

REFINITIV

# DELTA REPORT

## 10-Q

CARM - SESEN BIO, INC.

10-Q - MARCH 31, 2023 COMPARED TO 10-Q - SEPTEMBER 30, 2022

The following comparison report has been automatically generated

TOTAL DELTAS 5982

■ CHANGES 35

■ DELETIONS 1843

■ ADDITIONS 4104

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36296

**Carisma Therapeutics Inc.**

(Exact Name of Registrant as Specified in its Charter)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Delaware 26-2025616

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**FORM 10-Q**

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(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, 2022

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: **001-36296**

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**Sesen Bio, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of  
incorporation or organization)

26-2025616

(I.R.S. IRS Employer  
Identification No.)

245 First Street, Suite 1800  
Cambridge, MA

02142

3675 Market Street, Suite 200

Philadelphia, PA

(Address of principal executive offices)

19104

(Zip

Code)

Registrant's telephone number, including area code (617) 444-8550

Not applicable code: (267) 491-6422

(Former name, former address and former fiscal year, Name or Former Address, if changed since last report) Changed Since Last Report

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

Title of each class	Trading	Trading	Name of each exchange on which registered
	Symbol(s)	Symbol(s)	
Common Stock, \$0.001 par value per share	SESN	CARM	The Nasdaq Stock Market LLC

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

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

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

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

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

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

There were 202,757,012

As of May 10, 2023, the registrant had 40,254,666 shares of the registrant's common stock, outstanding as of \$0.001 par value per share, outstanding.

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## SESEN BIO, INC.

### FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Period Ended September 30, 2022 Report on Form 10-Q may include, but are not limited to, statements about:

- ☐ the timing and conduct of our ongoing Phase 1 clinical trial of CT-0508 and our planned clinical trial utilizing CT-0508 in combination with pembrolizumab;
- ☐ the timing and conduct of our preclinical studies and planned clinical trial of CT-0525 for solid tumors that overexpress HER2;
- ☐ the timing and conduct of our planned clinical trial of CT-1119 for advanced mesothelin-positive solid tumors;
- ☐ the timing and conduct of our planned clinical trial of CT-0729 for prostate-specific membrane antigen positive castrate resistant prostate cancer;
- ☐ our ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of our product candidates;
- ☐ our plans to conduct discovery and pre-clinical testing of the development of *in vivo* CAR-M therapeutics for up to twelve oncology targets, as well as multiple other targets and indications;
- ☐ our ability to successfully enroll patients in and complete clinical trials;
- ☐ our plans to conduct discovery and pre-clinical testing of other product candidates;
- ☐ our ability to realize the anticipated benefits of our research and development programs, strategic partnerships, research and licensing programs and academic and other collaborations;
- ☐ the timing of applying for and receiving, and our ability to maintain, marketing approvals from applicable regulatory authorities for our product candidates;

- our ability to obtain and maintain intellectual property protection and regulatory exclusivity for CT-0508, CT-0525 and any other product candidates we are developing or may develop in the future;
- acceptance of CT-0508, CT-0525 and any other product candidates, if and when approved, by patients, the medical community and third-party payors;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents and short-term investments;
- the potential advantages of our product candidates;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization and manufacturing capabilities and strategy;
- the impact of COVID-19 on our business and operations;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our competitive position;
- the impact of government laws and regulations;
- our ability to recognize the benefits of our merger, or the Merger, with Sesen Bio, Inc., or Sesen Bio, and the effect the completion of the Merger will have on our business relationships, operating results and business generally;
- the receipt of any payments under the contingent value rights issued to our stockholders in connection with the closing of the Merger, the realization of value for Sesen Bio legacy assets and the amount and timing of distributions to be made to our stockholders, if any; and
- political and economic developments.

In some cases, forward-looking statements can be identified by terminology such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “goals,” “will,” “would,” “could,” “should,” “continue” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.




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You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the “Company,” “Carisma,” “we,” “us,” and “our” refer to Carisma Therapeutics Inc. (formerly Sesen Bio, Inc.) and its consolidated subsidiaries.

References to “Legacy Carisma” refer to CTx Operations, Inc. (formerly CARISMA Therapeutics Inc.) and references to “Sesen Bio” refer to Sesen Bio, Inc. prior to completion of the Merger.

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CARISMA THERAPEUTICS INC.

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## PART I - I—FINANCIAL INFORMATION

### Item 1. Financial Statements

SESEN BIO, Statements.

CARISMA THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

Unaudited Consolidated Balance Sheets

(Unaudited; In thousands, except share and per share data)

	September 30, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 71,107	\$ 162,636
Short term marketable securities	106,427	—



Accounts receivables	—	21,011
Other receivables	14,297	3,482
Prepaid expenses and other current assets	527	18,476
Total current assets	192,358	205,605
Non-current assets:		
Restricted cash	30	20
Marketable securities	7,336	—
Property and equipment, net	—	43
Intangible assets	—	14,700
Goodwill	—	13,064
Long term prepaid expenses	—	7,192
Other assets	—	123
Total non-current assets	7,366	35,142
Total Assets	<b>\$ 199,724</b>	<b>\$ 240,747</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 514	\$ 2,853
Accrued expenses	33,800	8,255
Other current liabilities	381	460
Total current liabilities	34,695	11,568
Non-current liabilities:		
Contingent consideration	—	52,000
Deferred tax liability	—	3,969
Deferred revenue	—	1,500
Total non-current liabilities	—	57,469
Total Liabilities	34,695	69,037
Stockholders' Equity:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value per share; 400,000,000 shares authorized at September 30, 2022 and December 31, 2021; 202,757,012 and 199,463,645 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	202	199
Additional paid-in capital	493,629	487,768
Other comprehensive loss	(235)	—
Accumulated deficit	(328,567)	(316,257)
Total Stockholders' Equity	165,029	171,710
Total Liabilities and Stockholders' Equity	<b>\$ 199,724</b>	<b>\$ 240,747</b>

**The**

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
<b>Assets</b>		

<b>Current assets:</b>			
Cash and cash equivalents	\$	62,777	\$ 24,194
Marketable securities		76,190	27,802
Prepaid expenses and other assets		5,535	2,596
Total current assets		144,502	54,592
Property and equipment, net		8,107	8,628
Right of use assets – operating leases		3,493	4,822
Restricted cash		30	—
Deferred financing costs		—	4,111
Total assets	\$	156,132	\$ 72,153
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>			
<b>Current liabilities:</b>			
Accounts payable	\$	4,614	\$ 1,728
Accrued expenses		10,187	10,361
Deferred revenue		2,136	2,459
Operating lease liabilities		2,597	3,437
Finance lease liabilities		1,188	1,162
Other current liabilities		755	523
Total current liabilities		21,477	19,670
Deferred revenue		45,000	45,000
Convertible promissory note		—	33,717
Derivative liability		—	5,739
Operating lease liabilities		948	976
Finance lease liabilities		740	872
Other long-term liabilities		1,897	1,041
Total liabilities		70,062	107,015
<b>Commitments and contingencies (Note 5)</b>			
Convertible preferred stock		—	107,808
<b>Stockholders' equity (deficit):</b>			
Common stock \$0.001 par value, 100,000,000 shares authorized, 40,254,666 and 2,217,737 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively			
		40	2
Additional paid-in capital		268,759	1,197
Accumulated other comprehensive income (loss)		136	(41)
Accumulated deficit		(182,865)	(158,223)
Total Carisma Therapeutics Inc. stockholders' equity (deficit)		86,070	(157,065)
Noncontrolling interests		—	14,395
Total stockholders' equity (deficit)		86,070	(142,670)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$	156,132	\$ 72,153

See accompanying notes are an integral part of these condensed to unaudited interim consolidated financial statements.

