property rights that we licensed from Einstein were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates that employ the technology in-licensed from Einstein pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the normal statutory term of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Further, normal statutory patent terms may be limited in the U.S. in the event there is a determination that the claims in different patents are directed to obvious variants of the same invention, which can negatively impact the normal statutory patent term. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union, or EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and the scope of protection is not the full scope of the claims but is instead limited to the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical, nonclinical and preclinical data and launch their product

earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any drugs. For example, we may be sued if our product candidates cause or are perceived to cause injury or death or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state or foreign consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our potential drugs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- financial cost;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our insurance coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Government Regulation

Even if we complete the necessary nonclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of any of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Any of our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory

authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any of our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, under the Pediatric Research Equity Act of 2003, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by the Pediatric Committee of the EMA. For any of our product candidates for which we seek regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Finally, the FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional nonclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any of our product candidates, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

We are subject to regulation in respect of our research and federal funding.

Because our licensor (Einstein) has conducted research relating to our Einstein license agreement under federal grants and we may conduct further research under federal grants, we will be subject to federal regulation in how we conduct our research and the agreement terms relating to those grants. There are also ethical guidelines promulgated by various governments and research institutions that we are required to follow in respect of our research. These guidelines are orientated towards research and experimentation involving humans and animals. Failure to follow the regulations, agreement terms and accepted scientific practices would jeopardize our grants and our results and the use of the results in further research and approval circumstances. Because Einstein has used federal funding, the government retains a "march-in" right in connection with these grants, which is the right to grant additional licenses to practice inventions developed from grant funding.

In December 2023, the National Institute of Standards and Technology, or NIST, released for public comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, or the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march-in rights pursuant to the Bayh-Dole Act and includes a first-ever specification that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march-in determination and the exercise of "march-in" rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

Failure to obtain marketing approval in foreign jurisdictions would prevent any of our product candidates from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any of our product candidates in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the same or similar risks associated with obtaining FDA approval. In addition, in many

countries outside the United States, it is required that the product be approved for reimbursement before the product can be commercialized in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any jurisdiction, which would materially impair our ability to generate revenue.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For example, to the extent we seek regulatory approval or reimbursement in the European Union, we may be affected by ongoing regulatory reform, including the ongoing comprehensive overhaul of EU pharmaceutical legislation (the Pharma Package), which encompasses a broad range of measures, including changes to regulatory exclusivity, incentives to combat antimicrobial resistance, intellectual property exemptions for generic medicines, orphan products, and marketing authorization procedures, with full application anticipated in 2028; Regulation (EU) 2021/2282 on health technology assessment which entered into application on January 12, 2025, through a phased implemented until 2030, and introduces a single EU-level submission file for joint clinical assessments; and other legislative initiatives such as the proposed SPC Regulation revision, the proposed Critical Medicines Act, and the proposed Biotech Act.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We may seek orphan drug designation for one or more of our product candidates, but even if such designation is granted, we may be unable to maintain any benefits associated with orphan drug designation, including market exclusivity that prevents the FDA or the European Commission from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs the designation and approval of orphan medicinal products in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. In the EU, orphan market exclusivities are subject to change under the pending overhaul of the EU general pharmaceutical legislative framework described above.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition. In the EU, the exclusivity period in the European Union can be reduced to six years if at the end of the fifth year, a product no longer meets the criteria for orphan drug designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the exclusivity period under certain circumstances, including if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities or if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product.

The FDA and Congress may further reevaluate and revise the Orphan Drug Act and its regulations and policies.

If approved, our product candidates that are licensed and regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as its BLA does not reply on the reference product, sponsor's data or submit the application as a biosimilar application.

We believe that any of the product candidates we develop as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to reference medicinal product but that do not meet the definition of a generic medical product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

We may seek fast track designation or breakthrough therapy and priority review programs for our product candidates. Even if our product candidates receive one or more of these designations, the product candidate may not be subject to a faster review process nor does any such designation assure approval of our product candidates.

We aim to benefit from the FDA's fast track, breakthrough therapy and priority review programs. However, our product candidates may not receive an FDA fast track designation, breakthrough therapy designation, or priority review. Without fast track designation, submitting a BLA, and getting through the regulatory process to gain marketing approval is a lengthy process. Under fast track designation, the FDA may initiate review of sections of a fast track drug's BLA before the application is complete. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted.

The FDA has also established breakthrough therapy designation, which is for a product that is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. We may seek breakthrough therapy designation for one or more of our product candidates, but there can be no assurance that we will receive such designation.

Under the FDA's policies, a product candidate is eligible for priority review, or review within a six-month time frame from the time a complete BLA is accepted for filing, if the product candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A fast track or breakthrough therapy designated product candidate would ordinarily meet the FDA's criteria for priority review.

The FDA has broad discretion with respect to whether or not to grant these designations to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, any such designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to licensure compared to conventional FDA procedures. As a result, while we may seek and receive these designations for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw these designations if it believes that the designation is no longer supported by data from our clinical development program. A delay in the review process or in the approval of our potential products would delay revenue, if any, from their potential sales and would increase the capital necessary to fund these product development programs.

We may seek approval from the FDA or comparable foreign regulatory authorities to use accelerated development pathways for our product candidates. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we receive them at all. In addition, even if an accelerated approval pathway is available to us, it may not lead to expedited approval of our product candidates, or approval at all.

Under the Federal Food, Drug and Cosmetic Act, or the FDCA, and implementing regulations, the FDA may grant accelerated approval to a product candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective.

Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional applications for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may in the future conduct clinical trials for certain of our product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

The earlier clinical development work conducted for CUE-221 was led by Ascendant in China. We may in the future conduct one or more of our clinical trials with trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. If access to clinical trial sites or documentation is delayed or restricted, including for geopolitical reasons, the FDA may not accept such data in support of an IND or marketing application which would adversely affect our

development and approval plans. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us or the trial results. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- an evolving geopolitical landscape limiting or restricting access to foreign clinical trial sites and/or foreign clinical trial data and documentation;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

To obtain the necessary approval of our potential products, as a precondition, we will need to conduct various nonclinical and clinical trials, all of which will be costly and time-consuming, and may not provide results that will allow us to seek regulatory approval.

The number of nonclinical studies and clinical trials that will be required for regulatory approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the drug, the jurisdiction in which approval is sought and the applicable regulations. Regulatory agencies can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies may:

- not deem a product candidate to be safe or effective;
- interpret data from nonclinical studies and clinical trials differently than we do;
- not approve the manufacturing processes;
- conclude that our product candidate does not meet quality standards for durability, long-term reliability, biocompatibility, compatibility, or safety; and
- change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of any clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the United States. Foreign regulatory agencies may similarly have the ability to influence any clinical trials occurring outside the United States. Any of these occurrences could prove materially harmful to our operations and business.

Even if we, or any collaborators we may have, obtain marketing approvals for any of our product candidates, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more of our product candidates, we, and such collaborators, and our and their contract manufacturers will continue to need to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to generate revenue and achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

If we receive regulatory approval for any product candidate, we will be subject to ongoing obligations and continuing regulatory review, which may result in significant additional expense. Our product candidates, if approved, could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Any product candidate for which we obtain marketing approval will also be subject to ongoing regulatory requirements for labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post marketing information. For example, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to GMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with GMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. Comparable requirements apply abroad.

In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, may be subject to significant conditions of approval or may impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us. In addition, if any product fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue fines, warning letters, untitled letters or impose holds on clinical trials if any are still ongoing;
- mandate modifications to promotional materials or require provision of corrective information to healthcare practitioners;
- impose restrictions on the product or its manufacturers or manufacturing processes;
- impose restrictions on the labeling or marketing of the product;
- impose restrictions on product distribution or use;
- require post-marketing clinical trials;
- require withdrawal of the product from the market;
- refuse to approve pending applications or supplements to approved applications that we submit;
- require recall of the product;
- require entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;
- suspend , vary or withdraw marketing approvals;
- refuse to permit the import or export of the product;
- seize or detain supplies of the product; or

- issue injunctions or impose civil or criminal penalties.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any approval that we may have obtained and we may not achieve or sustain profitability. Further, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Similar restrictions apply to the approval of our products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of drugs, which are strictly regulated in the EU and are also subject to EU Member State laws. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.

Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other comparable regulatory authorities. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other comparable regulatory authorities may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. We will need to carefully navigate the FDA's and comparable regulatory authorities' various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the U.S. Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the U.S. Department of Health and Human Services, or HHS, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other comparable regulatory authority initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved

uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program, progress development efficiently, and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

The current U.S. administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees at various federal agencies, including the FDA. Recent FDA leadership and personnel changes could lead to disruptions and delays in FDA guidance, review and approval of our product candidate. Changes and cuts in FDA staffing have been reported by some within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention, and FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the U.S., and threatening access to federal agency contracts and other funding awards based on companies' otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. There is also substantial uncertainty as to how regulatory reform measures being implemented by the current administration, and other political developments, such as government shutdowns or work stoppages, would impact other U.S. regulatory agencies, such as the FDA, SEC, the Internal Revenue Service, and USPTO, on which our operations rely. For example, over the last several years and most recently in October 2025, the U.S. government has shut down and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs and NDAs/BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our relationships with healthcare providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any of our product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act, which imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses, and health care providers and their business associates and covered subcontractors;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to HHS information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state and local laws require certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. Additionally, some state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, or comparable foreign programs, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The provision of benefits or advantages to health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, such as the UK Bribery Act 2010, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. In addition, payments made to health care

professionals in certain European Union Member States must be publicly disclosed. Moreover, agreements with health care professionals often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If commercial third-party payors or government payors fail to provide coverage or adequate reimbursement, our revenue and prospects for profitability would be harmed.

There is increasing pressure on biotechnology and pharmaceutical companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology and pharmaceutical industries will likely face greater regulation and political and legal actions in the future.

There is increased uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within HHS, as CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement. Adverse pricing limitations may hinder our ability to recoup our investment in one or more future product candidates, even if our future product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any potential products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers, pharmacy benefit managers, and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for future products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the United States or foreign jurisdictions.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In March 2010, the PPACA was signed into law. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2033 unless additional congressional action is taken.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In August 2022, Congress enacted the Inflation Reduction Act of 2022, or the IRA, which established the Medicare Drug Price Negotiation Program, authorizing HHS to negotiate maximum fair prices for certain high-expenditure, single-source drugs and biologics covered under Medicare Part B and Part D. A single-source drug generally becomes eligible for selection once it has been approved for at least seven years (small molecules) or licensed for at least eleven years (biologics), and HHS may select up to 20 drugs annually for negotiation, with negotiated prices for each selection cycle taking effect approximately two years after selection; negotiated prices for the first selected drugs took effect on January 1, 2026. The IRA also imposes inflation rebates on Medicare Part B and Part D drugs whose prices increase faster than inflation, requiring manufacturers to pay CMS a rebate on the excess. These provisions, and related Part D benefit redesign changes, could reduce our revenue and profitability with respect to any product candidate that receives marketing approval and becomes subject to negotiation or inflation-rebate liability, and remain subject to ongoing CMS guidance, implementation litigation, and potential legislative amendment.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law or to otherwise narrow provisions of the PPACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law, which narrowed access to PPACA marketplace exchange enrollment and declined to extend the PPACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired PPACA subsidies.

In the EU, on January 12, 2025, Regulation (EU) 2021/2282 on Health Technology Assessment (the "HTA Regulation") entered into application through a phased implementation. The HTA Regulation initially applies to new active substances for oncology products and advanced therapy medicinal products, and will expand to orphan medicinal products in January 2028 and to all centrally authorized medicinal products by 2030. It is intended to increase cooperation among EU Member States in assessing clinical aspects of health technologies, including new medicinal products. The Regulation establishes a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA

evaluations. EU Member States, however, remain responsible for assessing non-clinical aspects, such as economic, ethical, and social considerations, and for making pricing and reimbursement decisions at the national level.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if approved.

The prices of prescription pharmaceuticals have been the subject of considerable legislative and executive actions in the United States. There have been U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada.

In addition, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

On December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as OECD countries with a GDP of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). The GLOBE and GUARD pilot programs are proposed to go into effect beginning October 1, 2026 and January 1, 2027, respectively.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or

additional pricing pressures. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payors are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

In countries outside of the United States, pricing and reimbursement schemes vary widely from country to country, the pricing of prescription pharmaceuticals may be subject to governmental control. In the EU for example, some EU Member States may restrict the range of products for which their national health insurance systems provide reimbursement. Other countries may control the process of medicinal products for human use or allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Such pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Political economic and regulatory developments may further complicate pricing negotiations. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medical products by the competent authorities of individual EU Member States. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and business plans, transactions, financial information, and other confidential information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the European Union's General Data Protection Regulation, or the GDPR, the United Kingdom's GDPR, or UK GDPR and collectively, GDPR, and China's Personal Information Protection Law, or PIPL, imposes strict requirements for processing personal data and provide for substantial fines for violations. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors.

The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues of the respective group of companies or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the European Commission to offer adequate data protection legislation and other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. For example, there are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the Court of Justice of the EU, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for international transfers of personal data from the EEA. This CJEU decision resulted in increased scrutiny on data transfers and increased our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the Court of Justice of the European Union (CJEU), C-703/25 P - Latombe v. Commission. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business. Following the withdrawal of the UK from the EU, the UK Data Protection Act of 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the EU have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act of 2018 and the GDPR, respectively. The UK and the U.S. have also agreed to a U.S.-UK "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the U.S. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the U.S.). Any changes or updates to these developments have the potential to impact our business.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. For example, some European regulators have ordered certain companies to

suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in certain data transactions or agreements.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the U.S. regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure or perceived failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; fines and penalties; adverse publicity; or substantial changes to our business model or operations.

We are subject to stringent federal and state privacy laws, information security laws, regulations, policies, and contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations at the federal and state levels of government that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure to comply with any of these laws and regulations could result in enforcement actions against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and to ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and

reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020, and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements.

In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency - the California Privacy Protection Agency - whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering additional laws that will go into effect in 2026 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023, a health privacy law that regulates the collection and sharing of health information. The law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities, and could lead to government enforcement actions, private litigation and significant fines and penalties against us, all of which could increase our cost of doing business and have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Further, we cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission, and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

On February 10, 2025, President Trump issued an Executive Order directing the Attorney General to review the guidelines and policies governing FCPA investigations and enforcement actions. Per the Executive Order, this review will result in new U.S. Department of Justice FCPA guidelines intended to enhance American economic competitiveness and to safeguard national security interests. During the 180-day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions will be reviewed. Additionally, after the Attorney General issues revised guidelines, the Executive Order directs her to assess whether “remedial measures” related to past FCPA actions are warranted. We will need to carefully navigate these developments.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may

result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our business operations will subject us to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We expect to generally contract with third parties for the disposal of these materials and wastes. However, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions and we may not have sufficient (or any) insurance to cover any such costs.

Risks Related to Owning Our Common Stock

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting shares of common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting shares of common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter. Smaller reporting companies have reduced disclosure obligations, such as an ability to provide simplified executive compensation information and only two years of audited financial statements.

We have elected to take advantage of certain of the reduced reporting obligations. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our stock price can be volatile and fluctuate significantly, and our stockholders may have difficulty selling their shares and/or suffer substantial losses.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "CUE." The price of our common stock has fluctuated, and is likely to continue to fluctuate, significantly in response to market and other factors, some of which are beyond our control, including those listed in this "Item 1A. Risk Factors" section and other, unknown factors. Our stock price may be affected by many factors, including:

- setbacks with respect to our research and development programs;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials;
- any adverse changes to our relationship with collaborators;
- results of internal and external studies and clinical trials;
- results of our business development efforts;
- variations in the level of expenses related to our existing product candidates or preclinical and clinical development programs;

- any intellectual property infringement actions in which we may become involved;
- variations in our results of operations;
- press reports, whether or not true, about our business;
- additions to or departures of our management;
- sales or perceived potential sales of additional shares of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- general economic and market conditions, including recent adverse changes in the domestic and international financial markets, the impacts of inflation and the implementation of trade barriers and tariffs and government action in response thereto.

Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors beyond our control may negatively affect the market price of our common stock, regardless of our actual operating performance, and cause the price of our common stock to decline rapidly and unexpectedly.

If we fail to maintain compliance with the continued listing requirements of Nasdaq, our common stock may be delisted and the price and liquidity of our common stock and our ability to access the capital markets could be negatively impacted.