SESEN BIO,

[Table of Contents](#)**CARISMA THERAPEUTICS INC.****CONDENSED CONSOLIDATED STATEMENTS OF INCOME (OPERATIONS)**  
**(Unaudited; In thousands, except per share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
License and related revenue	\$ 40,000	\$ —	\$ 40,000	\$ 6,544
Total revenue	40,000	—	40,000	6,544
Operating expenses:				
Research and development	2,931	4,967	37,636	18,273
General and administrative	8,141	8,699	32,705	20,797
Restructuring charge	10,947	5,522	10,947	5,522
Intangibles impairment charge	—	31,700	27,764	31,700
Change in fair value of contingent consideration	(1,800)	(114,000)	(52,000)	(52,240)
Total operating expenses	20,219	(63,112)	57,052	24,052
Income (Loss) from Operations	\$ 19,781	\$ 63,112	\$ (17,052)	\$ (17,508)
Other income (expense), net	676	1	867	(45)
Income (Loss) Before Taxes	\$ 20,457	\$ 63,113	\$ (16,185)	\$ (17,553)
Benefit from income taxes	—	8,561	3,875	8,273
Net Income (Loss) After Taxes	\$ 20,457	\$ 71,674	\$ (12,310)	\$ (9,280)
Net income (loss) attributable to common stockholders - basic	\$ 20,442	\$ 71,622	\$ (12,310)	\$ (9,280)
Net income (loss) attributable to common stockholders - diluted	\$ 20,442	\$ 71,623	\$ (12,310)	\$ (9,280)
Net income (loss) per common share - basic	\$ 0.10	\$ 0.36	\$ (0.06)	\$ (0.05)

Weighted-average common shares outstanding - basic	200,464	196,778	199,801	176,547
Net income (loss) per common share - diluted	\$ 0.10	\$ 0.36	\$ (0.06)	\$ (0.05)
Weighted-average common shares outstanding - diluted	200,947	201,017	199,801	176,547

*The accompanying notes are an integral part*

**Unaudited Consolidated Statements of these condensed consolidated financial statements.**

**SESEN BIO, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**Operations and Comprehensive Loss**

**(Unaudited; In thousands, except per share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	\$ 20,457	\$ 71,674	\$ (12,310)	\$ (9,280)
Unrealized (gain) loss on marketable securities	(46)	—	235	—
Total comprehensive income (loss)	\$ 20,503	\$ 71,674	\$ (12,545)	\$ (9,280)

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

**SESEN BIO, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

**(Unaudited; In thousands, except share and per share data)**

	Three Months Ended March 31,	
	2023	2022
Collaboration revenues	\$ 3,243	\$ 822
Operating expenses:		
Research and development	16,641	8,767
General and administrative	9,574	2,211
Total operating expenses	26,215	10,978
Operating loss	(22,972)	(10,156)
Change in fair value of derivative liability	(84)	(557)
Interest (expense) income, net	(1,477)	(599)
Pre-tax loss	(24,533)	(11,312)
Income tax expense	(109)	—
Net loss	\$ (24,642)	\$ (11,312)

Share information:

Net loss per share of common stock, basic and diluted	\$ (1.93)	\$ (5.49)
Weighted-average shares of common stock outstanding, basic and diluted	12,783,523	2,059,986
Comprehensive loss		
Net loss	\$ (24,642)	\$ (11,312)
Unrealized gain (loss) on marketable securities	177	(158)
Comprehensive loss	\$ (24,465)	\$ (11,470)

See accompanying notes to unaudited interim consolidated financial statements.

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss Investments		Accumulated Deficit	Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2021	199,463,645	\$ 199	\$ 487,768	\$ —	\$ (316,257)	\$	171,710
Net loss	—	—	—	—	(807)		(807)
Share-based compensation	—	—	1,894	—	—		1,894
Balance at March 31, 2022	199,463,645	\$ 199	\$ 489,662	\$ —	\$ (317,064)	\$	172,797
Net loss	—	—	—	—	(31,960)		(31,960)
Share-based compensation	—	—	1,802	—	—		1,802
Unrealized loss of investments	—	—	—	(281)	—		(281)
Balance at June 30, 2022	199,463,645	\$ 199	\$ 491,464	\$ (281)	\$ (349,024)	\$	142,358
Net income	—	—	—	—	20,457		20,457
Share-based compensation	3,293,367	3	2,165	—	—		2,168
Unrealized gain of investments	—	—	—	46	—		46
Balance at September 30, 2022	202,757,012	\$ 202	\$ 493,629	\$ (235)	\$ (328,567)	\$	165,029

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## CARISMA THERAPEUTICS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

Unaudited Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity  
(Deficit)

(Unaudited; In thousands, except share and per share data)

	Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity
<b>Balance at December 31, 2020</b>	140,449,647	\$ 140	\$ 306,554	\$ (315,921)	\$ (9,227)
Net loss	—	—	—	(55,512)	(55,512)
Share-based compensation	—	—	958	—	958
Exercises of stock options	30,610	—	39	—	39
Exercises of common stock warrants	852,840	1	468	—	469
Issuance of common stock under ATM Offering, net of issuance costs of \$2.2 million	30,645,702	31	72,512	—	72,543
<b>Balance at March 31, 2021</b>	171,978,799	\$ 172	\$ 380,531	\$ (371,433)	\$ 9,270
Net loss	—	—	—	(25,442)	(25,442)
Share-based compensation	—	—	1,260	—	1,260
Issuance of common stock under ATM Offering, net of issuance costs of \$2.0 million	16,482,152	16	64,245	—	64,261
<b>Balance at June 30, 2021</b>	188,460,951	\$ 188	\$ 446,036	\$ (396,875)	\$ 49,349
Net income	—	—	—	71,674	71,674
Share-based compensation	—	—	1,168	—	1,168
Exercises of stock options	3,000	—	3	—	3
Exercises of common stock warrants	1,195,219	1	656	—	657
Issuance of common stock under ATM Offering, net of issuance costs of \$1.2 million	9,804,475	10	38,147	—	38,157
<b>Balance at September 30, 2021</b>	<b>199,463,645</b>	<b>\$ 199</b>	<b>\$ 486,010</b>	<b>\$ (325,201)</b>	<b>\$ 161,008</b>

The

	Convertible preferred stock		Stockholders' Equity (Deficit)								
	Shares	Amount	Accumulated								
			Common stock		Additional paid-in capital	other comprehensive income (loss)	Accumulated deficit				
			Shares	Amount				Noncontrolling interests		Total	
Balance, December 31, 2022	8,700,885	\$ 107,808	2,217,737	\$ 2	\$ 1,197	\$ (41)	\$ (158,223)	\$ 14,395	\$(142,		
Stock-based compensation	—	—	—	—	265	—	—	—			
Unrealized gain on marketable securities	—	—	—	—	—	177	—	—			
Issuance of common stock for cash in pre-closing financing	—	—	3,730,608	4	30,636	—	—	—	30,		
Issuance of common stock upon settlement of convertible promissory note, accrued interest, and related derivative liability	—	—	5,059,338	5	42,442	—	—	—	42,		
Issuance of common stock to Sesen Bio shareholders in reverse capitalization	—	—	10,374,272	10	72,034	—	—	—	72,		

Conversion of convertible preferred stock and non-controlling interests to common stock	(8,700,885)	(107,808)	18,872,711	19	122,185	—	—	(14,395)	107,
Net Loss	—	—	—	—	—	—	(24,642)	—	(24,
Balance, March 31, 2023	—	\$ —	40,254,666	\$ 40	\$ 268,759	\$ 136	\$ (182,865)	\$ —	\$ 86,
Balance, December 31, 2021	8,700,885	\$ 107,808	2,059,072	\$ 2	\$ 816	\$ —	\$ (96,997)	\$ 14,395	\$ (81,
Exercise of stock options	—	—	2,572	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	89	—	—	—	—
Unrealized loss on marketable securities	—	—	—	—	—	(158)	—	—	(
Net loss	—	—	—	—	—	—	(11,312)	—	(11,
Balance, March 31, 2022	8,700,885	\$ 107,808	2,061,644	\$ 2	\$ 905	\$ (158)	\$ (108,309)	\$ 14,395	\$ (93,

See accompanying notes are an integral part of these condensed to unaudited interim consolidated financial statements.

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**CARISMA THERAPEUTICS INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Unaudited Consolidated Statement of Cash Flows**



(Unaudited; In thousands)

	Nine Months Ended September 30,	
	2022	2021
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (12,310)	\$ (9,280)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13	74
Share-based compensation	5,864	3,386
Change in fair value of contingent consideration	(52,000)	(52,240)
Intangibles impairment charge	27,764	31,700
Changes in operating assets and liabilities:		
Accounts receivable (net)	21,012	(1,107)
Other receivables	(10,816)	—
Prepaid expenses and other current assets	17,949	(23,665)
Long term prepaid expenses	7,192	—
Unrealized loss on marketable securities	(235)	—
Other assets	123	—
Accounts payable	(2,339)	807
Accrued expenses and other liabilities	21,497	(4,453)
Deferred revenue	(1,500)	(1,500)
Net cash provided by (used in) operating activities	<b>22,214</b>	<b>(56,278)</b>
<b>Cash Flows from Investing Activities:</b>		
Purchase of marketable securities	(113,763)	—
Disposal (purchase) of equipment	30	(4)
Net cash used in investing activities	<b>(113,733)</b>	<b>(4)</b>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from issuance of common stock under ATM Offering, net of issuance costs	—	174,961
Proceeds from exercises of stock options	—	42
Proceeds from exercises of common stock warrants	—	1,126
Net cash provided by financing activities	<b>—</b>	<b>176,129</b>
Net (decrease) increase in cash, cash equivalents and restricted cash	(91,519)	119,847
Cash, cash equivalents and restricted cash - beginning of period	162,656	55,409
Cash, cash equivalents and restricted cash - end of period	<b>\$ 71,137</b>	<b>\$ 175,256</b>
<b>Supplemental cash flow disclosure:</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ 127	\$ 131

The

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (24,642)	\$ (11,312)
Adjustment to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization expense	705	218
Stock-based compensation expense	265	89
Reduction in the operating right of use assets	1,329	381
Amortization of debt discount	1,283	623
Change in fair value of derivative liability	84	557
Accretion on marketable securities	(163)	—
Non-cash interest expense	41	59
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,623)	(1,607)
Accounts payable	2,823	2,612
Accrued expenses	(4,445)	(2,259)
Deferred revenue	(323)	45,619
Operating lease liabilities	(868)	(376)
Net cash (used in) provided by operating activities	(25,534)	34,604
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(34,460)	(63,244)
Proceeds from the sale of marketable securities	31,000	—
Purchases of property and equipment	(135)	(1,007)
Net cash used in investing activities	(3,595)	(64,251)
<b>Cash flows from financing activities:</b>		
Cash, cash equivalents and restricted cash acquired in connection with the reverse recapitalization	37,903	—
Payment of reverse recapitalization finance costs	(1,742)	—
Proceeds from the issuance of common stock in pre-closing financing	30,640	—
Payment of principal related to finance lease liabilities	(106)	—
Proceeds from failed sale-leaseback arrangement	1,092	—
Payment of finance liability from failed sale-leaseback arrangement	(45)	—
Proceeds from issuance of convertible promissory note	—	35,000
Net cash provided by financing activities	67,742	35,000
Net increase in cash and cash equivalents	38,613	5,353
Cash, cash equivalents and restricted cash at beginning of the period	24,194	28,551
Cash, cash equivalents and restricted cash at end of the period	\$ 62,807	\$ 33,904
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$ 45	\$ —
<b>Supplemental disclosure of non-cash financing and investing activities:</b>		
Conversion of convertible preferred stock and non-controlling interests upon Merger	\$ 122,204	\$ —

Conversion of convertible promissory note, accrued interest and derivative liability upon Merger	\$ 42,447	\$ —
Reverse recapitalization costs in accrued expenses	\$ 4,071	\$ —
Unrealized gain (loss) on marketable securities	\$ 177	\$ (158)
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ —	\$ 3,072
Allocation of debt proceeds to derivative liability	\$ —	\$ 3,820
Property and equipment in accounts payable	\$ 49	\$ 103

See accompanying notes are an integral part of these condensed to unaudited interim consolidated financial statements.

## SESEN BIO,

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## CARISMA THERAPEUTICS INC.

### Notes to the Interim Consolidated Financial Statements

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

#### 1. DESCRIPTION OF BUSINESS

Sesen Bio,

##### (1) Background

Carisma Therapeutics Inc. ("Sesen Bio" or the "Company"), a Delaware corporation formed in February 2008, Corporation (collectively with its subsidiaries, the Company), is a late-stage clinical/clinical-stage cell therapy company focused on advancing/advancing utilizing the Company's proprietary macrophage and monocyte cell engineering platform to develop transformative immunotherapies to treat cancer and other serious diseases. The Company has created a comprehensive cell therapy platform to enable the therapeutic use of engineered macrophages and monocytes, which belong to a subgroup of white blood cells called myeloid cells. The Company's initial focus is its proprietary Chimeric Antigen Receptor Macrophage (CAR-M) cell therapy platform, which redirects macrophages against specific tumor associated antigens and enables targeted fusion protein therapeutics for anti-tumor immunity by utilizing genetically modifying myeloid cells (macrophages and monocytes) to express chimeric antigen receptors (CARs), enabling the treatment potent innate immune cells to recognize specific tumor associated antigens on the surface of tumor cells. The Company's initial product candidates, CT-0508 and CT-

0525 are *ex vivo* autologous cell therapy product candidates, wherein immune cells from blood drawn from a patient are engineered outside of the body and reinfused into the same patient. The Company also has research programs to develop *in vivo* cell therapy macrophage products.

The Company's lead product candidate, CT-0508, is the first CAR-M to be evaluated in a human clinical trial and is intended to treat solid tumors that overexpress HER2. CT-0508 is currently being studied in a multi-center open label Phase 1 clinical trial in the U.S. This ongoing first-in-human study evaluates the safety, tolerability and manufacturing feasibility of CT-0508. The Company has completed enrollment of the first group of patients in this trial, with cancer, nine patients having been successfully dosed over a five-day dosing schedule. In November 2022, the Company presented preliminary clinical results from the first group of patients. CT-0508 was successfully manufactured using macrophages obtained from heavily pre-treated, advanced solid tumor patients and has shown high CAR expression, viability, and purity. In addition, CT-0508 has been generally well-tolerated after infusion with no dose-limiting toxicities reported to date from the nine patients enrolled in the first group. While the results from this early clinical trial data are both preliminary and limited, the Company believes the results indicate that CT-0508 can be detected within the tumor microenvironment (TME), lead to remodeling and activation of the TME, and potentially induce anti-tumor adaptive immunity. In addition to the first group of patients in this study, the Company initiated a second group to evaluate bolus dosing of patients and anticipate data from this group in the second half of 2023. The Company has also initiated several additional sub studies evaluating CT-0508 in the clinical setting. In addition to monotherapy treatment, the Company has observed synergistic potential of CT-0508 with a PD1 blocking T-cell checkpoint inhibitor in multiple preclinical models. As a result of those studies and the preliminary results from group 1 in the Company's clinical trial, the Company initiated a sub study to evaluate at least nine patients with the co-administration of CT-0508 and pembrolizumab in the first quarter of 2023. The Company anticipates the initial data from this sub study in the second half of 2023.

The Company's most advanced second product candidate, Vicineum™, CT-0525, is also known intended to treat solid tumors that overexpress HER2, is in preclinical development and is advancing to an IND filing. CT-0525 utilizes a novel approach to CAR-M therapy to accelerate the manufacturing process, increase the cell yield, and improve upon the potential anti-tumor effect by engineering patients' monocytes directly, without *ex vivo* differentiation into macrophages, as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of Pseudomonas exotoxin A for the treatment of non-muscle invasive bladder cancer ("NMIBC"). On July 15, 2022, the Company made currently does for CT-0508. The Company refers to this CAR-Monocyte approach as CAR-Mono. By increasing the strategic decision to voluntarily pause further development of Vicineum cell yield, the CAR-Mono approach enables a larger potential dose and improved trafficking, which may improve tumor control. The CAR-Mono approach reduces manufacturing time and leverages an automated, closed-system manufacturing process. CT-0525 is the Company's first CAR-Mono product candidate and is currently in the United States, pre-clinical process development stage. The decision was based on a thorough reassessment of Vicineum following recent discussions with Company expects to submit an IND to the United States U.S. Food and Drug Administration ("FDA"), which had implications on (FDA) for CT-0525 in the size, timeline second half of 2023, initiate clinical development shortly thereafter, and costs treat the

Company's first patient in the first half of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients 2024.

Beyond CT-0508 and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intends to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, CT-0525, the Company has turned its primary focus a broad pipeline of cell therapy assets in various stages of pre-clinical development. In addition to the careful assessment development of potentialex vivo CAR-M cell therapies, the Company is developing in vivo CAR-M gene therapies, wherein immune cells are directly engineered within the patient's body. To advance the Company's in vivo CAR-M therapeutics, the Company established a strategic alternatives collaboration with the goal of maximizing shareholder value.

#### **Anticipated ModernaTX Inc. (Moderna) (Note 10).**

#### **Reverse Merger with Sesen Bio**

**On March 7, 2023, the Company (formerly publicly-held Sesen Bio, Inc.) consummated a merger with CTx Operations, Inc. (formerly privately-held CARISMA Therapeutics Inc.**

Following ) (Legacy Carisma) pursuant to an extensive process Agreement and Plan of evaluating strategic alternatives, including identifying Merger and reviewing potential candidates for a strategic transaction, on September 20, 2022 Reorganization, as amended (the Merger Agreement), Sesen Bio, by and among the Company, Legacy Carisma and Seahawk Merger Sub, Inc. (Merger Sub), a Delaware corporation and wholly-owned subsidiary of Sesen Bio ("the Company. The Merger Sub"), and CARISMA Therapeutics Inc., a Delaware corporation ("Carisma"), entered into an Agreement and Plan provided for the merger of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Legacy Carisma, with Legacy Carisma continuing as a wholly-owned subsidiary of Sesen Bio the Company and the surviving

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#### **CARISMA THERAPEUTICS INC.**

#### **Notes to the Interim Consolidated Financial Statements**

corporation of the merger (the "Merger") Merger). Sesen Bio's board of directors unanimously approved Pursuant to the Merger Agreement, and resolved to recommend that Sesen Bio's stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

Sesen Bio's future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that Sesen Bio does not complete the Merger with Carisma, Sesen Bio may continue to review and evaluate a strategic alternatives, including, without limitation, another strategic transaction and/or pursue a liquidation and dissolution of Sesen Bio.