We are required to comply with the continued listing requirements of the Nasdaq Stock Market LLC, or Nasdaq, including, among other things, maintaining a minimum closing bid price of at least $1.00 per share, or the Minimum Bid Requirement, or shares of our common stock may be subject to delisting, which would have a material adverse effect on our business. In the past, we have received written notification from Nasdaq informing us that we failed to comply with the Minimum Bid Requirement. As previously disclosed, on May 12, 2025, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of Nasdaq indicating that we failed to comply with the Minimum Bid Requirement. On November 11, 2025, we received a written notice from the Staff granting us an additional 180 calendar day compliance period (until May 11, 2026) to regain compliance with the Minimum Bid Requirement.

On April 23, 2026, we effected a 1-for-30 reverse stock split of our issued and outstanding shares of common stock. On May 8, 2026, we received notification from the Staff that we regained compliance with the Minimum Bid Requirement for continued listing.

There can be no assurances that we will continue to maintain compliance with the requirements for listing our common stock on Nasdaq. Any potential delisting of our common stock could have a material adverse effect on the market for, and liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Any delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares of our common stock in the public market.

We may be subject to securities litigation, which is expensive and could divert management attention.

The price of our common stock can be volatile, and in the past companies that have experienced volatility in the market price of their common stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our securities and trading volume could decline.

The trading market for our securities is influenced by the research and reports that industry or securities analysts publish about us or our business. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts who cover us issues an adverse opinion about our company, the price of our securities would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly

publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our securities or trading volume to decline.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and product candidates and to cover operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. In addition, future debt financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

Our ability to use net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards.

We may have experienced an "ownership change" within the meaning of Section 382 in the past and there can be no assurance that we will not experience additional ownership changes in the future. As a result, our NOLs and business credits (including the R&D credit) may be subject to limitations and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs and R&D credit carryforwards could expire or otherwise become unavailable to offset future income tax liabilities. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

We incur significant costs as a result of being a public company and our management is required to devote substantial time to meet compliance obligations.

As a public company, and particularly as we are no longer an emerging growth company, we incur significant legal, accounting and other expenses. We are subject to reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, there are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Wall Street Reform and Protection Act that increase public companies' legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Provisions of our amended and restated certificate of incorporation, or the Certificate of Incorporation, and our amended and restated bylaws, or the Bylaws, and applicable provisions of Delaware law may delay or discourage transactions

involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate of Incorporation and Bylaws:

- authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our common stock and could include terms that may deter an acquisition of us;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies on our board of directors may be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum, or by a sole remaining director;
- provide that stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for director;
- provide that stockholders may only amend our Certificate of Incorporation and Bylaws upon a supermajority vote of stockholders; and
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims.

In addition, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the time such person came to beneficially own 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our Certificate of Incorporation provides, subject to certain exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our Certificate of Incorporation provides that, subject to limited exceptions and unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for all "internal corporate claims." "Internal corporate claims" mean claims, including claims in the right of the corporation, (i) that are based upon a violation of a duty by a current or former director or officer or stockholder in such capacity or (ii) as to which Title 8 of the Delaware Code confers jurisdiction upon the Court of Chancery, except for, as to each of (i) through (ii) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction.

The choice of forum provisions will not apply to claims arising under the Securities Act of 1933, as amended, or the Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction.

Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision that will be contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities may decrease.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over

financial reporting. Until such time as we are no longer a "smaller reporting company" with less than $100 million in annual revenue, and thereafter qualify as an accelerated filer or a large accelerated filer, our auditors will not be required to attest as to our internal control over financial reporting.

If we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, once required, provide an attestation report from our independent registered public accounting firm, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

If a significant number of our total outstanding shares are sold into the market, the market price of our common stock could drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours.

Additionally, in April 2026, we entered into a securities purchase agreement with accredited investors, pursuant to which we issued and sold to the investors in a private placement pre-funded warrants to purchase an aggregate of up to 2,727,272 shares of common stock and accompanying warrants to purchase an aggregate of up to 1,363,636 shares of common stock (or, in certain circumstances, pre-funded warrants to purchase common stock in lieu thereof) at a price of $11.00 per pre-funded warrant and accompanying warrant.

Additionally, in April 2026, in connection with the execution of the Ascendant License Agreement, we issued to Ascendant at an initial closing pre-funded warrants to purchase 551,724 shares of common stock.

In July 2026, we entered into a securities purchase agreement with accredited investors pursuant to which we, in a private placement, issued and sold to the investors an aggregate of (i) 1,418,070 shares of common stock at a price per share of $33.21 and (ii) to certain investors, in lieu of shares of common stock, pre-funded warrants to purchase up to 87,500 shares of common stock at a price per pre-funded warrants of $33.209.

We filed registration statements on Form S-3 for the resale of the securities issued in the April and July 2026, private placements and the securities issued to Ascendant in April 2026.

We currently have on file with the SEC a universal shelf registration statement which allows us to offer and sell up to $300.0 million of registered common stock, preferred stock, debt securities, warrants, subscription rights and/or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In addition, we have also entered into an open market sales agreement with Jefferies LLC, as sales agent, or the ATM Sales Agreement, pursuant to which we may offer and sell shares of our common stock under such registration statement for aggregate gross proceeds of up to $80.0 million under an "at-the-market" offering program. To date, we have sold $43.2 million of securities, net of commission paid, but excluding transaction expenses, pursuant to the ATM Sales Agreement.

In addition, we have filed registration statements registering all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to black-out periods and volume limitations applicable to affiliates.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

As part of our private placement in November 2022, we issued common stock warrants to purchase an aggregate of 306,280 shares of our common stock, and pre-funded warrants to purchase an aggregate of 51,048 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.0030 per share. Each pre-funded warrant is exercisable from the date of issuance. Each common stock warrant has an exercise price per share of common stock equal to $117.90, or if exercised for a pre-funded warrant in lieu thereof, $117.90 per pre-funded warrant. Each common stock warrant is exercisable from the date of issuance until November 16, 2027. Holders of pre-funded warrants and common stock warrants may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% of our outstanding common stock immediately after exercise, which limitation we refer to as the 2022 Beneficial Ownership Limitation. The holders may increase or decrease their 2022 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

As part of our underwritten public offering in September 2024, we issued common stock warrants to purchase an aggregate of 96,370 shares of our common stock, and pre-funded warrants to purchase an aggregate of 414,520 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.0030 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full. Each common stock warrant has an exercise price per share of common stock equal to $15.00. Each common stock warrant is exercisable from the date of issuance until September 30, 2029. Holders of pre-funded warrants and common stock warrants may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% or 9.99%, as elected by the holder, of our outstanding common stock immediately after exercise, which limitation we refer to as the 2024 Beneficial Ownership Limitation. The holders may increase or decrease their 2024 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

As part of our underwritten public offering in April 2025, we issued common stock warrants to purchase an aggregate of 208,333 shares of our common stock, and pre-funded warrants to purchase an aggregate of 382,307 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.0030 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full. Each common stock warrant has an exercise price per share of common stock equal to $23.70. Each common stock warrant is exercisable from the date of issuance until April 16, 2030. Holders of pre-funded warrants and common stock warrants may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% or 9.99%, as elected by the holder, of our outstanding common stock immediately after exercise, which limitation we refer to as the April 2025 Beneficial Ownership Limitation. The holders may increase or decrease their April 2025 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

As part of our underwritten public offering in December 2025, we issued common stock warrants to purchase an aggregate of 684,524 shares of our common stock, which include common stock warrants to purchase 89,286 shares of our common stock issued pursuant to the underwriters' option to purchase additional common stock and/or common stock warrants, and pre-funded warrants to purchase an aggregate of 773,810 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.0030 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full. Each common stock warrant has an exercise price per share of common stock equal to $9.00. Each common stock warrant is exercisable from the date of issuance until December 22, 2030. Holders of pre-funded warrants and common stock warrants may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% or 9.99%, as elected by the holder, of our outstanding common stock immediately after exercise, which limitation we refer to as the December 2025 Beneficial Ownership Limitation. The holders may increase or decrease their December 2025 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

As part of our private placement in April 2026, we issued pre-funded warrants to purchase an aggregate of 2,727,272 shares of our common stock, and common stock warrants to purchase an aggregate of 1,363,636 shares of common stock. Each pre-funded warrant has an exercise price of $0.001 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full. Each common stock warrant has an exercise price of $11.00 per share. Each common stock warrant is exercisable from the date of issuance until May 4, 2031. Holders of pre-funded warrants and common stock warrants may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% or 9.99%, as elected by the holders, of our outstanding common stock immediately after exercise, which limitation we refer to as the April 2026 Beneficial Ownership Limitation. The holder may increase or decrease their April 2026 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

In connection with the execution of the Ascendant License Agreement in April 2026, we issued to Ascendant pre-funded warrants to purchase an aggregate of 551,724 shares of our common stock. The pre-funded warrants have an exercise price of $0.001 per share. The pre-funded warrants are exercisable from the date of issuance until exercised in full. The holder

of the pre-funded warrants may not exercise any portion of the warrant to the extent that such exercise would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder to exceed 9.99% (together with its affiliates) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, which limitation we refer to as the Ascendant Beneficial Ownership Limitation. The holder may increase or decrease the Ascendant Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

As part of our private placement in July 2026, we issued pre-funded warrants to purchase an aggregate of 87,500 shares of our common stock. Each pre-funded warrant has an exercise price of $0.001 per share. Each pre-funded warrant is exercisable from the date of issuance until exercise in full. Holders of pre-funded may not exercise any portion of their warrants to the extent that they would beneficially own more than 4.99% or 9.99%, as elected by the holder, of our outstanding common stock immediately after exercise, which limitation we refer to as the July 2026 Beneficial Ownership Limitation. The holder may increase or decrease their July 2026 Beneficial Ownership Limitation to a percentage not in excess of 19.99% by giving notice to us.

Although the warrants issued in November 2022, September 2024, April 2025, December 2025, April 2026 and July 2026 are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and the holders of these warrants, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly. We have registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur. Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

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

The Company is updating the disclosure about the description of its business. The description of business supersedes the description of business previously included in Part I, Item 1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission (the "SEC") on March 16, 2026.

Overview

We are a clinical-stage biopharmaceutical company focused on advancing a portfolio of potentially transformative therapies aimed at enabling functional cures across immunological disorders. Our lead asset, CUE-221, is a novel humanized anti-IgE monoclonal antibody designed with a dual-mechanism of action that we are developing for allergic diseases. We have received topline results from a Phase 2 clinical trial of CUE-221 conducted in China by Genesis Life Sciences, a related company of Ascendant Health Ltd. (Ascendant), in patients with chronic spontaneous urticaria, or CSU. In addition, we have

developed the Immuno-STAT® platform designed to engineer therapies that selectively target disease-specific T cells in vivo without broad immune modulation. Our lead candidate to treat autoimmune diseases, CUE-401 was designed to induce the development of regulatory T cell populations (Tregs) leading to Treg-mediated tolerance and control of autoimmunity. In the fourth quarter of 2026, we initiated dosing of human subjects in our Phase 1 clinical trial of CUE-401.

Our Lead Programs

- CUE-221 (Ascendant-221, UB-221) is a humanized anti-IgE IgG1 monoclonal antibody designed with a precision engineered dual mechanism of action. CUE-221 binds to IgE at sites that are distinct from the binding sites for XOLAIR® or other similar anti-IgE monoclonal antibodies. In doing so, it maintains the capacity of total IgE to bind the CD23 receptor at the surface of B cells, resulting in reduced IgE synthesis. Therefore, CUE-221 is a functionally distinct novel anti-IgE antibody designed to not only neutralize free IgE with high potency, but also to prevent the synthesis of new IgE with the possibility to achieve B-cell quiescence through crosslinking of CD23, which could ultimately result in sustained disease control beyond drug exposure. The CUE-221 Phase 2 clinical trial in CSU produced positive topline results and clinical evidence providing initial validation of the clinical potential of a precision engineered anti-IgE dual mechanism of action. The study also demonstrated fundamental biological differences compared to XOLAIR®.
- CUE-401 is a bispecific fusion protein of 2 human cytokines: IL-2 and TGFβ, each engineered in an attenuated form so as to decrease their affinity for their respective cognate receptor to limit the potential for broader off-target or adverse immunomodulatory effects. The design of CUE-401 stemmed from the Nobel Prize winning discovery of the role of regulatory T cells (Tregs) in autoimmunity, granted in 2025, and the recognition that the cytokines IL-2 and TGF-beta, when acting in concert are essential components in establishing immune tolerance by fostering the development of Tregs.

Our Partnered Programs

- CUE-500 series is designed to selectively target and deplete disease-causing cells by redirecting existing anti-viral memory T cells toward pathogenic cell populations, including autoreactive B cells implicated in autoimmune diseases. We believe this approach may enable targeted immune modulation while potentially reducing the broader immune effects associated with certain existing therapies. CUE-501, which is being developed through our collaboration and license agreement with Boehringer Ingelheim, or BI, is focused on the treatment of autoimmune diseases driven by pathogenic B cells. We believe the modular design of the CUE-500 series may support development across multiple disease areas by incorporating different cell-targeting domains into the platform framework.
- Historically, we primarily focused our resources on the development of our CUE-100 series for oncology, namely the CUE-101 and CUE-102 drug product candidates, which are representative of our approach to selectively activate targeted CD8+ T cells against cancer, both of which have been licensed to ImmunoScape Pte. Ltd., or IMSCP, to advance a novel in vivo approach to cell therapy for the treatment of solid tumors. Through our Collaboration and License Agreement with IMSCP, IMSCP is developing a novel Seed-and-Boost immunotherapy that combines our clinically validated Immuno-STAT T-cell engagers, the CUE-100 series, with IMSCP's proprietary tumor-specific T cell receptors, or TCRs. The combination therapy is designed to overcome core limitations of existing cell therapies and to potentially establish a new standard of care with superior anti-tumor activity, durable T cell persistence and product scalability

We aim to leverage our robust pipeline and differentiated platform to establish new standards of care, forge strategic partnerships, and accelerate the clinical development of programs in immunology that we believe will make transformative differences in patients' lives.

Our Lead Programs

CUE-221

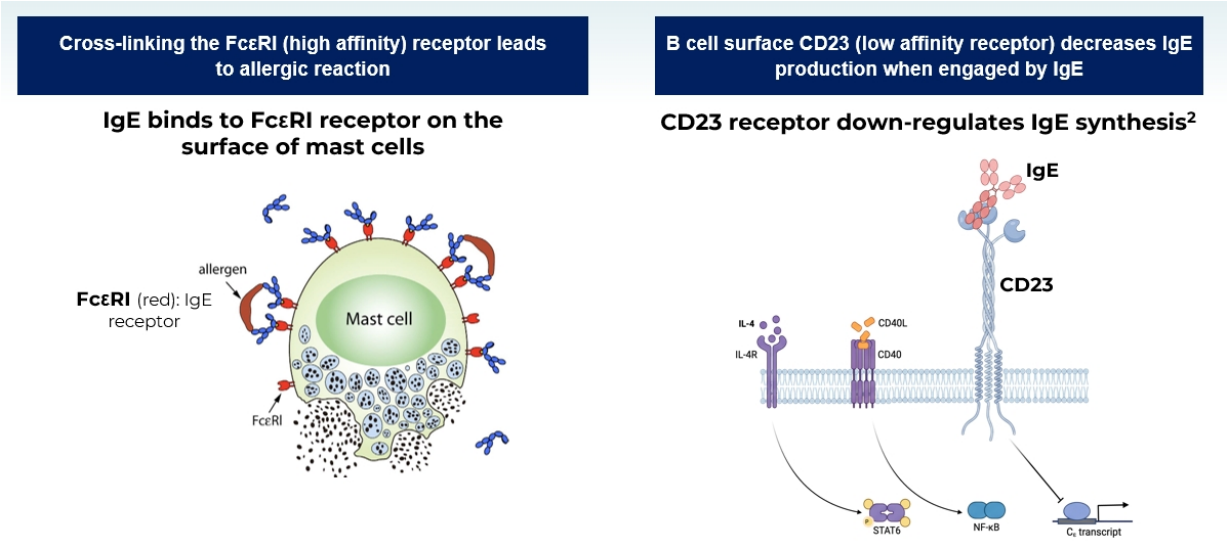
CUE-221 is a humanized anti-IgE IgG1 monoclonal resulting from precision engineering seeking to create a molecule that effectively neutralizes IgE and prevents its binding to the high affinity receptor expressed on the surface of mast cells, basophils, and eosinophils, while preserving the capacity of the neutralized IgE (i.e. bound to CUE-221) to engage the low affinity, CD23 receptor. Hence, CUE-221 is designed to have a dual mechanism of action: it neutralizes IgE with picomolar potency and leverages the naturally occurring CD23-mediated pathway, which results in suppression of new IgE synthesis

when IgE (either in free form or in complex with CUE-221) binds to CD23. By targeting key drivers of IgE-mediated disease, CUE-221 is designed to enable deeper and more sustained control of IgE levels, and therefore of allergic conditions.

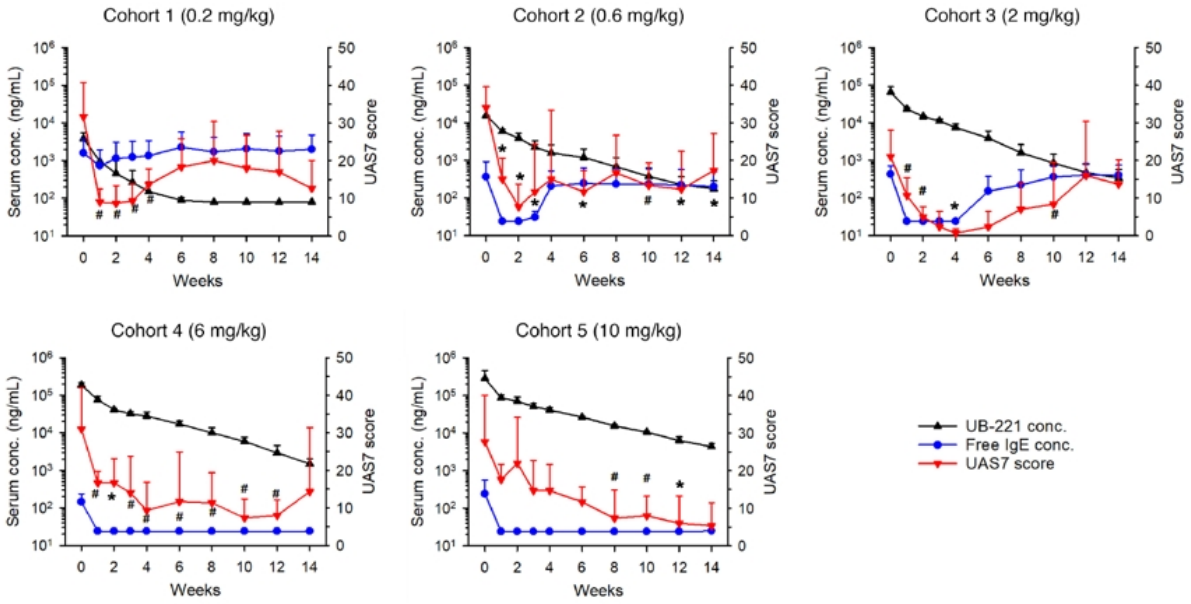
On April 30, 2026, we entered into an exclusive license agreement with Ascendant, to develop, manufacture and commercialize CUE-221. IgE-mediated allergic diseases remain an area of significant unmet medical need, as many patients continue to experience persistent symptoms despite available therapies. In addition, approved treatments directly targeting IgE remain limited.

CUE-221's mechanism of action is marked by two key receptors with which IgE interacts, shown in the figure below. The high-affinity receptor, or FcεRI, is expressed on mast cells and basophils and eosinophils. When IgE binds to the high-affinity receptor and is cross-linked by an allergen, it triggers cell activation and degranulation, leading to allergic responses, including severe reactions such as anaphylaxis. As a result, this is the pathway that most anti-IgE therapies are designed to block. The low-affinity receptor, or FcεRII, also known as CD23, plays an important regulatory role in IgE biology. Under conditions of elevated IgE, signaling through the low-affinity receptor expressed at the surface of B-cells acts as a natural negative feedback mechanism that helps suppress further production of new IgE.

Omalizumab blocks IgE interactions with the high-affinity receptor (FcεRI) to neutralize IgE but Omalizumab-IgE complexes cannot bind to the low-affinity receptor (CD23). In contrast, CUE-221 was designed with the goal that CUE-221-IgE complexes block binding to the high-affinity receptor (FcεRI) while preserving IgE engagement with CD23, thereby helping to suppress further production of new IgE. CUE-221 thus has the potential to enable deeper and more sustained control of free IgE levels, and therefore of allergic conditions.



Under Ascendant, CUE-221 properties were assessed in a Phase 1 single-ascending dose clinical trial in CSU patients. Pre-clinical experiments and results from the Phase 1 clinical trial were published in the Journal of Clinical Investigation in 2022. In the Phase 1 single ascending dose trial, CUE-221 demonstrated a favorable safety and tolerability profile with rapid and durable suppression of free IgE for longer than twelve weeks with a single ≥ 6 mg/kg dose administered intravenously, as shown in the figures below, consistent with its dual mechanism of action.



On September 20, 2026, we announced positive topline data from a Phase 2 clinical trial of CUE-221 in CSU, conducted in China by Genesis Life Sciences, an affiliate of Ascendant . This Phase 2 clinical trial enrolled 145 participants with moderate to severe CSU whose disease remained inadequately controlled despite treatment with H1 antihistamines.

The Phase 2 multicenter, randomized, double-blind, placebo and active comparator-controlled study was conducted in China and included a 16-week treatment period with a 20-week follow-up period post-treatment. Patients were randomized in a 2:2:2:1:1 ratio across five treatment groups to either subcutaneously deliver CUE-221 at 4 mg/kg, 2 mg/kg, or 1 mg/kg Q4W, or placebo Q4W, or omalizumab 300 mg Q4W. The primary endpoint was the proportion of patients who achieved HSS7=0 at week 12. A key secondary endpoint assessed complete response, defined as the proportion of patients who achieved UAS7=0 at week 12. The study was designed to test superiority over placebo. Omalizumab was included to enable comparative efficacy without planned statistical testing.

The primary endpoint of percentage of patients with HSS7=0 at week 12 was dose-responsive and met at all dose levels. The key secondary endpoint of percentage of patients with UAS7=0 at week 12 was dose-responsive and met statistical significance at the 4 mg/kg highest dose level.

Primary Endpoint of HSS7=0 at Week 12

	CUE-221 (Q4W)			Placebo Q4W	Omalizumab Q4W
	4 mg/kg (N=35)	2 mg/kg (N=36)	1 mg/kg (N=37)	(N=18)	300 mg (N=17)
Complete Resolution of Hives (HSS7=0)	54%	53%	43%	11%	41%
95% Confidence Interval	(37%, 71%)	(36%, 70%)	(27%, 61%)	(1%, 35%)	(18%, 67%)
P-values (vs placebo)	**$p < 0.005$**	**$p < 0.005$**	**$p < 0.05$**	NA	Not Tested

P-values based on Fisher's exact test; Clopper-Pearson 95% confidence interval

Key Secondary Endpoint of UAS7=0 at Week 12

	CUE-221 (Q4W)			Placebo Q4W	Omalizumab Q4W
	4 mg/kg (N=35)	2 mg/kg (N=36)	1 mg/kg (N=37)	N=18	300 mg (N=17)
Complete Response (UAS7=0)	46%*	39%	38%	11%	29%
95% Confidence Interval	(29%, 63%)	(23%, 57%)	(23%, 55%)	(1%, 35%)	(10%, 56%)

* p<0.05 P-values based on Fisher's exact test; Clopper-Pearson 95% confidence interval

The percentage of participants who achieved HSS7=0 further increased beyond the week 12 primary endpoint, peaking at week 22 across all CUE-221 dose groups. After a last dose was administered for all groups at Week 16, clinically meaningful benefit was maintained for up to 12 weeks off treatment (through week 28) at the 4 mg/kg dose level. A higher rate of complete resolution of hives was observed for the 4 mg/kg dose group relative to the lower dose groups and placebo, and post hoc analysis at Week 28 demonstrated a statistically significant difference versus omalizumab (delta = 36%, p<0.05), supporting the premise of fundamental difference between CUE-221 and omalizumab with respect to impacts on disease biology.

Complete Resolutions of Hives at Primary Endpoint, Peak Effect, and 12 Weeks Off Drug

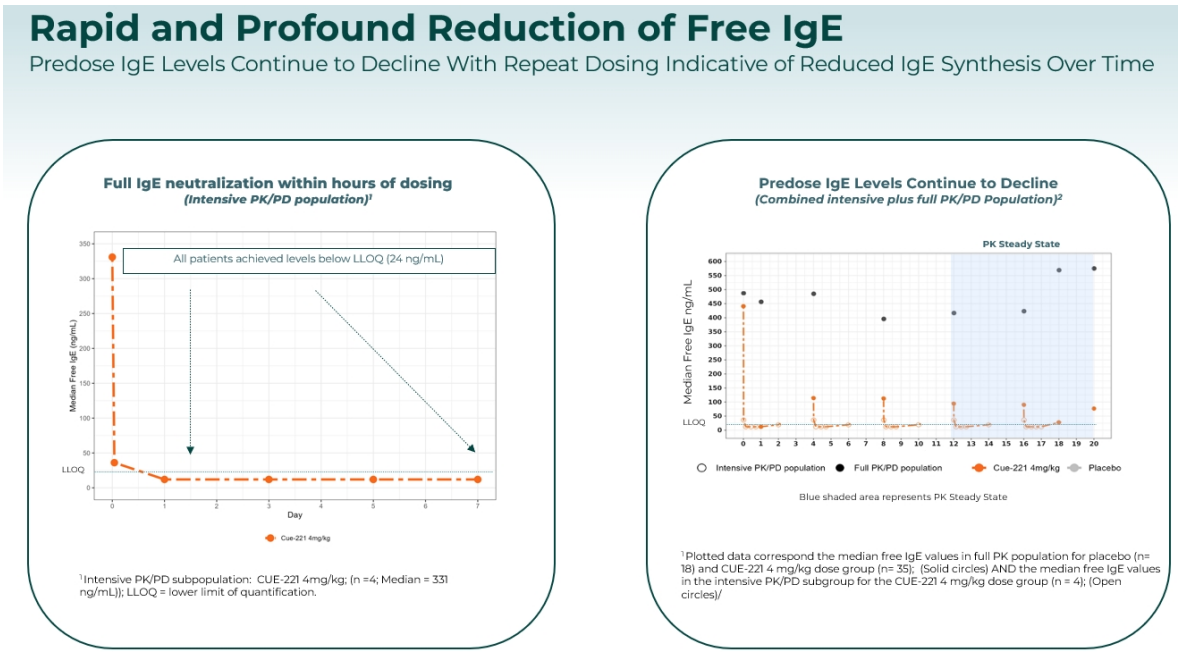
	CUE-221 (Q4W)			Placebo Q4W	Omalizumab Q4W	CUE 4mg/kg vs. Omalizumab
Time	4 mg/kg	2mg/kg	1 mg/kg	Placebo	300 mg	Δ in Percent
Week 12 *Primary*	54%	53%	43%	11%	41%	13%
Week 22 *Peak Effect*	69%	61%	57%	11%	41%	28%
Week 28 *12 weeks off drug*	60%	31%	24%	11%	24%	**36%***

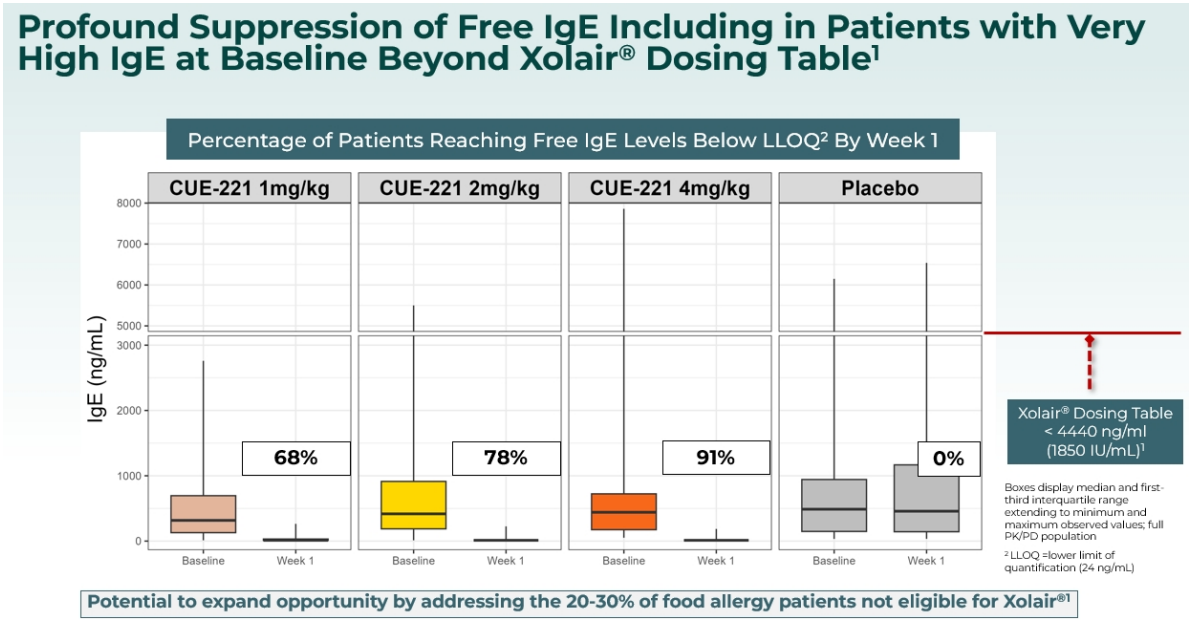
* p<0.05 P-values based on Fisher's exact test

This observed durable clinical benefit (HSS7=0) at week 28 (12 weeks after the last dose) in the 4mg/kg dose group persisted in the absence of clinically meaningful drug exposure, was not observed at lower doses, and was significantly greater than XOLAIR® (omalizumab) in a post-hoc analysis, implicating biological effects beyond IgE neutralization alone. These findings are consistent with CUE-221's dual mechanism of action designed to both neutralize IgE and prevent the synthesis of new IgE.

The study enrolled patients across a broad range of baseline IgE (median of 427 ng/mL [178 IU/mL], range 24 ng/mL to 7860, ng/mL), with approximately one-third having IgE ≥ 720 ng/mL (300 IU/mL).

CUE-221 demonstrated rapid, profound, dose-responsive free IgE suppression. At 4 mg/kg, all patients in the intensive PK subgroup achieved levels below the limit of quantification within hours of dosing with >91% of the overall population achieving these levels at the first post-dose assessment at week 1, including patients with baseline IgE exceeding the XOLAIR® food allergy dosing table. Median free IgE rose at the end of each 4-week dosing interval (26% of baseline at the end of the first dosing interval), with extent of return progressively diminishing at the end of each subsequent dosing interval.





In a prespecified subgroup analysis of patients with high baseline IgE ≥ 300 IU/mL, 78% of patients receiving 4 mg/kg achieved complete hive resolution (HSS7=0) at week 12 versus 0% with placebo ($P < 0.005$). A subsequent post-hoc analysis also demonstrated a statistically significant higher complete response (UAS7=0) rate of 67% versus 0% with placebo ($p < 0.05$), suggesting that baseline IgE may predict response in CSU and highlighting the clinical potential of CUE-221 in patients with high baseline IgE across disease states, including food allergy.

Demographics and baseline disease characteristics were generally well balanced across treatment groups. CUE-221 demonstrated a favorable safety profile. There were no treatment-related serious adverse events and no cases of hypersensitivity reactions including anaphylaxis. Injection site reactions (ISR) were infrequent, only one ISR was > grade 1, and none led to study discontinuation.

Collectively, the Phase 1 and Phase 2 CSU studies demonstrated favorable safety and tolerability, up to 10 mg/kg. No neutralizing antibodies have been observed. The phase 2 study identified 4 mg/kg as the dose at which differentiated clinical benefit emerged relative to lower doses and XOLAIR®. These findings, together with approximately 50% subcutaneous bioavailability compared with IV, enable exploration of higher exposures aimed at maximizing efficacy in CSU and expanding the addressable food allergy population to include the 20-30% of patients currently ineligible for treatment with XOLAIR®.

We believe these findings support continued clinical development of CUE-221 as a product candidate for food allergy and CSU. Our IND application for food allergy has been cleared by the FDA, enabling advancement of our clinical development program.