### **Viventia Acquisition**

In September 2016, the Company entered into a Share Purchase Agreement with Viventia changed its name from "Sesen Bio, Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Viventia"), the shareholders of Viventia named therein (the "Selling Shareholders") and, solely in its capacity as seller representative, Clairmark Investments Ltd., a corporation incorporated under the laws of the Province of Ontario, Canada (the "Share Purchase Agreement"), pursuant to which the Company agreed to and simultaneously completed the acquisition of all of the outstanding capital stock of Viventia from the Selling Shareholders (the "Viventia Acquisition"). In connection with "Carisma Therapeutics Inc." At the closing of the Viventia Acquisition, the Company issued 4.0 million Merger, (a) each then outstanding share of Legacy Carisma common stock and convertible preferred stock (including shares of its Legacy Carisma common stock issued in connection with the pre-closing financing transaction described below) were converted into shares of Sesen Bio common stock at an exchange ratio of 1.8994 shares of Sesen Bio for each share of Legacy Carisma (the Exchange Ratio), and (b) each then outstanding stock option to purchase Legacy Carisma common stock was assumed by Sesen Bio, with necessary adjustments to reflect the Exchange Ratio.

Except as otherwise indicated, references herein to "Carisma," the "Company," or the "Combined Company," refer to Carisma Therapeutics Inc. on a post-Merger basis, and references to "Legacy Carisma" refer to the Selling Shareholders, which at that time represented approximately 19.9% business of privately-held CARISMA Therapeutics Inc. prior to the completion of the voting power Merger. References to "Sesen Bio" refer to Sesen Bio, Inc. prior to the completion of the Merger.

Following the Merger, the shareholders of Legacy Carisma held 74.2% of the Combined Company, and the shareholders of Sesen Bio held 25.8% of the Combined Company.

### **Basis of Presentation and Exchange Ratio**

As discussed in Note 3, the Merger was accounted for as reverse capitalization under which the historical financial statements of the Company as of immediately prior to the issuance Merger are Legacy Carisma. All common stock, per share and related information presented in the consolidated financial statements and notes prior to the Merger has been retroactively adjusted to reflect the Exchange Ratio.

## **(2) Development-Stage Risks and Liquidity**

The Company has incurred losses since inception and has an accumulated deficit of \$182.9 million as of March 31, 2023. The Company anticipates incurring additional losses until such shares.

time, if ever, that it can generate significant sales from its product candidates currently in development. Management believes that cash, cash equivalents and marketable securities of \$139.0 million as of March 31, 2023 are sufficient to sustain planned operations through the end of 2024.

The Company is subject to those risks associated with any specialty biotechnology company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, under the Share Purchase Agreement, the Company operates in an environment of rapid technological change and is obligated to pay largely dependent on the services of its employees and consultants.

### (3) Summary of Significant Accounting Policies

#### *Interim Financial Statements*

The summary of significant accounting policies included in the Company's audited consolidated financial statements and related notes as of and for the year ended December 31, 2022 filed as Exhibit 99.4 to the Selling Shareholders certain post-closing contingent cash payments upon Company's Current Report on Form 8-K/A filed with the achievement of specified milestones and based upon net sales, in each case subject to the terms and conditions set forth in the Share Purchase Agreement, including: (i) a one-time milestone payment of \$12.5 million payable upon the first sale of Vicineum (the "Purchased Product"), in the United States; (ii) a one-time milestone payment of \$7.0 million payable upon the first sale of the Purchased Product in any one of certain specified European countries; (iii) a one-time milestone payment of \$3.0 million payable upon the first sale of the Purchased Product in Japan; and (iv) quarterly earn-out payments equal to 2% of net sales of the Purchased Product during specified earn-out periods. Such earn-out payments are payable with respect to net sales in a country beginning SEC on the date of the first sale in such country and ending on the earlier of (i) December 31, 2033, and (ii) fifteen years after the date of such sale, subject to early termination in certain circumstances if a biosimilar product is on the market in the applicable country. Under the Share Purchase Agreement, the Company, its affiliates, licensees and subcontractors are required to use commercially reasonable efforts, for the first seven years following the closing of the Viventia Acquisition, to achieve marketing authorizations throughout the world and, during the applicable earn-out period, to commercialize the Purchased Product in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China and Canada. Certain of these payments are payable to individuals or affiliates of individuals that became employees or members of the Company's board of directors. However, as of September 30, 2022, none of these individuals are active employees of the Company or members of the Company's board of directors.

### 2. BASIS OF PRESENTATION

April 4, 2023.

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with United States U.S. generally accepted accounting principles ("GAAP") (GAAP). Any reference references in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") (ASC) and Accounting Standards Updates ("ASUs"), Update (ASU) promulgated by the Financial Accounting Standards Board ("FASB") (FASB).

#### *Interim Financial Statements*

The accompanying unaudited interim condensed consolidated financial statements have been prepared from include the books and records accounts of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the United States Securities and Exchange Commission ("SEC"), which permit reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, which are, in its wholly owned subsidiaries. In the opinion of management, necessary for a fair presentation of the accompanying condensed interim consolidated balance sheets and statements of operations and comprehensive (loss) income, stockholders' equity (deficit) and cash flows have been made. Although these interim financial statements do not include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the information consolidated financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2023 and footnotes required for complete annual financial statements, management believes the disclosures are adequate to make the information presented not misleading. These unaudited interim its results of operations and cash flows for the nine three months ended September 30, 2022 March 31, 2023 and 2022. Operating results for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the full year. These unaudited year ending December 31, 2023. The interim condensed consolidated financial statements, and footnotes presented herein,

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**CARISMA THERAPEUTICS INC.**

**Notes to the Interim Consolidated Financial Statements**

do not contain all of the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the Company's audited annual consolidated financial statements and footnotes included in its Annual related notes as of and for the year ended December 31, 2022 filed as Exhibit 99.4 to the Company's Current Report on Form 10-K, as 8-K/A filed with the SEC on February 28, 2022, wherein a more complete discussion of significant accounting policies and certain other information can be found.

**April 4, 2023.**

***Use of Estimates***

The preparation of unaudited interim consolidated financial statements in accordance conformity with GAAP and the rules and regulations of the SEC requires the use of management to make estimates and assumptions based on judgments considered reasonable, which that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited interim consolidated financial statements and the reported amounts of



revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the Actual results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent could differ from other sources. Although management believes its estimates such estimates. Estimates and assumptions are reasonable when made, periodically reviewed, and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are based upon information available at the time they are made. Management evaluates the determined to be necessary.

Significant areas that require management's estimates and assumptions on an ongoing basis and, if necessary, makes adjustments. Due to the risks and uncertainties involved in the Company's business and evolving market conditions, and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results. The most significant estimates and judgments impact include the fair value of intangible assets; goodwill the Company's common stock and contingent consideration; income taxes (including the valuation allowance for deferred tax assets); derivative liability prior to the Merger, stock-based compensation assumptions, the estimated useful lives of property and equipment, and accrued research and development expenses.

## **Principles**

### **Fair Value of Consolidation**

The Company's condensed consolidated financial statements include Financial Instruments

Management believes that the accounts of the Company, its wholly owned subsidiaries Viventia and Seahawk Merger Sub, Inc. and its indirect subsidiary, Viventia Bio USA Inc. All intercompany transactions and balances have been eliminated in consolidation.

### **Foreign Currency Translation**

The functional currency of the Company and each of its subsidiaries is the US dollar.

## **3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The Company's complete summary of significant accounting policies can be found in "Item 15. Exhibits and Financial Statement Schedules - Note 3. Summary of Significant Accounting Policies" in the audited annual consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2021.

## **4. RECENT ACCOUNTING PRONOUNCEMENTS**

### **Adopted in 2022**

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06") ASU 2020-06 simplifies the complexity associated with applying US

GAAP for certain financial instruments with characteristics of both liability and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity's own equity. The ASU also amends the diluted earnings

per share ("EPS") guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, and should be applied on a full or modified retrospective basis. The Company adopted this guidance on a modified retrospective basis effective January 1, 2022 and it did not have an impact on the Company's financial position, results of operations including per-share carrying amounts or cash flows.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* ("ASU 2021-04"). ASU 2021-04 clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021-04 is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, and should be applied on a prospective basis. The Company adopted this guidance effective January 1, 2022 and it did not have an impact on the Company's financial position, results of operations including per-share amounts, or cash flows.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

## 5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash and cash equivalents, restricted cash, prepaid expenses and other current assets, and accounts payable on the Company's condensed consolidated balance sheets approximated their fair values as of September 30, 2022 and December 31, 2021 due to their short-term nature.