Food Allergy Overview

Food allergy is a significant and growing health problem in the United States, Europe and throughout the developed world. It is estimated that approximately 33 million Americans have been diagnosed with a food allergy, representing 1 in 10 adults and 1 in 13 children. Approximately 51% of food-allergic adults and 42% of food-allergic children in the United States have experienced a severe reaction from their food allergy. We believe the unmet need in food allergy is expanding, as claim lines with diagnoses of anaphylactic food reactions increased 377% between 2007 and 2016. Omalizumab, marketed as XOLAIR®, Novartis AG, was the first anti-IgE therapy approved by the FDA for food allergy, in early 2024, and has since experienced significant sales growth and a rapidly increasing number of treated patients, despite its FDA-approved dosing matrix that requires a patient's baseline body weight and total IgE levels. As a result, a significant portion of patients with severe allergic diseases are excluded from treatment because they fall outside of the recommended dosing range. We believe this demonstrates demand for anti-IgE therapy in this indication as well as the significant unmet need that remains.

Food allergy occurs when the immune system responds to a harmless food as if it were a threat. In a non-allergic patient, tolerance for food proteins develops early in life and the immune cells do not mount a response when food proteins are detected. In an allergic patient, the immune system is sensitized to one or more food proteins, or allergens ("sensitization" phase). As a result of this sensitization, the patient's immune system produces IgE antibodies, which are directed against that particular allergen. The IgE antibodies bind to mast cells and basophils via its receptor called FcεRI. When an IgE antibody bound to these immune cells encounters the allergen, it is directed against, the mast cells and basophils are activated and release histamine and other inflammatory mediators which then provoke the symptoms of an allergic reaction ("effector" phase). Symptoms may include hives, swelling, vomiting, abdominal pain, wheezing, breathlessness and lowered blood pressure. Allergic reactions can be triggered by exposure to minute quantities of the relevant food allergen and can be painful, frightening and potentially deadly. Severe and potentially life-threatening reactions are referred to as anaphylaxis, and such reactions require urgent medical attention and often result in treatment at hospital emergency departments.

The most common approach to manage food allergy is strict avoidance of food allergens and emergency treatment of allergy symptoms in the event of an accidental exposure. Strict avoidance can be difficult to achieve and the burdens of practicing avoidance can have a substantial negative impact on the quality of life of food-allergic patients and their families. Moreover, accidental exposures, especially in children, remain a common issue, and food-allergic patients typically must carry rescue medication to treat severe and possibly life-threatening allergic reactions. The most widely used rescue medication is epinephrine, which blunts certain symptoms of the allergic reaction but does not treat the allergic reaction itself. While epinephrine is useful as a rescue medication, it may not be sufficient to counteract the effects of the allergic reaction.

Desensitization therapy, which consists of repeated administrations of increasing quantities of an allergen in order to decrease the immune response to that allergen, is the most common proactive approach to treating food allergy. Of note, this approach is specific for a given food allergen (e.g. peanuts) and, as patients are often sensitized to more than one food allergen, this will make the desensitization approach more complex. Oral immunotherapy, or OIT, which involves the oral consumption of increasing doses of a food-based product on a daily basis over a period of months, has the potential to produce a high degree of desensitization and a proprietary form of OIT, Palforzia®, is approved in the United States and the European Union for the treatment of peanut allergy in children aged 4-17 years. OIT, however, has a number of limitations, such as a relatively high rate of systemic side effects, limitations it places on many activities of daily living, including exercise, and unpredictability of tolerance in the setting of intercurrent illness. Palforzia® (Société des Produits Nestlé S.A.) was withdrawn from the United States market in July 2026 and is in the process of being withdrawn globally.

Other desensitization approaches under clinical investigation include sublingual immunotherapy, or SLIT, which involves the administration of increasing amounts of food extract under a patient's tongue, and epicutaneous immunotherapy, or EPIT, which involves the use of a patch that causes allergens to be absorbed by the skin to initiate desensitization. Both

SLIT and EPIT approaches have shown some clinical success with less severe side effect profiles compared to OIT; like OIT, however, they generally are specific to a single food allergen.

Anti-IgE therapy aimed at blocking the binding of IgE to mast cells and basophils is another therapeutic approach. The anti-IgE antibody omalizumab was recently approved by the FDA for the reduction of allergic reactions, including anaphylaxis, that may occur upon accidental exposure to one or more foods in patients with IgE-mediated food allergy. Anti-IgE mAbs such as omalizumab bind to IgE, eliminating most of the IgE in the systemic circulation and preventing IgE from binding to mast cells and basophils. Omalizumab reduces the availability of all IgE, not just IgE that recognize a specific allergen, so omalizumab can block reactions to multiple food allergens.

A significant unmet need remains in food allergy for complete, sustained protection against clinically meaningful allergen exposure. The rapid, profound IgE suppression observed in the CUE-221 Phase 2 CSU study, together with its dual mechanism of action, supports its potential to protect against higher amounts of food allergens and extend treatment to patients whose baseline IgE exceeds the range covered by the Xolair® food allergy dosing table.

Chronic Spontaneous Urticaria Overview

CSU is one of a group of skin conditions that are characterized by hives, redness, itching and swelling, lasting for greater than six weeks. The trigger for CSU is unknown. Symptoms result from the degranulation of dermal mast cells and IgE signaling likely contributes to inappropriate mast cell activation. CSU affects 1% of the general population, with women affected more often than men. Though both children and adults can be diagnosed with CSU, patients typically show initial symptoms in the third to fifth decades of life.

Current treatment guidelines for CSU recommend the use of oral H1-antihistamines as a first-line therapy, with dose escalation of up to four times the standard dose in patients with insufficient response. Overall, less than 10% of CSU patients reach compete control with H1-antihistamines and can be prescribed omalizumab, with less than 50% reaching complete disease control. A significant unmet need remains in CSU. Results from the Phase 2 CSU study show that CUE-221 has the potential to increase the proportion of patients achieving complete disease control beyond that seen with omalizumab. With efficacy not yet plateauing, extended treatment and higher doses could further improve response rates, transforming CSU care and expand the treatment market.

CUE-401

In autoimmune disease, regulatory T cells, or Tregs, are the master regulators of maintaining immune homeostasis, or balance, and health. Autoreactive T cells, referred to as T effector cells, or Teff cells, are reactive against “self” proteins and foster inflammation and induce chronic tissue damage. Tregs are important to maintaining immune balance in that they possess the ability to “regulate” (hence their name), dampen and control the Teff cells.

Our lead candidate, CUE-401, is a bispecific fusion protein designed to promote immune tolerance by modulating key components of the immune system, including the induction of newly formed (induced) Tregs, or iTregs, from Teff cells, the expansion of existing or natural regulatory T cells, or nTregs, and the reduction of pro-inflammatory autoreactive cells. Through the co-activity of engineered variants of TGF-β and IL-2, CUE-401 has the therapeutic potential to re-establish immune balance and induce tolerance across a range of T cell mediated autoimmune and inflammatory diseases.

CUE-401 has been engineered to harness the capacity of TGF-β, in concert with the complementary signaling of IL-2, to induce peripheral Tregs which we believe will provide long-lasting tolerance, the ultimate goal for treating autoimmune diseases. This novel design provides for “conditional binding” to help avoid off target activity and has generated highly positive data in multiple preclinical autoimmune animal disease models.

In these preclinical animal models, CUE-401 behaves as a master switch to reduce inflammation and pro-inflammatory cells, as well as convert autoreactive Teff cells into iTregs, which express FOXP3, the hallmark transcription factor that characterizes stable Tregs. These findings suggest that CUE-401 acts by establishing a “tolerance positive feedback loop” that not only increases nonspecific Treg populations (natural Tregs) but also reduces and converts specific autoreactive T cells into trans-differentiated iTregs that are specific to the disease-causing autoantigens.

We believe these results, along with advances in the manufacturing of CUE-401, have substantially reduced the risk profile for the development of this program, and we have submitted IND to the FDA and plan to begin a Phase 1 study of CUE-401 by the end of 2026. Our Phase 1 trial for CUE-401 will consist of a two-part study, comprised of a single ascending

dose and a multiple ascending dose in healthy volunteers, further including cohort(s) of atopic dermatitis patients. We anticipate that these early clinical trial results will provide pharmacokinetic and pharmacodynamic evidence, emerging evidence of clinical impact in an autoimmune disease, and further support the underlying premise of establishing immune balance and inducing durable immune tolerance with CUE-401. We believe this could represent a potential breakthrough as a new standard of care in multiple autoimmune disease indications.

Our Partnered Programs

CUE-500 Series

The CUE-500 series has been developed to enable targeted anti-viral T cell-mediated depletion of pathogenic cell types, including autoreactive B cells. We believe these biologics have the potential to achieve immune balance in autoimmune patients and are significantly differentiated from other competing approaches such as bifunctional antibody drug conjugates, pan-T cell engagers, IL-2 muteins, TNFR2 agonists, and CAR-T therapies.

The CUE-500 series represents a novel approach to selectively target disease-causing cells by redirecting existing anti-viral memory T cells to target and deplete such disease-causing cells. CUE-501, for which we entered into a collaboration and license agreement with Boehringer Ingelheim International GmbH, or BI, in April 2025, is being developed to target and deplete autoimmune disease-causing B cells, in patients with autoimmune disease caused by autoreactive, pathogenic B cells. Targeted B cell depletion is widely recognized in the industry as a clinically validated and important approach for the treatment of B cell mediated autoimmune and inflammatory diseases, and we believe the selective mechanism of action exploiting the anti-viral memory T cell repertoire will provide highly effective killing of the targeted cells while preventing or substantially reducing the side effect profile often experienced with competing approaches.

Due to its modularity, we believe that the CUE-500 series has therapeutic potential across multiple disease areas. The mode of redirecting a defined population of already existing anti-viral T cells may apply to many pathogenic cell types readily addressed by swapping different cell-targeting antibody domains into the CUE-500 series framework.

We believe the preclinical data generated to date for CUE-401 and the CUE-500 series demonstrates the intended mechanistic effect of these novel approaches for the potential treatment of autoimmune disease, and each represents potential breakthrough therapeutic opportunities for significant patient populations and potential near-term value creation opportunities for our shareholders.

CUE-100 Series

Historically, we primarily focused our resources on the development of our CUE-100 series for oncology, namely the CUE-101 and CUE-102 drug product candidates, which are representative of our approach to selectively activate targeted CD8+ T cells against cancer, both of which have been licensed to ImmunoScape Pte. Ltd., or IMSCP, to advance a novel in vivo approach to cell therapy for the treatment of solid tumors. Under our Collaboration and License Agreement with IMSCP, IMSCP is developing a novel Seed-and-Boost immunotherapy that combines our clinically validated Immuno-STAT T-cell engagers, the CUE-100 series, with TCR-T cells that comprise IMSCP's proprietary tumor-specific T cell receptors, or TCRs. The combination therapy is designed to overcome core limitations of existing cell therapies and to potentially establish a new standard of care with superior anti-tumor activity, durable T cell persistence and product scalability.

Our License Agreement with Ascendant Health

On April 30, 2026, we entered into a License Agreement, as amended on August 14, 2026, or the Ascendant License Agreement, with Ascendant Health Sciences Ltd., a Cayman Limited Company, or the Licensor. Pursuant to the Ascendant License Agreement and subject to certain rights retained by the Licensor, the Licensor granted the Company: (1) the exclusive and sublicensable rights to develop, manufacture, commercialize and otherwise exploit the Licensor's anti-IgE monoclonal antibody known as Ascendant-221, which was formerly known as UB-221 (together with certain related molecules, the Licensed Molecules) and products containing a Licensed Molecule, (the Licensed Products) throughout the world (except the mainland of China, Hong Kong, Macau and Taiwan (together, the Ascendant Territory)) (such territory of the Company, the Cue Territory) for any and all uses; and (2) the non-exclusive and sublicensable rights to manufacture the Licensed Molecules and Licensed Products in the Ascendant Territory (other than China) solely for the purposes of developing and commercializing the Licensed Molecules and Licensed Products in the Cue Territory.

As consideration for the rights granted to the Company by the Licensor, the Company paid the Licensor $15.0 million as the upfront payment and agreed to pay up to an aggregate of $676.5 million in additional potential milestone payments, and

tiered royalty payments (at percentages ranging from high single-digit to low double-digit) on future net sales of Licensed Products. The additional milestone payments include $5.0 million upon the completion of manufacturing technology transfer, $6.5 million upon the completion of data and know-how transfer, up to $205.0 million upon the achievement of specified development and regulatory milestone events, including upon receipt of threshold data from a specified Phase 2 clinical trial (the Phase 2 Milestone), and up to $460.0 million upon the achievement of specified commercial milestone events. In the event the Company grants a sublicense of its rights under the Ascendant License Agreement within the first 18 months after the effective date of the Ascendant License Agreement, certain sublicensing revenues received by the Company will be shared with Licensor at specified percentages between 20% and 40% for a period of up to 18 months after the effective date. In addition, in the event of a specified change of control transaction with respect to the Company within the first 18 months after the effective date of the Ascendant License Agreement, certain milestone payments will accelerate, in an amount up to $215.0 million.

Under the Ascendant License Agreement, royalty payments will be payable on a product-by-product and country-by-country basis outside of the Ascendant Territory during the period commencing on the first commercial sale and continuing until the later of: (a) the 10-year anniversary of the date of such first commercial sale; (b) the expiration of the relevant patent claims; and (c) the expiration of the relevant regulatory exclusivity (the Royalty Term). Subject to a certain floor, the Company's royalty payments will be reduced by specified percentages for patent expiration, biosimilar entry, payments for third party intellectual property, compulsory sublicenses or drug pricing programs. The Company's royalty payments are also subject to reduction in connection with royalty rates owed to an upstream academic licensor.

The Ascendant License Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the applicable Royalty Term, unless the Ascendant License Agreement is earlier terminated by the Licensor or the Company in accordance with the Ascendant License Agreement. Subject to certain exceptions and requirements, the Ascendant License Agreement may be terminated: by the Company for any or no reason; by a party for the other party's material breach that is not cured within a specified period; by a party for the other party's bankruptcy, insolvency, dissolution, liquidation or winding up; or by the Licensor if the Company does not pay the amounts owed under the Ascendant License Agreement upon achievement of the Phase 2 Milestone within the payment period specified therein, which period may be extended by the Company on a month-to-month basis by making payments to the Licensor of $1.0 million per month for a maximum of six months.

Our License Agreement with Albert Einstein College of Medicine

On January 14, 2015, or the Effective Date, we entered into a license agreement, as amended and restated on July 31, 2017 and as further amended on October 30, 2018, January 13, 2024 and April 10, 2025, or the Einstein License, with Albert Einstein College of Medicine, or Einstein, for certain patent rights, or the Patents, relating to our core technology platform for the engineering of biologics to control T cell activity, precision, immune-modulatory drug product candidates, and two supporting technologies that enable the discovery of costimulatory signaling molecules (ligands) and T cell targeting peptides. We hold an exclusive worldwide license, with the right to sublicense, import, make, have made, use, provide, offer to sell, and sell all products, processes and services that use the Patents, including certain technology received from Einstein related thereto, which we refer to as the Licensed Products.

The Einstein License is a royalty-bearing license obligating us to pay a percentage of proceeds received from sales of categories of Licensed Products at low single digit rates. We have also agreed to share a portion of our proceeds that we derive from other agreements, like sublicense agreements, that we may enter into relating to the Licensed Products. The percentage of such proceeds that we are required to pay Einstein ranges from the low to mid-teens, depending on how far we have developed a Licensed Product before we enter into an agreement relating to the Licensed Product. These percentages are reduced for sales of Licensed Products in countries where a competing product exists and for products or services involving the use or incorporation of technology received from Einstein relating to synapse for targeted T cell activation molecules, receptor ligand identification or platforms for T cell monitoring. In addition to our obligation to pay royalties based upon a percentage of proceeds from sales of Licensed Products, we have also agreed to pay Einstein annual maintenance fees. The maintenance payments are non-refundable, but are creditable against any royalty payments we pay under the Einstein License. For the year ended December 31, 2025, there were no payments related to Einstein license maintenance fees under the Einstein License, as they were creditable against actual payments owed to Einstein during the twelve-month period.

Under the Einstein License, we are also obligated to make milestone payments corresponding to: (i) approval of the first IND by the U.S. Food and Drug Administration, or the FDA, or foreign equivalent for a Licensed Product; (ii) approval of any subsequent IND application or foreign equivalent for a "new indication" for a Licensed Product; (iii) initiation of Phase 2 clinical trials or foreign equivalent on a Licensed Product; (iv) initiation of Phase 2 clinical trials or foreign equivalent for

a “new indication” for a Licensed Product; (v) initiation of Phase 3 clinical trials or foreign equivalent on a Licensed Product; (vi) initiation of Phase 3 clinical trials or foreign equivalent for a “new indication” for a Licensed Product; (vii) the first commercial sale of a Licensed Product; (viii) the first commercial sale of each “new indication” for one of our previously approved Licensed Products; and (ix) cumulative sales of certain Licensed Products reaching certain threshold amounts. The aggregate amount of milestone payments made under the Einstein License may equal up to $1.85 million for each Licensed Product and up to $1.85 million for each new indication of a Licensed Product. Additionally, the aggregate amount of one-time milestone payments based on cumulative sales of all Licensed Products may equal up to $5.75 million. At December 31, 2025, we have made payments totaling $1.2 million since inception with respect to achievement of these milestones.

In addition to our obligations to make the cash payments to Einstein described above, under the Einstein License we issued Einstein 671,572 shares of our Common Stock immediately prior to completion of the initial public offering of our common stock completed on December 27, 2017.

The Einstein License expires upon the expiration of our 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. Under the Einstein License, we will be obligated to make royalty payments to Einstein, with respect to certain Licensed Products, for the longer of 15 years from the first sale of such products in each country or for the duration of any market exclusivity period granted by a regulatory agency for such product and, with respect to certain Licensed Products sold by sublicensees, the longer of 10 years from the first sale of such products in each country or for so long as the sublicensee agrees to pay royalties on such products. We have the right to terminate the Einstein License at any time upon 60 days’ written notice to Einstein; provided, however, that we will lose intellectual property rights related to the Patents if we choose to terminate the Einstein License in this manner. Each party has the right to terminate the Einstein License if the other party is in default or breach of any condition of the Einstein License with a right to cure any such breach within 60 days from receipt of notice of such default or breach, unless the other party has disputed the alleged breach in good faith. Either party can also terminate the Einstein License if the other party voluntarily files for bankruptcy or other similar insolvency proceedings, makes a general assignment for the benefit of creditors, or is the subject of an involuntary bankruptcy petition that is not dismissed within 90 days. If we fail to pay any sum that is due and payable to Einstein within 30 days after receiving written notice of our default from Einstein, then Einstein has the option of terminating the Einstein License unless we pay within 45 days of such notice all delinquent sums with interest.

The Einstein License also obligates us to meet certain due diligence requirements, or the Diligence Milestones, as follows:

- update our research and development plan annually;
- initiate Phase 1 clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase 2 clinical trials on a Licensed Product within a number of years from the Effective Date;
- initiate Phase 3 clinical trials on a Licensed Product or an FDA approved clinical trial designed to support a biologics license application within a number of years from the Effective Date;
- submit an application for FDA approval to market and sell a Licensed Product within a number of years from the Effective Date;
- have our first commercial sale of an FDA Licensed Product within a number of years from the Effective Date; and
- spend a minimum amount per year on product development until our first commercial sale of a Licensed Product.

If we fail to meet any of the Diligence Milestones, Einstein will have the right to terminate the Einstein License if such Diligence Milestone is not satisfied within thirty days from receiving a written notice of default from Einstein. Under certain circumstances and upon prior notice to Einstein, we may have the right to an additional extension of our Diligence Milestones if, despite our commercially reasonable efforts we are not able to satisfy the Phase 3 clinical trial Diligence Milestone or any subsequent Diligence Milestone. As of the date of this report, we have met all required Diligence Milestones.

On April 10, 2025, we entered into an amendment to the Einstein License. Pursuant to the amendment, Einstein consented to our entry into the BI Collaboration and License Agreement (as defined below) and our grant of a sublicense to BI. In addition, we and Einstein agreed to amend certain diligence obligations and specified upstream payment obligations that may be owed to Einstein by us, solely in connection with the sublicense to BI. In the second quarter of 2025, we paid Einstein $0.9 million in fees in relation to our grant of the sublicense of the Einstein License to BI.

Our Collaboration Agreement with LG Chem

On November 6, 2018, we entered into a Collaboration, License and Option Agreement, as amended from time to time, or the LG Chem Collaboration Agreement, with LG Chem Ltd., or LG Chem, pertaining to the development of CUE-101 and CUE-102 Immuno-STATs in Australia and in certain countries in Asia, or the LG Chem Territory.

In furtherance of pursuing strategic options pertaining to CUE-101, on March 11, 2025, we regained our rights to the LG Chem Territory for the CUE-101 program, which had previously been licensed to LG Chem, and LG Chem terminated all of its rights to the same program. We also agreed to make future payments to LG Chem, if and when one or more potential scenarios related to the CUE-101 program occur, up to a predetermined aggregate amount.

On April 13, 2026, LG Chem sent us a notice of termination of the LG Chem Collaboration Agreement with respect to the CUE-102 Program targeting WT1 expressing cancers and the CUE-103 Program (which was never initiated), effective sixty (60) days from the date of the notice of termination. Cue and LG Chem are currently negotiating a final amendment relating to certain LG Chem rights in the LG Chem Territory.

Our Collaboration and Option Agreement with Ono Pharmaceutical

Effective March 6, 2025, we regained worldwide development and commercialization rights for CUE-401, which had previously been licensed to Ono Pharmaceutical pursuant to a Collaboration and Option Agreement entered into in February 2023. Also, see discussion our License Agreements in the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Reports on form 10-Q for the quarters ended March 31, 2026 and June 30, 2026.

Our Collaboration and License Agreement with Boehringer Ingelheim International

On April 10, 2025, we entered into a Collaboration and License Agreement, or the BI Collaboration and License Agreement, with BI to research, develop and commercialize differentiated B cell depletion molecules, including CUE-501.

Under the terms of the BI Collaboration and License Agreement, we and BI will conduct collaborative research focused on CUE-501 during a four-year period or, if earlier, the completion of activities under the research plans, or the BI Research Term. In addition to, or instead of, CUE-501, BI may elect, at its sole discretion, to include additional or alternative compounds targeted at B cell depletion. BI will have an exclusive, royalty-bearing, worldwide, sublicensable license, under our applicable patents and know-how, to develop, manufacture and commercialize such compounds and their derivatives, or BI Licensed Products, for all uses, and BI shall be responsible for all further research, preclinical and clinical development, manufacturing, regulatory approvals, and commercialization of BI Licensed Products at its expense. During the BI Research Term, we are prohibited from developing or commercializing any molecule for applications in B cell depletion. We executed an amendment to the BI Collaboration and License Agreement, effective May 29, 2026, under which Cue will perform additional research activities for BI. Also, see discussion our License Agreements in the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Reports on form 10-Q for the quarters ended March 31, 2026 and June 30, 2026.

Our Collaboration and License Agreement with ImmunoScape

On November 6, 2025, IMSCP exercised its option, or the Option, to obtain licenses to research, develop and commercialize molecules from our CUE-100 series, including CUE-101 and CUE-102, subject to certain exclusions, for all oncology indications pursuant to a Collaboration and License Agreement, effective November 6, 2025, between us and IMSCP, or the IMSCP Collaboration and License Agreement. The licenses provided pursuant to the IMSCP Collaboration and License Agreement include a co-exclusive development license for five years or, if longer, for so long as IMSCP has a specified number of CUE-100 series molecules under active development and, pursuant to which, we retain non-exclusive research rights to support our other programs, or the co-exclusive development license. We also retain our rights to the CUE-100 series, including CUE-101 and CUE-102, for use in any manner other than as a component of a cell therapy product for 18 months past the effective date of the IMSCP Collaboration and License Agreement. The licenses also include an exclusive commercial license to IMSCP for any CUE-100 series molecule that IMSCP advances to IND-enabling studies while the co-exclusive development license is in effect. The licensed series of molecules will be further developed and potentially commercialized by IMSCP. The Option was exercised pursuant to an Option Agreement between us and IMSCP, dated October 22, 2025, or the Option Agreement. In connection with entry into the Option Agreement and IMSCP's exercise of the Option, we received an aggregate of $9.5 million, net of withholding taxes, in the fourth quarter of 2025 and were entitled to

receive an additional $5.0 million before the first anniversary of the effective date of the IMSCP Collaboration and License Agreement.

On November 6, 2026, the Company and IMSCP entered into a Second Amendment to the IMSCP Collaboration and License Agreement (the "Second Amendment"), pursuant to which, among other things, the Company's right to receive the additional $5.0 million payment was amended such that the Company is entitled to receive a $5.5 million payment from IMSCP as follows: (a) $3.0 million on or before November 27, 2026, (b) $1.5 million on or before July 30, 2027, and (c) $1.0 million on or before November 27, 2027. Pursuant to the IMSCP Collaboration and License Agreement (after giving effect to the Second Amendment), the Company (a) received equity of IMSCP equal to 40% of the issued and outstanding equity of IMSCP and is entitled to receive additional equity, in the form of warrants, upon certain dilution events in the future, (b) received time-based payments of $10.0 million in the fourth quarter of 2025, (c) is entitled to receive an additional time-based payment of $5.5 million (as described above), and (d) is entitled to receive high single-digit royalties on global net sales and low- to mid-double digit royalties from sublicensing royalties and income. The IMSCP Collaboration and License Agreement includes customary termination provisions, including IMSCP's ability to terminate the agreement in its entirety on 60 days' advanced written notice to the Company.

Also, see discussion our License Agreements in the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Reports on form 10-Q for the quarters ended March 31, 2026, June 30, 2026 and September 30, 2026.

Our Intellectual Property

We believe that our current patents and patent applications and any future patents and other proprietary rights that we own, or control through licensing, are and will be essential to our business. We believe that these intellectual property rights will affect our ability to compete effectively with others. We also rely and will rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants, advisors and other parties. Our success will depend in part on our ability, and the ability of our licensors, to obtain, maintain (including making periodic filings and payments) and enforce patent protection for our/their intellectual property, including those patents and patent applications to which we have secured exclusive rights.

As of September 18, 2026, we owned or had in-licensed 202 issued patents (including 34 issued U.S. patents), and 226 pending patent applications, including 58 U.S. utility applications, 1 U.S. provisional application, 9 PCT (international) applications, and 158 foreign patent applications.

Our owned and licensed patents and patent applications describe certain features of our technologies, including, CUE-221, our Immuno-STAT platform, our Neo-STAT platform, CAR-T and ex-vivo applications of our Immuno-STAT platform, our RDI-STAT platform, our CUE-300 Series platform, including CUE-301, our CUE-400 Series platform, including CUE-401, as well as specific biologic molecules, drug product candidates and methods of treatment using our Immuno-STATs. In addition, we have pending applications that cover CUE-501 and the CUE-500 series and their use in oncology and autoimmune indications. We plan to spend considerable resources and focus in the future on obtaining U.S. and foreign patents. We have and will continue to actively protect our intellectual property. No assurances can be given that any of our patent applications will result in the issuance of a patent or that the examination process will not require us to narrow our claims. In addition, any issued patents may be contested, circumvented, found unenforceable or invalid, and we may not be able to successfully enforce our patent rights against third parties. No assurance can be given that others will not independently develop a similar or competing technology or design around any patents that may be issued to us. We intend to expand our international operations in the future and our patent portfolio, copyright, trademark and trade secret protections may not be available or may be limited in foreign countries.

Each of our patents, if and when granted, will generally have a term of 20 years from its respective U.S. or international non-provisional priority filing date, subject to available extensions. They are thus set to expire no earlier than dates ranging from 2033 to 2046, although patents that specifically cover our drug product candidates will expire no earlier than June 2035, subject to available extensions.

Competition

CUE-221 is a humanized anti-IgE IgG1 monoclonal antibody intended to treat allergic diseases, including food allergy and CSU. If approved for food allergy, we could face branded competition from omalizumab (XOLAIR®). In addition, Omlyco® is an omalizumab biosimilar approved by FDA and it is likely that other omalizumab biosimilars will become available before CUE-221 is approved. There are several companies developing anti-IgE treatments that may be approved for food allergy and CSU, including GSK and LongBio Pharma. Additionally, some food allergen specific immunotherapies are currently in development and may be approved. If approved for CSU, we could face branded competition from omalizumab, as well as biosimilars. There are several large and specialty pharmaceutical companies, as well as biotechnology companies, with products in late-stage clinical development for CSU, including Sanofi, Novartis, Otsuka, and Celldex.

Our Immuno-STAT platform offers a differentiated approach by targeting disease-relevant T cells without inducing systemic toxicity seen in traditional immunotherapies. While we believe that our drug product candidates, technology, knowledge and experience provide us with significant competitive advantages, we face substantial competition from many different sources, including established and emerging pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others, who may have drug product candidates in further stages of development than ours.

We also compete with other companies working to develop cytokines to restore immune balance, as well as those developing other therapeutic modalities, including monoclonal antibodies, bi-specific antibodies, cell therapies, and vaccines with application in treating patients living with autoimmune disease. Potential competitors in the cytokine-based therapy space include Amgen, Bristol-Myers Squibb, Merck & Co., Nektar Therapeutics, Sanofi S.A., TRex Bio, and RegCell, Inc. In the regulatory T cell therapies space, potential competitors include Coya Therapeutics, Quell Therapeutics, EVOQ Therapeutics, and Sonoma Biotherapeutics.

We believe that our approach provides us with a superior competitive advantage and differentiation, with a potentially first-in-class, bifunctional TGF-β and IL-2 designed to address the underlying mechanism of disease by rebalancing the Treg and effector cell ratio.

Many of our competitors have greater financial, technical and human resources than we do. Additionally, many competitors have greater experience in product discovery and development, obtaining FDA and other regulatory approvals, and commercialization capabilities, which may provide them with a competitive advantage. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trials sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We expect any drug product candidate that we commercialize, either independently or with our strategic partners, will compete with existing, market-leading products and believe that our ability to compete will depend on our ability to execute on the following objectives:

- design, develop and commercialize products that are superior to other products in the market in terms of, among other things, safety, efficacy, convenience, or price;
- obtain patent and/or other proprietary protection for our processes and drug product candidates;
- obtain required regulatory approvals;
- obtain favorable reimbursement, formulary and guideline status; and
- collaborate with others in the design, development and commercialization of our products.

Established competitors may invest heavily to discover and develop novel compounds that could make our drug product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to obtain approval, to overcome price competition and to be commercially successful, if approved. If we are not able to compete effectively, our business will not grow and our financial condition and operations will suffer.

Government Regulation and Licensure of Products

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources and may have a significant impact on our business.

Licensure and Regulation of Biologics in the United States

In the United States, our drug product candidates are regulated as biological products, or biologics, under the Public Health Service Act, or the PHSA, and the Federal Food, Drug and Cosmetic Act, or the FDCA, and their implementing regulations and guidance. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. The failure to comply with the applicable U.S. requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may subject a sponsor to delays in the conduct of the study, regulatory review and approval, and/or administrative or judicial sanctions. A sponsor seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests or studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations and standards and other applicable regulations;
- completion of the manufacture, under current Good Manufacturing Practices, or GMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- design of a clinical protocol and submission to the FDA of an investigational new drug application, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with current Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a biologics license application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with GMP requirements and to assure that the chemistry, methods, and controls, or CMC, for the product are adequate to preserve the product's identity, strength, quality, and purity, and, if applicable, the FDA's current good tissue practice for the use of human cellular and tissue products;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCPs and the integrity of clinical data in support of the BLA;
- payment of substantial application and program fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- securing FDA approval of the BLA and licensure of the new biologic product allowing marketing in the United States for particular indications and under certain conditions; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Nonclinical Studies

Before testing any biologic product candidate in humans, a product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal or other nonclinical studies. These studies are generally referred to as IND-enabling studies. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act, if applicable. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

The IND Process

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin or recommence.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period or following commencement of the clinical trial, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or CMC. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing planned clinical studies in a timely manner.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. The IRB or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Sponsors, IRBs, clinical trial sites, and investigators are subject to GCP bioresearch monitoring inspections by the FDA.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee, or DMC. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on certain available data from the study to which only the DMC has access. Finally, research activities involving infectious agents, hazardous chemicals, recombinant DNA, and genetically altered organisms and agents may be subject to review and approval of an Institutional Biosafety Committee in accordance with U.S. National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.
- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is *potentially* effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such trials are typically referred to as Phase 4 or post-approval clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any post-approval clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting post-approval clinical trials could result in withdrawal of approval for products.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to public notification of noncompliance, civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

Clinical Studies Outside the United States in Support of FDA Approval

In connection with our clinical development program, we may conduct trials at sites outside the United States. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of U.S. approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be

considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. The FDA has signaled that foreign GCP inspections will be increasing alongside greater transparency of GCP inspection outcomes.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Interactions with FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report, or DSUR. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other trials or nonclinical or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-BLA meetings, as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues, which should be limited to no more than two focused topics and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

At the conclusion of these meetings, the FDA will typically provide its responses to questions posed by the sponsor regarding the clinical development program. The FDA will not indicate whether a BLA will be approved, but it will provide guidance to the sponsor on various questions, including whether an application should be submitted in the first place on the basis of the studies and data proposed by the sponsor. The agency may also generally express support for the sponsor's approach in the clinical development program but indicate that questions concerning whether the data support approval will be subject to review by the agency following its acceptance for filing of the BLA. The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement thereto must contain data that are adequate to assess the safety, potency and purity of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation.