Certain of the Company's financial instruments, are measured at including cash equivalents and accounts payable, approximate fair value using a three-level hierarchy that prioritizes due to the inputs used short-term nature of those instruments. The Company considered the carrying value of its convertible promissory note (Note 6) as of December 31, 2022 to measure fair value. This approximate fair value hierarchy prioritizes due to its short-term nature. The derivative liability was recorded at its estimated fair value prior to its derecognition in March 2023 upon conversion of the associated convertible promissory notes.

### Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimizes minimize the use of unobservable inputs, inputs to the extent possible. The three levels Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value are as follows:

**Level 1:** Inputs are quoted prices for identical instruments in active markets.

**Level 2:** Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets to the extent that observable inputs are not active; available, thereby allowing for situations in which there is little, if any, market activity for the asset or model-derived valuations whose inputs are observable or whose significant liability at the measurement date.

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## CARISMA THERAPEUTICS INC.

### Notes to the Interim Consolidated Financial Statements

The following fair value drivers are observable.

**Level 3:** Inputs are unobservable and reflect hierarchy table presents information about the Company's own assumptions, based on the best information available, including the Company's own data.

The following tables set forth the carrying amounts assets and fair values of the Company's financial instruments liabilities measured at fair value on a recurring basis basis:

(in thousands)	Fair value measurement at reporting date using			
	(Level 1)	(Level 2)	(Level 3)	
<b>March 31, 2023:</b>				
Assets:				
Cash equivalents – money markets accounts	\$ 7,002	\$ —	\$ —	
Marketable securities – U.S. Treasuries	\$ 76,190	\$ —	\$ —	
<b>December 31, 2022:</b>				
Assets:				
Cash equivalents – money markets accounts	\$ 7,794	\$ —	\$ —	
Marketable securities – U.S. Treasuries	\$ 27,802	\$ —	\$ —	
Liability:				
Derivative liability – redemption feature on convertible promissory note	\$ —	\$ —	\$ 5,739	

The following is a summary of the Company's marketable securities as of September 30, 2022 March 31, 2023:

Gross

	Amortized	unrealized	
	cost	gain	Fair value
Available-for-sale marketable securities			
U.S. Treasury securities	\$ 76,054	\$ 136	\$ 76,190

The table presented below is a summary of the changes in fair value of the Company's derivative liability associated with the redemption feature of the Company's convertible promissory note (Level 3 measurement):

	Three Months Ended March 31,	
(in thousands)	2023	2022
Balance at the beginning of the period	\$ 5,739	\$ —
Balance at issuance	—	3,820
Change in fair value	84	557
Derecognition upon conversion of convertible promissory note	(5,823)	—
Balance at the end of the period	\$ —	\$ 4,377

During the three months ended March 31, 2023 and December 31, 2021 (in thousands):

September 30, 2022						
	Carrying Amount	Fair Value	Fair Value Measurement Based on			
			Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>						
Marketable securities:						
Money market funds (cash equivalents)	\$ 11,450	\$ 11,450	\$ 11,450	\$ —	\$ —	—
Marketable securities	\$ 113,763	\$ 113,763	\$ —	\$ 113,763	\$ —	—
<b>Liabilities:</b>						
Contingent consideration	\$ —	\$ —	\$ —	\$ —	\$ —	—

December 31, 2021						
	Carrying Amount	Fair Value	Fair Value Measurement Based on			
			Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>						

Money market funds (cash equivalents)	\$	16,382	\$	16,382	\$	16,382	\$	—	\$	—
<b>Liabilities:</b>										
Contingent consideration	\$	52,000	\$	52,000	\$	—	\$	—	\$	52,000

2022, there were no transfers between Level 1, Level 2 and Level 3.

### **Concentration of credit risk**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company evaluates transfers between fair value levels at maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.

### **Segment information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the end chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

### **Net loss per share**

Basic net loss per share of each reporting period. There were no asset or liability transfers between fair value levels during common stock is computed by dividing net loss by the nine months ended September 30, 2022 and the year ended December 31, 2021.

### **Contingent Consideration**

On September 20, 2016, the Company acquired Viventia through the issuance weighted-average number of shares of common stock plus contingent consideration, outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or

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## **CARISMA THERAPEUTICS INC.**

### **Notes to the Interim Consolidated Financial Statements**

conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic

net loss per share due to the fact that when a net loss exists, potentially dilutive securities are not included in the calculation as their impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	March 31,	
	2023	2022
Convertible preferred stock and exchangeable shares	—	9,936,148
Stock options	4,184,047	3,553,288
Conversion of convertible promissory note	—	3,258,151
	<u>4,184,047</u>	<u>16,747,587</u>

#### *Recently adopted accounting pronouncements*

In June 2016, the FASB issued ASU 2016-13 *Financial Instruments - Credit Losses*, which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. This standard is effective for fiscal years beginning after December 15, 2022. The Company adopted the guidance using a modified retrospective approach as of January 1, 2023 which resulted in no cumulative-effect adjustment to accumulated deficit and did not have a material impact on the Company's consolidated financial statements.

#### (4) Merger with Sesen Bio

On March 7, 2023, Legacy Carisma completed the Merger with Sesen Bio as discussed in Note 1. The Merger was accounted for as a reverse recapitalization under GAAP because the primary assets of Sesen Bio were cash, cash equivalents and marketable securities. For financial reporting purposes Legacy Carisma was determined to be the accounting acquirer based upon the terms of the Merger and other factors, including: (i) Legacy Carisma stockholders own approximately 74.2% of the Combined Company, (ii) Legacy Carisma holds the majority (six of seven) of board seats of the Combined Company and (iii) Legacy Carisma management holds all key positions of management. Accordingly, the Merger was treated as the equivalent of Legacy Carisma issuing stock to acquire the net assets of Sesen Bio. As a result of the Merger, the net assets of Sesen Bio were recorded at their acquisition-date fair value in the consolidated financial statements and the reported operating results prior to the Merger are those of Legacy Carisma. Immediately after the Merger, there were 40,254,666 shares of the Company's common stock outstanding.

The following table shows the net assets acquired in the Merger (in thousands):

	March 7, 2023
Cash and cash equivalents	\$ 37,873

Marketable securities	44,588
Prepaid expenses and other assets	1,316
Restricted cash	30
Accounts payable and accrued expenses	(3,499)
Total net assets acquired	80,308
Less: Transaction costs	(8,264)
Total net assets acquired less transaction costs	\$ 72,044

Subsequent to March 7, 2023, the Company paid \$4.6 million of severance and personnel costs related to Sesen Bio.

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**CARISMA THERAPEUTICS INC.**  
**Notes to the Interim Consolidated Financial Statements**

**(5) Commitments and Contingencies**

***Leases***

The Company has operating leases for its lab and office space in Philadelphia, Pennsylvania. The Company's operating leases have term end dates ranging from 2023 to 2029. The Company also has obligations under an arrangement for the use of certain lab equipment that are classified as finance leases that commenced in 2022 and have end dates ranging from 2024 to 2025.

The Company's operating and finance lease right-of-use (ROU) assets and the related lease liabilities are initially measured at the present value of future lease payments over the lease term. The Company is responsible for payment of certain real estate taxes, insurance and other expenses on certain of its leases. These amounts are generally considered to be variable and are not included in the measurement of the ROU assets and lease liability. The Company accounts for non-lease components, such as maintenance, separately from lease components.

The Company carries lab equipment from failed sale leasebacks, as property and equipment, net on the accompanying consolidated balance sheets. The ongoing lease payments are recorded as reductions to the finance liability and interest expense. As of March 31, 2023, the Company had a \$2.7 million financing liability recorded in other current liabilities and other long-term liabilities on the unaudited consolidated balance sheet.

The elements of the lease costs were as follows (in thousands):

	Three months ended March 31,	
	2023	2022
Operating lease cost	\$ 1,433	\$ 465
Finance lease cost:		
Amortization of lease assets	297	—
Interest on lease liabilities	45	—
Total finance lease cost	342	—
Total lease cost	\$ 1,775	\$ 465

Lease term and discount rate information related to leases was as follows:

	March 31,	
	2023	2022
Weighted-average remaining lease term (in years)		
Operating leases	2.2	2.2
Finance leases	1.9	—
Weighted-average discount rate		
Operating leases	9.5 %	9.4 %
Finance leases	9.0 %	— %

Supplemental cash flow information (in thousands):

	Three Months Ended	
	March 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash used in operating leases	\$ 1,448	\$ 461
Operating cash used in finance leases	\$ 45	\$ —
Financing cash used in finance leases	\$ 106	\$ —



## CARISMA THERAPEUTICS INC.

### Notes to the Interim Consolidated Financial Statements

Future maturities of lease liabilities were as follows as of March 31, 2023 (in thousands):

	Operating Leases	Finance Leases
Fiscal year ending:		
2023 (remaining nine months)	\$ 2,713	\$ 1,150
2024	213	600
2025	219	338
2026	226	—
2027	233	—
Thereafter	423	—
Total future minimum payments	4,027	2,088
Less imputed interest	(482)	(160)
Present value of lease liabilities	\$ 3,545	\$ 1,928

#### Licensing and Sponsored Research Agreements

Under a license agreement (Penn License Agreement) with The Trustees of the University of Pennsylvania (Penn), the Company is required to make annual payments of \$10,000 through 2021 and \$25,000 in annual payments thereafter. Penn is eligible to receive up to \$10.9 million per product in development upon the achievement of certain clinical, regulatory and commercial milestone events. There are additional milestone payments required to be paid of up to \$30.0 million per product in commercial milestones, and up to an additional \$1.7 million in development and regulatory milestone payments for the first CAR-M product directed to mesothelin. Additionally, the Company is obligated to pay Penn single-digit royalties based on its net sales.

In March 2023, the Company entered into a manufacturing and supply agreement (Novartis Agreement) with Novartis Pharmaceuticals Corporation (Novartis) for the manufacturing of the Company's CT-0508 product candidate. The Novartis Agreement is for five years and shall renew automatically for additional one-year periods unless and until terminated by either party. In addition, to purchasing of the manufacturing of the product, the Company will pay \$1.0 million per calendar year, payable in quarterly payments, for reserved capacity starting on the date on which the Novartis site is declared ready to produce CT-0508 as determined by the Company. In the event of termination without cause by the Company, a termination fee equal to \$4.0 million will be payable by Carisma to Novartis which pursuant to the terms of the agreement can be credited in full against amounts due for a Share Purchase Agreement. The Company substitute product.

#### Contingencies

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the acquired assets and liabilities based on their estimated fair values as amount of the acquisition date and finalized its purchase accounting for the Viventia Acquisition during the third quarter of 2017. The contingent consideration relates to amounts potentially payable to the former shareholders of Viventia under the Share Purchase Agreement. Contingent consideration is measured at its estimated fair value at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant inputs, including internally developed financial forecasts, probabilities of success, and the timing of certain milestone events and achievements, which are not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. The Company continues to believe that Vicineum has benefits for patients and healthcare providers that assessment and/or remediation can be maximized through reasonably estimated.

On February 3, 2023, a company with purported stockholder filed a larger infrastructure, and as such intends to seek a partner for the further development of Vicineum. Additionally, during the second quarter of 2022, the Company observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the bacillus Calmette-Guérin ("BCG") shortage. Accordingly, during the second quarter of 2022, the Company concluded that it no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights had been out-licensed pursuant to the exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") (the "Qilu License Agreement") (as further described in Note 17. "License Agreements" below). As of June 30, 2022, Qilu held the exclusive license to develop Vicineum in the Greater China region, and accordingly, the \$1.8 million estimated earnout payment in the Greater China region remained as long-term contingent consideration as of June 30, 2022.

The Company and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, the Company will regain the rights to develop, manufacture and commercialize Vicineum in Greater China. However, the Company does not plan to develop or commercialize Vicineum in that region or any other, as it is pursuing the Merger with Carisma. The Company is also seeking to sell or out-license Vicineum and all the related obligations related to Vicineum. The Company expects that any partner who acquires or licenses Vicineum from the Company will be obligated to make any payments,

including those related to sales in the Greater China region (if any), that become payable to the former shareholders of Viventia under the Share Purchase Agreement. If a sale or license of Vicineum has not occurred at the time the Merger is completed, Carisma has indicated it may continue to seek a sale or license of Vicineum and has no plans to develop Vicineum. Accordingly, as of September 30, 2022, the Company concluded that it no longer expects to owe any future earnout payments related to the Greater China region and reduced its remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

The contingent consideration balance as of December 31, 2021 was \$52.0 million which was based upon projected world-wide net sales. The estimated fair value of the Company's contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved through 2033, the level of commercial sales of Vicineum forecasted for the US, Europe, Japan, China and other potential markets and discount rates ranging from 8.0% to 9.3% as of December 31, 2021.

The following table sets forth a summary of the change in the fair value of the Company's contingent consideration liability, measured on a recurring basis at each reporting period (in thousands).

<b>Balance at December 31, 2021</b>	<b>\$</b>	<b>52,000</b>
Change in fair value of contingent consideration		(52,000)
<b>Balance at September 30, 2022</b>	<b>\$</b>	<b>—</b>

The fair value of the Company's contingent consideration was determined based on the present value of projected future cash flows associated with sales-based milestones and earnouts on net sales and is heavily dependent on discount rates to estimate the fair value at each reporting period. Earnouts were determined using an earnout rate of 2% on all commercial net sales of Vicineum through December 2033. The discount rate applied to the 2% earnout was derived from the Company's weighted-average cost of capital, which was 9.3% as of December 31, 2021. As of December 31, 2021, the balance also reflected potential milestone payments which constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021. The decrease in the fair value of contingent consideration of \$52.0 million for the nine months ended September 30, 2022 was driven by the Company's decision to voluntarily pause further development of Vicineum **complaint** in the United States and seek a partner to acquire or license the asset and assume all associated liabilities.

## 6. RECEIVABLES

The accounts receivable balance as of December 31, 2021 was \$21.0 million, comprised primarily of a \$20 million milestone achieved in December 2021 due to F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") initiating a Phase II clinical trial in the fourth quarter of 2021. In January 2022 the payment of \$20 million was received. Additionally, in June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as a "Technology Transfer". As such, the Company recorded \$0.9 million of revenue and accounts receivable **District Court** for the additional purchase price resulting from Qilu's obligation to pay the Company an amount equal to **District of Delaware against Sesen Bio and its recovery board** of value-added tax ("VAT"). The accounts receivable balance as of September 30, 2022 was zero.

The other receivables balance as of September 30, 2022 was \$14.3 million compared to \$3.5 million as of December 31, 2021. The increase of \$10.8 million was primarily driven by expected insurance recovery of \$13.4 million related to the preliminary settlements of the Securities Litigation and Derivative Litigation (as defined in Note 10. "Commitments and Contingencies" below). This amount was partially offset by the receipt of \$2.4 million for German VAT recovery in the first half

of 2022, related to drug substance sent to Baxter in 2020 and 2019 and other individually immaterial changes of \$0.2 million.

## 7. PREPAID EXPENSES

The prepaid expenses balance as of September 30, 2022 was \$0.5 million compared to \$25.7 million as of December 31, 2021. In light of the Company's decision to voluntarily pause further development of Vicineum in the United States, the Company evaluated prepaid balances and determined that the prepayments for the manufacturing of Vicineum, including consumables, had no future economic benefit or value. Pursuant to ASC Topic 730, *Certain Nonrefundable Advance Payment*, the Company expensed \$25.2 million of prepayments during the second quarter of 2022.

## 8. INTANGIBLE ASSETS AND GOODWILL

### Intangibles

Intangible assets on the Company's condensed consolidated balance sheets are the result of the Viventia Acquisition in September 2016. The following table sets forth the composition of intangible assets as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
IPR&D intangible assets:		
Vicineum European Union rights	\$ —	\$ 14,700
<b>Total Intangibles</b>	<b>\$ —</b>	<b>\$ 14,700</b>

The fair value of the acquired intangible assets for the European Union ("EU") rights of Vicineum is determined using a risk-adjusted discounted cash flow approach, which includes probability adjustments for projected revenues and operating expenses based on the success rates assigned to each stage of development for each geographical region; as well as discount rates applied to the projected cash flows.

During the second quarter of 2022, the Company observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. On July 15, 2022, the Company made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of a potential partnering deal to conclude the fair value of the Company's intangible asset of Vicineum EU rights. The Company concluded that the carrying value of the Company's intangible asset of Vicineum EU rights of \$14.7 million was fully impaired and was reduced to zero in the second quarter of 2022.

### Goodwill

Goodwill on the Company's condensed consolidated balance sheets is the result of the Viventia Acquisition in September 2016. During the second quarter of 2022, the Company observed continued trends in the Company's market capitalization as compared to the carrying value of its single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, size, length and cost of a clinical trial, and time to potential market launch. The Company identified these changes as potential impairment indicators and performed a quantitative impairment analysis, in advance of the Company's typical annual assessment date of October 1 and concluded that the carrying value of its goodwill of \$13.1 million was fully impaired and was reduced to zero in the second quarter of 2022.