Compliance with GMP Requirements

The FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with GMPs. The GMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from GMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product.

Submission and Filing for Review of a BLA

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In the event that the FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. The FDA may request additional information and studies, and the application must be resubmitted with the additional information. The resubmitted application is subject to review before the FDA accepts it for filing.

Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the sponsor, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors. While the costs associated with review of an application are typically covered by the PDUFA user fee program, other activities, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes, may impact the FDA's review and approval of marketing applications. Average review times at the agency have fluctuated in recent years, as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical

employees and stop critical activities. In connection with its review of an application, the FDA will typically submit information requests to the applicant and set deadlines for responses thereto. The FDA will also inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with a submission, including component manufacturing, finished product manufacturing and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the data submitted in support of the application. Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Decisions on BLAs

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter, or CRL, or an approval letter. To reach this determination, the FDA must determine whether there is substantial evidence that the product is effective and that expected benefits of the proposed product outweigh its potential risks to patients. This assessment is informed by the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks.

If the application is not approved, the FDA will issue a CRL, which will contain the conditions that must be met in order to secure final approval of the application, and, when possible, will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a CRL may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications.

The FDA may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including post-approval clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries.

The FDA may prevent or limit further marketing of a product based on the results of post-approval studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Review Programs

The FDA is authorized to expedite the review of applications in several ways. None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.
- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. The FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Fast Track Designation.* Product candidates are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, this designation enables a company to petition the FDA to initiate review of sections of a BLA before the application is complete, a process known as rolling review.

Accelerated Approval

Biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post approval regulatory requirements as well as any post approval requirements that the FDA has imposed as part of the approval process. For example, the sponsor will be required to report certain adverse reactions and production problems to the FDA, build and validate interoperable electronic tracing systems, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. Although health care providers may prescribe products for off-label uses in their professional judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the U.S. Department of Justice, or the Office of the Inspector General of the U.S. Department of Health and Human Services, or HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing regulatory exclusivity, including orphan exclusivity, for biologic products. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Regulatory Exclusivity

The Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act, or the BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." To date, the FDA has licensed a number of biosimilar products and interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. An application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly.

Patent Term Restoration and Extension

A patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND clearing the clinical investigation involving human beings and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Federal and State Data Privacy and Security Laws

Under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans, and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes, and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their regulations, including the omnibus final rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements. Finally, both the FTC and HHS's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the U.S. Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

Additionally, in 2018, California enacted legislation that has been dubbed the first "GDPR-like" (referring to the EU General Data Protection Regulation, or GDPR) law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency—the California Privacy Protection Agency—whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering additional laws that will go into effect in 2026 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion

of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

Review, Approval and Regulation of Drug Products in the European Union

To market any product outside of the United States, a sponsor must also comply with numerous regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, a sponsor will need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries , before it can commence clinical trials or marketing of the product in those countries. This process in the EU generally follows the same lines as in the United States and requires the satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication.

Preclinical Studies

Before a product enters clinical testing in the EU, the sponsor must conduct preclinical studies to demonstrate the safety of the investigational product for such clinical testing. These studies must be conducted in compliance with the principles of GLP, as set forth in EU Directive 2004/10/EC. In particular, preclinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with GLP principles, which reflect the requirements of the Organization for Economic Co-operation and Development.

Human Clinical Trials in Support of a Marketing Authorization

Clinical trials in the EU are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the prior Clinical Trials Directive 2001/20/EC, or CTD. The CTR is designed to simplify and streamline the authorization, conduct and transparency of clinical trials in the EU. Specifically, the Regulation, which is directly applicable in all Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned Member State. Individual Member States retain the power to authorize the conduct of clinical trials on their territory.

As in the United States, sponsors conducting certain clinical studies in the EU must post clinical trial information at the CTIS website: https://eudract.ema.europa.eu.

Pediatric Studies

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP), agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. This requirement also applies when a sponsor wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is

in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Marketing Authorization

In the EU, medicinal products can only be commercialized after a related marketing authorization (MA), has been granted. To obtain a marketing authorization, or MA, an applicant must submit a -Marketing Authorization Application ("MAA") either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU Member States, including the decentralized procedure, national procedure, or mutual recognition procedure. An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission, or EC, that is valid throughout the European Economic Area (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for certain types of product candidates, including those (i) derived from certain biotechnological processes, (ii) designated as orphan products, (iii) advanced therapy medicinal products (ATMPs), and (iv) that have a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases . However, the centralized procedure is optional for product candidates with a new active substance indicated for the treatment of other diseases and product candidates that are highly innovative or for which a centralized process is in the interest of patients.

Under the centralized procedure, the EMA's CHMP is responsible for conducting an initial assessment of a product candidate and the data supporting approval of the MAA. The maximum timeframe for the evaluation of an MAA is 210 days, excluding interruptions when additional information or written or oral explanation is to be provided by the sponsor in response to questions from the CHMP. Accelerated evaluation with a time limit of 150 days may be granted by the CHMP in exceptional cases.

On the basis of its review, the CHMP provides a scientific opinion on whether or not an MA should be granted for a product candidate. The EC then decides whether to grant or refuse MA in light of the opinion delivered by the CHMP. .The decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product candidate is applying to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference Member State, or RMS, prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States which, within 90 days of receipt, must decide whether to approve the assessment report. If the relevant EU Member State cannot approve the RMS's assessment report due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the EC, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

Periods of Authorization and Renewals

An MA is initially valid for five years and may be renewed after five years following a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. In connection with seeking a renewal, the MA holder must provide the EMA or the competent authority of the EU Member State with a consolidated version of the version of the Common Technical Document providing up-to-date data in respect of quality, safety and efficacy or the medicine, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The EC or the competent authority of the EU Member State may decide, on justified grounds relating to pharmacovigilance, to proceed with an additional five-year period of MA. Once definitively renewed, the MA shall be valid for an unlimited period. If a renewed MA is not followed by the actual placing of the medicine on the EU market (in the case of the centralized

procedure) or on the market of the authorizing EU Member State within three years after renewal, and is no longer actually present on the applicable market for three consecutive years, the MA ceases to be valid.

Post-Approval and Additional Regulatory Requirements

Following the issuance of an MA for a medicine, the sponsor of the MA is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These requirements include compliance with the EU's stringent pharmacovigilance or safety reporting rules, which may include post-authorization studies and additional monitoring obligations. Further, the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the EC Guidelines for Good Manufacturing Practice, or EU cGMP. These requirements include compliance with the EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.

The advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another.

In addition, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Payments made to physicians and other health care professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with health care professionals may require prior notification or approval by the health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment

Regulatory Exclusivity

New products approved on the basis of a complete data package currently qualify for eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents sponsors that seek MA of generic products from referencing the innovator's data in support of an abbreviated application. During the additional two-year period of market exclusivity, a generic MAA can be submitted and the innovator's data may be referenced in that application, but no generic medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period may be extended to a maximum of 11 years if, during the first eight years of those ten years, the MA holder for the innovative product obtains an authorization for one or more new therapeutic indications which are determined to bring a significant clinical benefit in comparison with existing therapies.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Reform

On December 11, 2025, the European Parliament and Council reached a provisional political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the Pharma Package. The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package—comprised of a new directive and regulation to replace existing legislation—aims to modernize the EU regulatory framework. Following endorsement of the compromise texts by the Council's Committee of Permanent Representatives (COREPER) and approval by the European Parliament's Committee on Public Health (SANT) in March 2026, the proposed revisions must now be formally adopted by the Council of the EU and the European Parliament in plenary, currently anticipated by fall 2026. The reform encompasses a broad range of measures, including changes to regulatory exclusivity, incentives to combat antimicrobial resistance, intellectual property

exemptions for generic medicines, orphan products, and marketing authorization procedures. The new framework is expected to enter into force in late 2026 and to be subject to transitional arrangements, with full application not anticipated before.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the July 2020 CJEU judgement invalidating the so-called EU-U.S. Privacy Shield, the EC adopted an adequacy decision for the EU-U.S. Data Privacy Framework in July 2023. This adequacy decision permits U.S. companies who self-certify under the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the CJEU, C-703/25 P—*Latombe v. Commission*. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the so-called standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any drug product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such drug product candidates. Even if any drug product candidates we may develop are approved, sales of such drug product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such drug product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, drug product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any drug product candidates we may develop could reduce physician utilization of such drug product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future..

Outside the United States, ensuring adequate coverage and payment for any drug product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any drug product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other countries may control the prices of medicinal products for human use or allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations.

In addition, EU Member States often require the completion of additional health technology assessments that compare the cost- effectiveness of a particular product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. At the EU level, on January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation), entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It enables EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may

constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the federal civil monetary penalty and false statement laws and regulations relating to pricing and submission of pricing information for government programs, including penalties for knowingly and intentionally overcharging 340b eligible entities and the submission of false or fraudulent pricing information to government entities;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, or PPACA, as amended by the Health Care Education Reconciliation Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within HHS information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state and local laws require certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. Additionally, some state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. By way of example, the United States and state governments continue to propose and

pass legislation designed to reduce the cost of healthcare. In March 2010, Congress enacted the PPACA, which, among other things, includes changes to the coverage and payment for products under government health care programs.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2032 unless additional congressional action is taken.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In August 2022, Congress enacted the Inflation Reduction Act of 2022, or the IRA, which established the Medicare Drug Price Negotiation Program, authorizing HHS to negotiate maximum fair prices for certain high-expenditure, single-source drugs and biologics covered under Medicare Part B and Part D. A single-source drug generally becomes eligible for selection once it has been approved for at least seven years (small molecules) or licensed for at least eleven years (biologics), and HHS may select up to 20 drugs annually for negotiation, with negotiated prices for each selection cycle taking effect approximately two years after selection; negotiated prices for the first selected drugs took effect on January 1, 2026. The IRA also imposes inflation rebates on Medicare Part B and Part D drugs whose prices increase faster than inflation, requiring manufacturers to pay CMS a rebate on the excess. These provisions, and related Part D benefit redesign changes, could reduce our revenue and profitability with respect to any drug product candidate that receives marketing approval and becomes subject to negotiation or inflation-rebate liability, and remain subject to ongoing CMS guidance, implementation litigation, and potential legislative amendment.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law or to otherwise narrow provisions of PPACA. For example, on July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was signed into law, which narrowed access to PPACA marketplace exchange enrollment and declined to extend the PPACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired PPACA subsidies.

Pharmaceutical Price Initiatives

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. A number of states have submitted Section 804 Importation Program proposals to the FDA with the goal of obtaining authority to import drugs from Canada, subject to conditions. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada.

The Trump Administration has also taken a number of actions to reduce the costs of pharmaceutical products. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing

agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, or CMMI, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as OECD countries with a GDP of $400 billion and a per capita GDP that is at least 60% of the US per capita GDP (an initial list of 19 reference countries is included in the proposed rule). The GLOBE and GUARD pilot programs are proposed to go into effect beginning October 1, 2026 and January 1, 2027, respectively.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug product candidates or additional pricing pressures. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payors are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Additional Regulations

In addition to the foregoing, state, and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling, and disposal of various biologic, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in foreign countries that impose similar obligations.

Human Capital

As of September 30, 2026, we had 37 full-time employees. The majority of our employees are located in Massachusetts. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we believe our relationship with our employees is good. Additionally, we utilize independent contractors and other third parties to assist with various aspects of our drug and product development.

We recognize the value of our employees and are committed to being a workplace that encourages respect, collaboration, communication, transparency and integrity. We seek to hire employees with diverse backgrounds and

perspectives. Our success starts and ends with having the best talent, and as a result, we are focused on attracting, developing and retaining our employees. We offer employees a competitive and comprehensive benefits package. The principal purposes of our incentive plans are to attract, retain and motivate selected employees, consultants, advisors and directors through the granting of stock-based compensation awards and cash-based performance bonus awards, as applicable. We support employees attending industry conferences and obtaining professional licenses. We use a variety of human capital measures in managing our business, including: workforce demographics; inclusion; and employee health and safety.

(c) Director and Officer Trading Arrangements

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

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit	Filing Date	Registration/File No.
4.1	Form of Pre-Funded Warrant to Purchase Common Stock Issued to the Investors		8-K	4.1	7/10/2026	001-38327
10.1	Form of Securities Purchase Agreement, dated as of July 9, 2026, by and among the Company and the Investors		8-K	10.1	7/10/2026	001-38327
10.2	Form of Registration Rights Agreement, dated as of July 9, 2026, by and among the Company and the Investors		8-K	10.2	7/10/2026	001-38327
10.3*	Employment Agreement, dated as of July 28, 2026, by and between the Company and James Ahlers	X				
10.4#	Amendment to License Agreement with Ascendant Health Ltd.		10-Q	10.7	8/14/2026	001-38327
31.1	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
31.2	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	X				
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS	Inline 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 With Embedded Linkbase Documents	X				
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, has been formatted in Inline XBRL.	X				

* Indicates management compensatory plan, contract or arrangement.
# Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

Cue Biopharma, Inc.

Dated: November 16, 2026

By: /s/ Shao-Lee Lin

Shao-Lee Lin
President and Chief Executive Officer
(Principal Executive Officer)

Cue Biopharma, Inc.

Dated: November 16, 2026

By: /s/ James Ahlers

James Ahlers
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.3

CUE BIOPHARMA, INC.
EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement") is made by and between Cue Biopharma, Inc., a Delaware corporation ("Cue" or the "Company"), and James Ahlers ("Executive," and together with Cue, the "Parties").

WHEREAS, the Company and Executive desire to enter into this Agreement to set forth the conditions under which Executive will be employed by the Company.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises contained herein and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. POSITION AND DUTIES.

(a) As of the Effective Date (as defined below), Cue shall employ Executive as its Chief Financial Officer. Executive shall report to the Chief Executive Officer of the Company (the "**CEO**") and shall have the duties and authority commensurate with Executive's position, as well as such other duties commensurate with such position that may be assigned by the CEO.

(b) Executive's principal place of providing services to the Company will initially be Executive's residence in California. Executive acknowledges that remote working is subject to the needs of the business and the Company's policies as in effect from time to time. The Company reserves the right, in its discretion, to require Executive to perform services at a Company-designated location on a full-time or part-time basis and to modify or withdraw any remote working arrangement at any time. Executive will engage in business travel as required by Executive's job duties.

(c) Executive shall devote all of Executive's business time, energy, judgment, knowledge and skill and Executive's best efforts to the performance of Executive's duties and responsibilities for Cue, provided that the foregoing shall not prevent Executive from performing those outside activities set forth on **Exhibit A** hereto, so long as such activities do not individually or in the aggregate inhibit, interfere with, or prohibit the timely performance of Executive's duties and responsibilities hereunder and do not create a potential business or fiduciary conflict.

2. EFFECTIVE DATE; TERM OF EMPLOYMENT. Executive's employment and this Agreement shall take effect on July 30th, 2026 (the "**Effective Date**"), and shall continue in effect until terminated in accordance with Section 7 below (the "**Term of Employment**"). During the Term of Employment, Executive shall be an at-will employee of the Company, and Executive's employment may be terminated by either Executive or the Company at any time, with or without Cause (as defined below) or advance notice, subject to the provisions set forth in Section 7 below.

3. BASE SALARY. During the Term of Employment, Cue shall pay Executive a base salary

("**Base Salary**") at the annualized rate of $450,000, payable in accordance with the regular payroll practices of Cue. The Base Salary shall be subject to all applicable taxes and withholdings, shall be subject to periodic review, and may be adjusted from time to time by the Company in its sole discretion.

4. ANNUAL BONUS. Following the end of each calendar year during the Term of Employment, Executive shall be eligible to receive an annual incentive bonus for the prior year (the "**Annual Bonus**"), subject to achievement that year of key performance indicators for Cue, with the level of achievement, the key performance indicators, and actual amount of the Annual Bonus determined by the Company in its sole discretion. Executive's target Annual Bonus for each calendar year shall be up to 45% of the Base Salary. Any Annual Bonus awarded to Executive shall be paid by the Company on such date as scheduled by management, on which date the Annual Bonus shall be considered earned.