The following table sets forth a summary of the change in goodwill as of September 30, 2022 and December 31, 2021 (in thousands):

<b>Balance at December 31, 2021</b>	<b>\$</b>	<b>13,064</b>
Impairment loss		(13,064)
<b>Balance at September 30, 2022</b>	<b>\$</b>	<b>—</b>

## 9. ACCRUED EXPENSES

The following table sets forth the composition of accrued expenses as of September 30, 2022 and December 31, 2021 (in thousands):

	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Research and development	\$ 1,242	\$ 1,841
Payroll-related expenses	2,043	2,967
Restructuring charge related	6,365	1,497
Professional fees	381	597
Legal expenses, including preliminary litigation settlement	23,720	1,344
Other	49	9
<b>Total Accrued Expenses</b>	<b>\$ 33,800</b>	<b>\$ 8,255</b>

## 10. COMMITMENTS AND CONTINGENCIES

### Legal Proceedings

From time to time, the Company may become subject to legal proceedings, claims, and litigation arising in the ordinary course of business. When the Company becomes aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. In accordance with authoritative guidance, the Company records loss contingencies in its financial statements only for matters in which losses are probable and can be reasonably estimated. Where a range of loss can be reasonably estimated with no best estimate in the range, the Company records the minimum estimated liability. If the loss is not probable or the amount of the loss cannot be reasonably estimated, the Company discloses the nature of the specific claim if the likelihood of a potential loss is reasonably possible, and the amount involved is material. The Company continuously assesses the potential liability related to the Company's pending litigation and revises its estimates when additional information becomes available. The Company is not currently a party to any material legal proceedings, other than as described below.

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits, captioned *Bibb Plumley v. Sesen Bio, Inc., et al.*, Case No. 1:21-cv-07025, *Cizek v. Sesen Bio, Inc., et al.*, Case No. 1:21-cv-07309, and *Markman v. Sesen Bio, Inc. et al.*, Case No. 1:21-cv-08308 were filed against 23-cv-00131 (D. Del.) ("the Company and certain of its officers in the US District Court for the Southern District of New York, Plumley Complaint"). The three complaints alleged violations of Sections 10(b) and 20(a) Plumley Complaint asserts claims under Section 14(a) of the Exchange Act and Rule 10b-5 14a-9 promulgated thereunder based on for allegedly false and misleading statements made by in the Company concerning its BLA for Vicineum for proxy statement/prospectus filed as part of the treatment of BCG-unresponsive NMIBC. The three complaints sought compensatory damages Registration Statement in connection with the Merger and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption *In re Sesen Bio, Inc. Securities Litigation*, Master File No. 1:21-cv-07025-AKH (the "Securities Litigation"), and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dreshaj (collectively, the "Lead Plaintiffs") collectively

as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and Section 20(a) of the Exchange Act for alleged "control person" liability with respect to such allegedly false and Rule 10b-5 promulgated thereunder on misleading statements and seeks, among other relief, an order enjoining the same theory as Merger and an award for plaintiffs' fees and costs. On February 7, 2023, another purported stockholder filed a complaint in the prior complaints. The defendants moved to dismiss the Amended Complaint on March 7, 2022, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, the Company and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, the Company and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to the Company and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against the Company and the other defendants. The settlement payment is being funded by the Company and its insurance carriers. On September 1, 2022, the US United States District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The court has set a final settlement approval hearing for January 23, 2023 at 10:00 a.m. local time.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. against Sesen Bio Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against the Company's its board of directors, and certain of its officers in the US District Court for the District of Massachusetts, with the Company named as nominal defendant. On January 12, 2022, a third derivative complaint captioned TangFranchi v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against 1:23-cv-01041 (S.D.N.Y.) ("the Company's board of directors and certain of its officers (the "State Derivative Litigation" Franchi Complaint"). The three derivative complaints allege breach of fiduciary duties, waste of corporate assets, Franchi Complaint contains substantially similar allegations and violations of federal securities laws based claims and seeks substantially similar relief as the Plumley Complaint. Additionally, on statements made by the Company concerning its BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021 February 9, 2023, the court consolidated the two federal court cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538 (the "Federal Derivative Litigation"). On December 22, 2021, the court entered a joint stipulation among the parties to stay the Federal Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On May 1, 2022, the plaintiffs another purported stockholder filed a verified consolidated shareholder derivative complaint in the Federal Derivative Litigation. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the



Securities Litigation. On July 6, 2022, the Company and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). Pursuant to that agreement, the individual defendants will cause the Company to adopt certain enhancements to its corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of the Company, provide broad customary releases to the individual defendants. On August 22, 2022, the parties entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of Settlement related to the Derivative Litigation confirms that the Company previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, the Company will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$0.6 million payment for plaintiffs' attorneys fees due to the benefits the corporate governance enhancements are intended to provide to the Company. The payment of plaintiffs' attorneys fees is being funded by the Company. On September 2, 2022, the court issued an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. The court has set a final settlement approval hearing for November 8, 2022 at 2:00 p.m. local time.

During the second quarter of 2022, the Company deemed the settlements of the Securities Litigation and the Derivative Litigation probable and amounts reasonably estimable and recorded \$21.6 million to litigation related liability. During the third quarter of 2022, the Company paid \$0.6 million to be held in escrow United States District Court for the plaintiffs' attorneys fees Southern District of New York against Sesen Bio and \$21.0 million remains as a litigation related liability as of September 30, 2022.

The Company, its board of directors, captioned *Menzer v. Sesen Bio, Inc., et al.*, 23-cv-01119 (S.D.N.Y.) ("the Menzer Complaint"). The Menzer Complaint contains substantially similar allegations and claims and seeks substantially similar relief as the Plumley Complaint and the individual defendants continue to deny all allegations of any wrongdoing but are seeking to settle the Securities Litigation and the Derivative Litigation to avoid the uncertainty, risk, expense and distraction of protracted litigation.

Subsequent to September 30, 2022, on October 21, 2022, Franchi Complaint. In April 2023, the Company received two separate letters executed a confidential fee agreement to resolve the stockholders' claim for attorney's fees and on November 4, 2022, the Company received one letter from purported stockholders demanding that the Company amend the Registration Statement filed expenses in connection with the SEC on October 14, 2022 (the "Registration Statement") Plumley Complaint, Franchi Complaint, and Menzer Complaint. The amount of the confidential fee agreement was reasonably estimated and probable to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by the Company's financial advisor be incurred as of March 31, 2023, resulting in support a \$0.2 million accrued settlement as of its fairness opinion, and the background and process leading March 31, 2023.

## CARISMA THERAPEUTICS INC.

**Notes to the execution of the Merger Agreement. The Company believes that these demands are without merit and intends to vigorously defend against them. See discussion in Note 19. "Subsequent Events." Interim Consolidated Financial Statements**

### Executive Employment Agreements

The Company has entered into employment agreements or offer letters with certain of its key executives, providing for separation payments and benefits in certain circumstances, as defined in the agreements.

### Termination Fees associated with the Anticipated Merger with Carisma

The Merger Agreement contains certain termination rights of each of the Company and Carisma. Upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay the Company a termination fee of \$5.49 million and/or reimburse the Company expenses up to a maximum of \$1.75 million. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company

## 11. LEASES

During the third quarter of 2022, the Company entered into a Lease Termination Agreement (the "Lease Termination Agreement") pursuant to which the Company terminated its operating lease agreement for its 31,000 square foot facility in Winnipeg, Manitoba which consists of manufacturing, laboratory, warehouse, and office space and agreed to end the lease by September 30, 2022. As part of the execution of the Lease Termination Agreement, the Company paid the landlord the all-inclusive sum of CAD \$1.2 million (USD \$0.9 million). Operating lease costs under this lease, including the related operating costs, were \$81,000 and \$245,000 for the three and nine months ended September 30, 2022, respectively, and \$79,000 and \$245,000 for the three and nine months ended September 30, 2021, respectively.

The right of use asset total was zero as of September 30, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the asset component of the Company's operating leases was recorded as operating lease right-of-use assets and reported within other assets on the Company's condensed consolidated balance sheets. The short-term lease liability was zero as of September 30, 2022 and \$123,300 as of December 31, 2021. As of December 31, 2021, the short-term lease liability was recorded in other current liabilities on the Company's condensed consolidated balance sheets. There was no long-term operating

lease liability as of September 30, 2022 or December 31, 2021. Operating lease cost is recognized on a straight-line basis over the term of the lease.

In addition, the Company has short-term property leases for modular office space for 1) its corporate headquarters in Cambridge, MA and 2) office space in Philadelphia, PA. The Company intends to terminate both leases

### (6) Stockholders' Equity

On March 7, 2023 in connection with the closing of the anticipated Merger, with Carisma. The short-term lease in Philadelphia the following is renewed reflected on a month-to-month basis. The short-term lease in Cambridge ends in June 2023. The minimum monthly rent for these office spaces is \$2,500 and \$17,200, respectively, which is subject to change if and as the Company adds space to or deducts space from the leases.