5. INITIAL GRANTS.

(a) As a material inducement to Executive entering into employment with the Company and subject to approval by the Board of Directors of the Company (the "**Board**"), Executive will be granted a nonstatutory stock option (the "**Initial Option**") to purchase 51,000 and an initial RSU grant of 25,500 shares of common stock of the Company (collectively, the "**Initial Grants**"). The Initial Grants will be made pursuant to the Company's 2026 Inducement Stock Incentive Plan (the "**Plan**") and will be subject to the terms and conditions set forth in award agreements with respect to such Initial Grants. The Initial Option will have an exercise price per share equal to the fair market value at the time of grant determined in accordance with the Plan. The Initial grant's will vest in equal quarterly installments over four (4) years from the Effective Date, subject to Executive's continued service.

(b) All equity awards will be subject to the terms and conditions of the Company's applicable stock plan and applicable award agreements and remain subject to the approval and discretion of the Board.

6. EMPLOYEE BENEFITS

(a) BENEFIT PLANS. During the Term of Employment, Executive shall be eligible to participate, in accordance with and subject to any terms and conditions thereof, any employee benefit plans that Cue has adopted or may adopt, maintains or contributes to for the benefit of its employees generally, except to the extent such plans are duplicative of the benefits otherwise provided to Executive hereunder. Executive's participation shall be subject to the applicable plan documents and generally applicable Cue policies. Notwithstanding the foregoing, Cue may modify or terminate any employee benefit plan at any time.

(b) HOLIDAYS/PERSONAL TIME OFF/SICK TIME. During the Term of Employment, Executive shall be eligible for the public holidays on which the business of the Company is officially closed in accordance with the Company's holiday policy. In addition, Executive shall be entitled to paid vacation time in accordance with Cue's policy applicable to senior management employees as in effect from time to time. Finally, Executive shall be entitled

to one week (5 business days) of sick days each year, which may be used by Executive for their own health or for the health of a family member, and includes time taken for preventive care or diagnosis, to attend medical appointments, for care or treatment of an existing health condition, for specified purposes if the employee or a family member is a victim of violence, and for other reasons covered by applicable law, as detailed in the Company's Employee Handbook.

(c) BUSINESS EXPENSES. During the Term of Employment, upon presentation of reasonable substantiation and documentation as Cue may require from time to time, Executive shall be reimbursed in accordance with Cue's expense reimbursement policy, for all reasonable out-of-pocket business expenses incurred and paid by Executive during the Term of Employment and in connection with the performance of Executive's duties hereunder.

(d) INDEMNIFICATION AND INSURANCE. During the Term of Employment, the Company shall provide Executive with indemnification, advancement of expenses and insurance coverage to the fullest extent provided under the Company's bylaws and to the fullest extent provided to other C-Suite executives of the Company.

7. TERMINATION. This Agreement and the Term of Employment shall terminate on the first to occur of the following:

(a) **DISABILITY.** Upon 30 days' prior written notice by Cue to Executive of termination due to Disability while a Disability exists. "**Disability**" shall mean Executive is unable to perform the essential duties of Executive's position by reason of a medically determinable physical or mental impairment that is potentially permanent in character or that can be expected to last for a continuous period of not less than 12 months from the start of such Disability.

(b) **DEATH.** Automatically upon the death of Executive.

(c) **CAUSE.** Immediately upon written notice by Cue to Executive of a termination for Cause. "**Cause**" shall mean a good faith determination by the Company of:

(i) the commission of any act by Executive constituting financial dishonesty against Cue or its Affiliates, which act would be chargeable as a felony under applicable law;

(ii) Executive's engaging in any other act of fraud, intentional and material misrepresentation, moral turpitude, illegality, discrimination, harassment, or retaliation that would (a) materially adversely affect the business or the reputation of Cue or any of its Affiliates with their respective current or prospective customers, suppliers, lenders or other third parties with whom such entity does or might do business or (b) expose Cue or any of its Affiliates to a risk of civil or criminal legal damages, liabilities or penalties;

(iii) the repeated and material failure by Executive to follow the reasonable and lawful directives of the CEO;

(iv) any material misconduct, material and willful violation of Cue's or its Affiliates' written policies applicable to Executive, or willful and deliberate breach of duty by

Executive in connection with the business affairs of Cue or its Affiliates; or

(v) Executive's material breach of this Agreement.

Executive shall be given written notice detailing the specific Cause event and a period of 10 days following Executive's receipt of such notice to cure such event (if susceptible to cure, as determined by the Company) to the reasonable satisfaction of the Company. Notwithstanding anything to the contrary contained herein, Executive's right to cure as set forth in the preceding sentence shall not apply if there are habitual or repeated breaches by Executive. A termination for Cause shall be deemed to include a determination by the Company following Executive's termination of service that circumstances existing prior to such termination would have entitled Cue to have terminated Executive for Cause, in which case Executive shall be treated as a Bad Leaver in accordance with **Section 10(f)**. All rights Executive has or may have under this Agreement (including as set forth in **Section 7(d)** below) shall be suspended automatically during the pendency of any investigation by the Company, or during any negotiations between the Company and Executive, regarding any actual or alleged act or omission by Executive of the type described in this definition of Cause. For purposes of the foregoing, no act, or failure to act or refusal to act, on the part of Executive shall be considered "willful" unless it is done, or omitted to be done, by Executive in bad faith or without reasonable belief that Executive's action or omission was in the best interests of Cue.

(d) **GOOD REASON**. Upon written notice by Executive to Cue of a termination for Good Reason. "**Good Reason**" shall mean the occurrence of any of the following events, without the consent of Executive, unless such events are fully corrected in all material respects by Cue within 30 days following written notification by Executive to Cue of the occurrence of one of the events:

(i) a material diminution in Executive's Base Salary or Annual Bonus opportunity in a manner that is not applied proportionately to all other senior executive officers of the Company;

(ii) a material diminution in Executive's authority, responsibilities or duties set forth in **Section 1** above, other than temporarily while physically or mentally incapacitated, as permitted by applicable law; or

(iii) a material breach by Cue of a material term of this Agreement.

Executive shall provide Cue with a written notice detailing the specific circumstances alleged to constitute Good Reason within 30 days after the first occurrence of such circumstances, and actually terminate employment within 30 days following the expiration of Cue's 30-day cure period described above (subject to the Company's correction of the grounds for Good Reason within such cure period). Otherwise, any claim of such circumstances as Good Reason shall be deemed irrevocably waived by Executive.

(e) **WITHOUT CAUSE.** Immediately upon written notice by Cue to Executive of an involuntary termination without Cause (other than for death or Disability).

(f) **VOLUNTARY TERMINATION.** Upon 60 days' prior written notice by Executive to Cue of Executive's voluntary termination of employment without Good Reason (which termination Cue may make effective earlier than any notice date, in which event Cue will

pay to Executive, within thirty days following the early termination date, the Base Salary Executive would have received between the early termination date and the end of the 60-day notice period, had Executive remained employed through such notice period).

8. CONSEQUENCES OF TERMINATION.

(a) **DEATH/DISABILITY.** In the event that Executive's employment ends on account of Executive's death or Disability, Executive or Executive's estate, as the case may be, shall be entitled to the following (with the amounts due under **Sections 8**(**a**)(**i**) through **8**(**a**)(**iv**) below to be paid within 60 days following termination of employment, or such earlier date as may be required by applicable law):

(i) any unpaid Base Salary through the date of termination;

(ii) any Annual Bonus for the year prior to the year in which such termination occurs that the Board has approved but has not yet been paid to Executive, to be paid when annual bonuses for such prior year are paid to actively employed employees of Cue;

(iii) reimbursement for any unreimbursed business expenses incurred by Executive through the date of termination; and

(iv) all other payments, benefits or fringe benefits to which Executive shall be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (collectively, **Sections 8**(**a**)(**i**) through **8**(**a**)(**iv**) hereof shall be hereafter referred to as the "**Accrued Benefits**").

(b) **TERMINATION FOR CAUSE; UPON RESIGNATION WITHOUT GOOD REASON**. If Executive's employment is terminated (i) by Cue for Cause; or (ii) by Executive without Good Reason, Cue shall pay to Executive within 60 days following termination of employment, or such earlier date as may be required by applicable law:

(i) any unpaid Base Salary through the date of termination;

(ii) reimbursement for any unreimbursed business expenses incurred through the date of termination; and

(iii) all other payments, benefits or fringe benefits to which Executive shall be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant.

(c) **TERMINATION WITHOUT CAUSE; UPON RESIGNATION FOR GOOD REASON**. If Executive's employment by Cue is terminated (i) by Cue other than for Cause or due to Executive's death or Disability, or (ii) by Executive for Good Reason (each, a "**Qualifying Termination**"), subject to Executive's compliance with **Section 9** below and Executive's

continued compliance with **Section 10** below, and subject to **Section 21** below, Cue shall pay or provide Executive the following:

(i) the Accrued Benefits;

(ii) a lump sum cash severance payment in an amount equal to the sum of (x) nine (9) months of Base Salary, plus (y) the target Annual Bonus for the year of termination, prorated based on the number of days that Executive is employed in such year through the date of termination, with such lump sum payable on the first payroll date of Cue that occurs more than 60 days after Executive's termination (collectively, the "**Severance Amount**");

(iii) if Executive elects COBRA coverage for health and/or dental insurance in a timely manner, the Company shall pay the monthly premium payments for such timely elected coverage (consistent with what was in place at termination) when each premium is due until the earliest of the following: (i) nine (9) months following termination; (ii) the date Executive obtains new employment that offers health and/or dental insurance that is reasonably comparable to that offered by the Company; and (iii) the date COBRA continuation coverage would otherwise terminate in accordance with the provisions of COBRA; and

(iv) if the Qualifying Termination occurs within the period commencing on the date ninety (90) days prior to a Change in Control (as defined in the Company's 2025 Stock Incentive Plan ("**SIP**")) and ending on the date twenty-four (24) months following a Change in Control, and notwithstanding anything in the SIP to the contrary, (a) one hundred percent (100%) of Executive's stock options, stock appreciation rights, restricted stock units and restricted shares in each case that are issued and outstanding under a Company equity compensation plan ("**Equity Awards**") other than Equity Awards with performance-based vesting conditions ("**Performance Awards**") shall become fully vested as of the date of such termination/resignation, and such Equity Awards shall remain exercisable (if exercisable) until the earlier of one year from any termination/resignation or the latest date on which those Equity Awards expire or are eligible to be exercised under the applicable award agreements, and (b) the service-based vesting condition of any Performance Award shall be deemed fully satisfied as of the date of such termination/resignation and such performance goals applicable to the Performance Awards shall be deemed to be achieved at the greater of target or actual performance as of the Change in Control, and such Performance Awards shall remain exercisable (if exercisable) until the earlier of one year from such termination/resignation or the latest date on which those Equity Awards expire or are eligible to be exercised under the applicable award agreements. Notwithstanding the foregoing, in no event shall Executive's Equity Awards receive less favorable treatment in connection with a Change in Control than is afforded to any other SIP participant's awards.

Payments and benefits provided under this **Section 8**(**c**) shall be in lieu of any termination or severance payments or benefits to which Executive may be eligible under any of the plans, policies or programs of Cue or any similar state statute or regulation. Should Executive die prior to the payment of the Severance Amount, the Severance Amount shall be paid to the heirs or estate of Executive in accordance with the schedule set forth herein.

(d) **OTHER OBLIGATIONS.** Upon any termination of Executive's employment

with Cue, Executive shall automatically be deemed to have resigned from any and all positions Executive then holds as an officer, director or fiduciary of Cue and any other entity that is part of the same consolidated group as Cue or in which capacity Executive serves at the direction of or as a result of Executive's position with Cue; and Executive shall, within 10 days of such termination, take all actions as may be necessary under applicable law or requested by Cue to effect any such resignations.

(e) **EXCLUSIVE REMEDY.** The amounts payable to Executive following termination of employment hereunder pursuant to **Sections 8(a),** (**b**) and (**c**) above shall be in full and complete satisfaction of Executive's rights under this Agreement and any other claims that Executive may have in respect of Executive's employment with Cue or any of its Affiliates, and Executive acknowledges that such amounts are fair and reasonable, and are Executive's sole and exclusive remedy, in lieu of all other remedies at law or in equity, with respect to the termination of Executive's employment hereunder or any breach of this Agreement.

(f) **NO MITIGATION OR OFFSET.** Executive shall not be required to seek or accept other employment or otherwise to mitigate damages as a condition to the receipt of benefits pursuant to this **Section 8,** and amounts payable pursuant to this **Section 8** shall not be offset or reduced by any amounts received by Executive from other sources.

(g) **NO WAIVER OF ERISA-RELATED RIGHTS.** Nothing in this Agreement shall be construed to be a waiver by Executive of any benefits accrued for or due to Executive under any employee benefit plan (as such term is defined in the Employee Retirement Income Security Act of 1974, as amended) maintained by Cue, if any, except that Executive shall not be entitled to any severance benefits pursuant to any severance plan or program of Cue other than as provided herein.

(h) **CLAWBACK.** All awards, amounts or benefits received or outstanding under this Agreement shall be subject to clawback, cancellation, recoupment, rescission, payback, reduction or other similar action in accordance with the terms of any applicable law related to such actions, as may be in effect from time to time. Cue may take such actions as may be necessary to effectuate any provision of applicable law relating to clawback, cancellation, recoupment, rescission, payback or reduction of compensation, whether adopted before or after the Effective Date, without further consideration or action.

9. RELEASE. Any and all amounts payable and benefits or additional rights, beyond the Accrued Benefits, provided pursuant to this Agreement following termination from employment shall only be payable if Executive delivers to Cue and does not revoke a separation and general release of claims agreement in favor of Cue in a form to be provided by Cue (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, reaffirmation of Executive's continuing obligations under this Agreement, and an agreement not to compete with the Company for twelve (12) months following Executive's separation from employment, as and to the extent permitted by then applicable law). Such release shall be furnished to Executive within five business days after Executive's date of termination and must become irrevocable within 60 days following termination (or such shorter period as requested by Cue).

10. CONFIDENTIALITY, NON-DISCLOSURE, AND ASSIGNMENT OF INVENTIONS.

(a) **CONFIDENTIALITY**.

(i) **COMPANY INFORMATION.** At all times during the Term of Employment and thereafter, Executive shall hold in strictest confidence, and shall not use, except in connection with the performance of Executive's duties, and shall not disclose to any person or entity, any Confidential Information of Cue. "**Confidential Information**" means any Cue proprietary or confidential information, technical data, trade secrets or know-how, including

research, product plans, products, services, customer lists and customers, markets, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, marketing, distribution and sales methods and systems, sales and profit figures, finances and other business information disclosed to Executive by Cue, either directly or indirectly in writing, orally or by drawings or inspection of documents or other tangible property. However, Confidential Information does not include any of the foregoing items which has become publicly known and made generally available through no wrongful act of Executive.

(ii) **EXECUTIVE-RESTRICTED INFORMATION.** During the Term of Employment, Executive shall not improperly use or disclose any proprietary or confidential information or trade secrets of any person or entity with whom Executive has an agreement or duty to keep such information or secrets confidential.

(iii) **THIRD PARTY INFORMATION.** Executive recognizes that Cue has received and in the future shall receive from third parties their confidential or proprietary information subject to a duty on Cue's part to maintain the confidentiality of such information and to use it only for certain limited purposes. At all times during the Term of Employment and thereafter, Executive shall hold in strictest confidence, and shall not use, except in connection with the performance of Executive's duties, and shall not disclose to any person or entity except in connection with the performance of Executive's duties and consistent with Cue's agreement with such third party, such third party confidential or proprietary information, and shall not use it except as necessary in performing Executive's duties, consistent with Cue's agreement with such third party.

(b) **NONDISPARAGEMENT.** During the Term of Employment and at all times thereafter, and except as otherwise permitted by **Section 10(g)** below, Executive shall not make negative comments or otherwise disparage Cue or any company or other trade or business that "controls," is "controlled by" or is "under common control with," Cue within the meaning of Rule 405 of Regulation C under the Securities Act, including any "subsidiary corporation" of Cue within the meaning of Section 424(f) of the Internal Revenue Code of 1986 ("**Affiliates**") or any of their officers, directors, managers, employees, consultants, equity holders, agents or products. The foregoing shall not be violated by truthful statements made (i) in response to legal process or arbitral or court proceedings (including depositions in connection with such proceedings) or (ii) in the course of Executive discharging Executive's duties for Cue.

(c) **COOPERATION.** Upon the receipt of reasonable notice from Cue, while employed by Cue and for two (2) years thereafter, Executive shall respond and provide information

with regard to matters in which Executive has knowledge as a result of Executive's employment with Cue, and shall provide reasonable assistance to Cue, its Affiliates and their respective representatives in defense of any claims that may be made against Cue or its Affiliates, and shall assist Cue and its Affiliates in the prosecution of any claims that may be made by Cue or its Affiliates, to the extent that such claims may relate to the period of Executive's employment with Cue (collectively, the "**Claims**"). Executive shall promptly inform Cue if Executive becomes aware of any lawsuits involving Claims that may be filed or threatened against Cue or its Affiliates. Executive also shall promptly inform Cue (to the extent that Executive is legally permitted to do so) if Executive is asked to assist in any investigation of Cue or its Affiliates (or their actions) or another party attempts to obtain information or documents from Executive (other than in

connection with any litigation or other proceeding in which Executive is a party-in-opposition) with respect to matters Executive believes in good faith to relate to any investigation of Cue or its Affiliates, in each case, regardless of whether a lawsuit or other proceeding has then been filed against Cue or its Affiliates with respect to such investigation, and shall not do so unless legally required or otherwise permitted by **Section 10(g)** below. During the pendency of any litigation or other proceeding involving Claims, Executive shall not communicate with anyone (other than Executive's attorneys and tax and/or financial advisors and except to the extent either permitted by **Section 10(g)** below or that Executive determines in good faith is necessary in connection with the performance of Executive's duties hereunder) with respect to the facts or subject matter of any pending or potential litigation or regulatory or administrative proceeding involving Cue or any of its Affiliates without getting the prior written consent of Cue. Upon presentation of appropriate documentation, Cue shall pay or reimburse Executive for all reasonable counsel fees, out-of-pocket travel, duplicating or telephonic expenses incurred by Executive in accordance with Cue's applicable policies in complying with this **Section 10(c),** and Executive shall be compensated by Cue at a reasonable hourly rate for assistance given after the end of employment; provided, however, that Executive shall not be paid for any time spent testifying in any arbitration, trial, administrative hearing or other proceeding.

(d)**OWNERSHIP OF INFORMATION, IDEAS, CONCEPTS, IMPROVEMENTS, DISCOVERIES AND INVENTIONS, AND ALL ORIGINAL WORKS OF AUTHORSHIP.**

(i) As between the Parties, all information, ideas, concepts, improvements, discoveries and inventions, whether patentable or not, which are conceived, made, developed or acquired by Executive or which are disclosed or made known to Executive, individually or in conjunction with others, during Executive's employment and which relate to Cue's business, products or services (including all such information relating to corporate opportunities, research, financial and sales data, pricing and trading terms, evaluations, opinions, interpretations, acquisition prospects, the identity of clients or customers or their requirements, the identity of key contacts within the client or customers' organizations or within the organization of acquisition prospects, or marketing and merchandising techniques, prospective names and marks) are and shall be the sole and exclusive property of Cue. Moreover, all drawings, memoranda, notes, records, files, correspondence, manuals, models, specifications, computer programs, maps and all other writings or materials of any type embodying any of such information, ideas, concepts, improvements, discoveries and inventions are and shall be the sole and exclusive property of Cue.

(ii) In particular, Executive hereby specifically assigns and transfers to Cue all of Executive's worldwide right, title and interest in and to all such information, ideas, concepts, improvements, discoveries or inventions, and any United States or foreign applications for patents, inventor's certificates or other industrial rights that may be filed thereon, and applications for registration of such names and marks. During the Term of Employment and thereafter, Executive shall assist Cue and its nominee at all times in the protection of such information, ideas, concepts, improvements, discoveries or inventions, both in the United States and all foreign countries, including the execution of all lawful oaths and all assignment documents requested by Cue or its nominee in connection with the preparation, prosecution, issuance or enforcement of any applications for United States or foreign letters patent, and any application for the registration of such names and marks.

(iii) Moreover, if during the Term of Employment, Executive creates any original work of authorship fixed in any tangible medium of expression which is the subject matter of copyright (such as reports, videotapes, written presentations, computer programs, drawings, maps, architectural renditions, models, manuals, brochures or the like) relating to Cue's business, products or services, whether such work is created solely by Executive or jointly with others, Cue shall be deemed the author of such work if the work is prepared by Executive in the scope of Executive's employment; or, if the work is not prepared by Executive within the scope of Executive's employment but is specially ordered by Cue as a contribution to a collective work, as a part of any written or audiovisual work, as a translation, as a supplementary work, as a compilation or as an instructional text, then the work shall be considered to be work made for hire and Cue shall be the author of the work. In the event such work is neither prepared by Executive within the scope of Executive's employment or is not a work specially ordered and deemed to be a work made for hire, then Executive shall assign, and by these presents, does assign, to Cue all of Executive's worldwide right, title and interest in and to such work and all rights of copyright therein. Both during the Term of Employment and thereafter, Executive shall assist Cue and its nominee, at any time, in the protection of Cue's worldwide right, title and interest in and to the work and all rights of copyright therein, including the execution of all formal assignment documents requested by Cue or its nominee and the execution of all lawful oaths and applications for registration of copyright in the United States and foreign countries; *provided, however,* that Executive shall be compensated by Cue at a reasonable hourly rate for assistance given after the end of Executive's employment.

(iv) Notwithstanding the foregoing provisions of this **Section 10(d)**, Cue hereby notifies Executive that the provisions of this **Section 10(d)** shall not apply to any inventions that qualify fully under the provisions of Section 2870, attached hereto as **Exhibit B**.

(e) **RETURN OF COMPANY PROPERTY.** On the date of Executive's termination of employment with Cue for any reason (or at any time prior thereto at Cue's request), Executive shall return all property belonging to Cue or its Affiliates (including any Cue or Affiliate-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents or property belonging to Cue or an Affiliate).

(f) **EFFECT OF EXECUTIVE BECOMING A BAD LEAVER.** Notwithstanding any provision of this Agreement to the contrary, if (i) Executive breaches any of the applicable covenants set forth or referenced in this Agreement at any time during the period commencing on the Effective Date and ending 12 months after Executive's termination of employment with Cue for any reason and (ii) Executive fails to cure such breach within 10 days of the effective date of written notice of such breach given by Cue, then Executive shall be deemed a "**Bad Leaver.**" If Executive is or becomes a Bad Leaver, then (i) any severance being paid to Executive pursuant to this Agreement or otherwise shall immediately cease upon commencement of such action and (ii) Executive shall be liable to repay to Cue any severance previously paid to Executive by Cue, less $100 to serve as consideration for the release described in **Section 9** above.

(g) **PERMITTED DISCLOSURES**. Executive acknowledges that nothing in this Agreement or elsewhere prohibits or restricts Executive from (i) communicating with, or voluntarily providing information Executive believes indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities and Exchange Commission), and/or (ii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Executive has reason to

believe is unlawful;. Executive is not required to notify the Company of any such communications. Further, notwithstanding Executive's confidentiality and nondisclosure obligations, Executive is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

11. EQUITABLE RELIEF AND OTHER REMEDIES. Executive acknowledges that Cue's remedies at law for a breach or threatened breach of any of the provisions of **Section 10(a) – (e)** above would be inadequate and in the event of such a breach or threatened breach, in addition to any remedies at law, Cue, without posting any bond, shall be entitled to seek to obtain equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy that may then be available, without the necessity of showing actual monetary damages or the posting of a bond or other security.

12. NO ASSIGNMENTS. This Agreement is personal to each of the Parties. Except as provided in this **Section 12,** neither Party may assign or delegate any rights or obligations hereunder without first obtaining the written consent of the other Party. Cue may assign this Agreement to any of its Affiliates or to any successor to all or substantially all of the business and/or assets of Cue, *provided* that Cue shall require such Affiliate or successor to expressly assume and agree to perform this Agreement in the same manner and to the same extent that Cue would be required to perform it if no such succession had taken place. As used in this Agreement, "Cue" and the "Company" shall mean Cue and any Affiliate or successor to its business and/or assets that assumes and agrees to perform the duties and obligations of Cue under this Agreement by operation of law or otherwise.

13. NOTICE. Any notice that either Party may be required or permitted to give to the other shall be in writing and may be delivered personally, by electronic mail or via a postal service, postage prepaid, to such electronic mail or postal address and directed to such person as Cue may notify Executive from time to time; and to Executive at Executive's electronic mail or postal address as shown on the records of Cue from time to time, or at such other electronic mail or postal address as Executive, by notice to Cue, may designate in writing from time to time.

14. CONDITIONS ON OFFER AND EMPLOYMENT. This offer of employment and Executive's employment hereunder is contingent upon Executive's satisfactory completion of a reference and background (including criminal background) check. Executive's employment hereunder is further contingent upon Executive providing to the Company, within three (3) days of the Effective Date, documentation of Executive's eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. Should any of these conditions not be satisfied following the Effective Date, as determined by the Company in its sole discretion, then Executive's employment shall immediately end and such termination shall be deemed a termination for Cause.

15. SECTION HEADINGS; INCONSISTENCY. The section headings used in this

Agreement are included solely for convenience and shall not affect, or be used in connection with, the interpretation of this Agreement. In the event of any inconsistency between the terms of this Agreement and any form, award, plan or policy of Cue, the terms of this Agreement shall govern and control.

16. SEVERABILITY. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any action in any other jurisdiction, but this Agreement shall be reformed, construed and enforced in such jurisdiction.

17. COUNTERPARTS. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

18. APPLICABLE LAW; CHOICE OF VENUE AND CONSENT TO JURISDICTION; SERVICE OF PROCESS.

(a) All questions concerning the construction, validity and interpretation of this Agreement and the performance of the obligations imposed by this Agreement shall be governed by the internal laws of the State of California applicable to agreements made and wholly to be performed in such state without regard to conflicts of law provisions of any jurisdiction.

(b) For purposes of resolving any dispute that arises directly or indirectly from the relationship of the Parties evidenced by this Agreement, the Parties hereby submit to and consent to the exclusive jurisdiction of the State of California and further agree that any related litigation shall be conducted solely in a court of the State of California (or, if appropriate, a federal court located within California), where this Agreement is made and/or to be performed, and no other courts.

(c) Each Party may be served with process in any manner permitted under California law, or by United States registered or certified mail, return receipt requested.

19. MISCELLANEOUS. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and such officer or director as may be designated by Cue. No waiver by either Party at any time of any breach by the other Party of, or compliance with, any condition or provision of this Agreement to be performed by such other Party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. This Agreement together with all exhibits hereto sets forth the entire agreement of the Parties in respect of the subject matter contained herein and supersedes any and all prior agreements or understandings between Executive and Cue or its Affiliates with respect to the subject matter hereof. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof, have been made by either Party that are not expressly set forth in this Agreement.

20. REPRESENTATIONS. Executive represents and warrants to Cue that (a) Executive has the legal right to enter into this Agreement and to perform all of the obligations on Executive's part to be performed hereunder in accordance with its terms, and (b) Executive is not a party to any agreement or understanding, written or oral, and is not subject to any restriction, which, in either case, could prevent Executive from entering into this Agreement or performing all of

Executive's duties and obligations hereunder.

21. TAX MATTERS.

(a) **WITHHOLDING.** Any and all amounts payable under this Agreement or otherwise shall be subject to, and Cue may withhold from such amounts, any federal, state, local or other taxes as may be required to be withheld pursuant to any applicable law or regulation.

(b) **SECTION 409A COMPLIANCE**.

(i) The intent of the Parties is that payments and benefits under this Agreement be exempt from (to the extent possible) or compliant with Section 409A ("**Section 409A**") of the Internal Revenue Code of 1986 and the regulations and guidance promulgated thereunder, as amended (collectively, the "**Code**") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted accordingly. To the extent that any provision hereof is modified in order to comply with Section 409A, such modification shall be made in good faith and shall, to the maximum extent reasonably possible, maintain the original intent and economic benefit to the Parties of the applicable provision without violating the provisions of Section 409A. In no event shall Cue be liable for any additional tax, interest or penalty that may be imposed on Executive by Section 409A or damages for failing to comply with Section 409A.

(ii) A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits that constitute "nonqualified deferred compensation" under Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within die meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." Notwithstanding anything to the contrary in this Agreement, if Executive is deemed on the date of termination to be a "specified employee" under Section 409A, then with regard to any payment or the provision of any benefit that is considered "nonqualified deferred compensation" under Section 409A payable on account of a "separation from service," such payment or benefit shall not be made or provided until the earlier of (A) the expiration of the six-month period measured from the date of such "separation from service" of Executive, and (B) the date of Executive's death, to the extent required under Section 409A. Upon the expiration of the foregoing delay period, all payments and benefits delayed pursuant to this **Section 20(b)(ii)** (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed to Executive in a lump sum on the first business day following the six-month period, and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(iii) To the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Section 409A, (A) all expenses or other reimbursements hereunder shall be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by Executive, (B) any right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit and (C) no such reimbursement, expenses eligible for reimbursement or in-kind benefits provided in any taxable year shall in any way affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

(iv) For purposes of Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and

distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days, the actual date of payment within the specified period shall be at the sole discretion of the Company.

(v) Notwithstanding any other provision of this Agreement to the contrary, in no event shall any payment under this Agreement that constitutes "nonqualified deferred compensation" for purposes of Section 409A be subject to offset by any other amount unless otherwise permitted by Section 409A.

(c) **MODIFICATION OF PAYMENTS**. In the event it shall be determined that any payment, right or distribution by Cue or any other person or entity to or for the benefit of Executive pursuant to the terms of this Agreement or otherwise, in connection with, or arising out of, Executive's employment with Cue or a change in ownership or effective control of Cue or a substantial portion of its assets (a "**Payment**") is a "parachute payment" within the meaning of Code Section 280G on account of the aggregate value of the Payments due to Executive being equal to or greater than three times the "base amount," as defined in Code Section 280G (the "**Parachute Threshold**"), so that Executive would be subject to the excise tax imposed by Code
Section 4999 (the "**Excise Tax**") and the net after-tax benefit that Executive would receive by reducing the Payments to the Parachute Threshold is greater than the net after-tax benefit Executive would receive if the full amount of the Payments were paid to Executive, then the Payments payable to Executive shall be reduced (but not below zero) so that the Payments due to Executive do not exceed the amount of the Parachute Threshold, reducing first any Payments under **Section 8** above.

[*Remainder of Page Intentionally Left Blank*]

BY SIGNING THIS AGREEMENT BELOW, EXECUTIVE ACKNOWLEDGES THAT EXECUTIVE:

(1) HAS READ AND UNDERSTOOD THE ENTIRE AGREEMENT;

(2) HAS HAD THE OPPORTUNITY TO ASK QUESTIONS AND CONSULT COUNSEL OR OTHER ADVISORS ABOUT THE AGREEMENT'S TERMS; AND

(3) AGREES TO BE BOUND BY THE AGREEMENT.

IN WITNESS WHEREOF, Cue has caused this Agreement to be executed in its name and on its behalf, and Executive acknowledges understanding and acceptance of, and agrees to, the terms of this Agreement.

CUE BIOPHARMA, INC.	**James Ahlers**
/s/ Shao-Lee Lin	/s/ James Ahlers
By: Shao-Lee Lin	
Chief Executive Officer	
Date: 7/28/2026	Date: 7/27/2026

Exhibit A

EXHIBIT B

CALIFORNIA LABOR CODE SECTION 2870 INVENTION ON OWN TIME – EXEMPTION FROM AGREEMENT

THIS IS TO NOTIFY EMPLOYEE, in accordance with Section 2872 of the California Labor Code, that:

a) Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention that the employee developed entirely on his or her own time without using the employer's equipment, supplies, facilities, or trade secret information except for those inventions that either:

(1) Relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer, or

(2) Result from any work performed by the employee for his or her employer.

b) To the extent a provision in an employment agreement purports to require an employee to assign an invention otherwise excluded from being required to be assigned under subdivision (a), the provision is against the public policy of this state and is unenforceable.

The foregoing limited exclusion does not apply to any patent or invention covered by a contract between the Company and the United States or any of its agencies requiring full title to such patent or invention to be in the United States.

EXHIBIT 31.1

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

I, Shao-Lee Lin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cue Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2026

/s/ Shao-Lee Lin
Name: Shao-Lee Lin
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, James Ahlers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cue Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2026

/s/ James Ahlers
Name: James Ahlers
Title: Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with this Quarterly Report on Form 10-Q of Cue Biopharma, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shao-Lee Lin, President and Chief Executive 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 my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Shao-Lee Lin
Name: Shao-Lee Lin
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: November 16, 2026

EXHIBIT 32.2

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 period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Ahlers, 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 my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James Ahlers
Name: James Ahlers
Title: Chief Financial Officer
(Principal Financial Officer)

Date: November 16, 2026