## 12. STOCKHOLDERS' EQUITY



## Equity Financings

### ATM Offering

The Company has entered into an Open Market Sale Agreement <sup>SM</sup> with Jefferies LLC ("Jefferies"), dated November 29, 2019, as amended by Amendment No. 1 dated October 30, 2020, Amendment No. 2 dated February 17, 2021 and Amendment No. 3, dated June 1, 2021 (as amended, the "Sale Agreement"), under which the Company may issue and sell shares <sup>consolidated statements</sup> of its common stock, par value \$0.001 per share, from time to time through Jefferies (the "ATM Offering"). In June and July 2021, the Company filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of \$200 million of common stock pursuant to the Sale Agreement of which \$97.8 million of common stock remain available for future issuance as of September 30, 2022. Sales of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including but not limited to sales made directly on or through the Nasdaq Stock Market or any other existing trading market for the Company's common stock. The Company may sell shares of its common stock efficiently from time to time but has no obligation to sell any of its common <sup>convertible preferred</sup> stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon the Company's instructions, which include a prohibition on sales below a minimum price set by the Company from time to time. The Company has provided Jefferies with customary indemnification rights, and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. The Company did not sell any shares of common stock pursuant to the Sale Agreement during the nine months ended September 30, 2022. The Company raised \$175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of \$3.17 per share during the nine months ended September 30, 2021. The Company raised \$38.2 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of \$4.01 per share during the three months ended September 30, 2021. Share issuance costs, including sales agent commissions, related to the ATM Offering totaled \$1.2 million and \$5.4 million during the three and nine months ended September 30, 2021, respectively.

### Preferred Stock

Pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), the Company is authorized to issue 5.0 million shares of "blank check" preferred stock, \$0.001 par value per share, which enables its board of directors, from time to time, to create one or more series of preferred stock. Each series of preferred stock issued shall have the rights, preferences, privileges and restrictions as designated by the board of directors. The issuance of any series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the Company's common stock. The Company had no preferred stock issued and outstanding as of September 30, 2022 and 2021.

### Common Stock

Following approval by the Company's stockholders on May 3, 2021, an amendment became effective to the Certificate of Incorporation that increased the number of authorized shares of common stock from 200 million to 400 million, of which approximately 203 million and 199 million shares were issued and outstanding as of September 30, 2022 and December 31, 2021, respectively. In addition, the Company had reserved for issuance the following amounts of shares of its common stock for the purposes described below as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021

Shares of common stock issued	202,757	199,464
Shares of common stock reserved for issuance for:		
Warrants	199	199
Stock options	16,202	15,703
Restricted stock units	4,695	3,041
Shares available for grant under 2014 Stock Incentive Plan	3,725	8,933
Shares available for sale under 2014 Employee Stock Purchase Plan	2,300	2,300
<b>Total shares of common stock issued and reserved for issuance</b>	<b>229,878</b>	<b>229,640</b>

The voting, dividend and liquidation rights of holders of shares of common stock are subject to and qualified by the rights, powers and preferences of holders of shares of preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders; provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Company's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more such series, to vote thereon. There shall be no cumulative voting.

Dividends may be declared and paid on the common stock from funds lawfully available thereof as and when determined by the board of directors and subject to any preferential dividend or other rights of any then-outstanding preferred stock. The Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, dividends on its common stock, other than the CVR (as further described in Note 17. "License Agreements" below) and any special cash dividend that the Company may pay to its stockholders in connection with the consummation of the Merger.

Upon the dissolution or liquidation of the Company, whether voluntary or involuntary, holders of common stock will be entitled to receive all assets of the Company available for distribution to its stockholders, subject to any preferential or other rights of any then-outstanding preferred stock.

#### Warrants

All of the Company's outstanding warrants are non-tradeable and equity-classified because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*. The following table sets forth the Company's warrant activity stockholders' equity (deficit) for the three months ended September 30, 2022 (in thousands):

Issued	Exercise Price	Expiration	December 31, 2021	Issued	(Exercised)	(Cancelled)	September 30, 2022
Mar-2018	\$0.55*	Mar-2023	132	—	—	—	132
Nov-2017	\$0.55*	Nov-2022	12	—	—	—	12
May-2015	\$11.83	Nov-2024	28	—	—	—	28
Nov-2014	\$11.04	Nov-2024	27	—	—	—	27
			<b>199</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>199</b>

\*Exercise price shown March 31, 2023 and 2022: (i) reflects modification and (ii) is subject to further adjustment based on down round provision added by amendment described in "Item 15. Exhibits and Financial Statement Schedules -

Note 12. Stockholders' Equity (Deficit)" in the audited annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

### 13. EARNINGS (LOSS) PER SHARE

A net loss cannot be diluted. Therefore, when the Company is in a net loss position, basic and diluted loss per common share are the same. If the Company achieves profitability, the denominator sale of a diluted earnings per common share calculation includes both the weighted-average number of 3,730,608 shares outstanding and the number of common stock equivalents, if in a pre-closing funding at \$8.21 per share for total proceeds of \$30.6 million, (ii) the inclusion issuance of such 5,059,338 shares of common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and unvested restricted stock awards and units using upon the treasury stock method, along with the effect, if any, from outstanding convertible securities. The majority settlement of the Company's outstanding warrants to purchase common \$35.0 million convertible promissory note, accrued interest and related derivative liability, (iii) the conversion of convertible preferred stock have participation rights to any dividends that may be declared in the future and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

Additionally, an entity that presents earnings per share shall recognize the value of the effect of an anti-dilution provision in an equity-classified freestanding financial instrument in the period the anti-dilution provision is triggered. That effect shall be treated exchangeable shares previously presented as a deemed dividend and as a reduction of income available to common stockholders in basic earnings per share. The deemed dividend is added back to income available to common stockholders when applying the treasury stock method for diluted earnings per share.

For periods with net income, diluted net earnings per share is calculated by either (i) adjusting the weighted-average noncontrolling interests into 18,872,711 shares outstanding for the dilutive effect of common stock, equivalents outstanding for (iv) the period as determined using the treasury stock method or (ii) the two-class method considering common stock equivalents, whichever is more dilutive. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. Accordingly, the Company applied the two-class method to calculate basic and diluted net earnings per share issuance of 10,374,272 shares of common stock to Sesen Bio stockholders as consideration for the three months ended September 30, 2022 Merger.

#### (7) Stock-based Compensation

##### 2017 Stock Incentive Plan

Legacy Carisma adopted the CARISMA Therapeutics Inc. 2017 Stock Incentive Plan, as amended (the Legacy Carisma Plan), that provided for the grant of incentive stock options to employees, directors, and September 30, 2021 consultants. The maximum term of options granted under the Legacy Carisma Plan was ten years, and stock options typically vested over a four-year period. The Company's stock options vest based on the terms in the awards agreements and generally vest over four years.

For purposes Upon completion of the diluted net loss per share calculation, common stock equivalents are excluded from the calculation if their effect would be anti-dilutive.

The following table illustrates the determination of earnings (loss) per share for each period presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
(in thousands, except per share amounts)				
<b>Basic Earnings (Loss) Per Share:</b>				
Numerator:				
Net income (loss)	\$ 20,457	\$ 71,674	\$ (12,310)	\$ (9,280)
Less: Income attributable to participating securities - basic	(15)	(52)	—	—
Net income (loss) attributable to common stockholders - basic	<u>\$ 20,442</u>	<u>\$ 71,622</u>	<u>\$ (12,310)</u>	<u>\$ (9,280)</u>
Denominator:				
Weighted average common shares outstanding - basic	200,464	196,778	199,801	176,547
Net income (loss) per share applicable to common stockholders - basic	<u>\$ 0.10</u>	<u>\$ 0.36</u>	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>
<b>Dilutive Earnings (Loss) Per Share:</b>				
Numerator:				
Net income (loss)	\$ 20,457	\$ 71,674	\$ (12,310)	\$ (9,280)
Less: Income attributable to participating securities - diluted	(15)	(51)	—	—
Net income (loss) attributable to common stockholders - diluted	<u>\$ 20,442</u>	<u>\$ 71,623</u>	<u>\$ (12,310)</u>	<u>\$ (9,280)</u>
Denominator:				
Weighted average shares outstanding	200,464	196,778	199,801	176,547
Dilutive impact from:				
Stock options and employee stock purchase plan	20	4,239	—	—
Restricted stock units & performance based stock units	463	—	—	—
Weighted average common shares outstanding - diluted	<u>200,947</u>	<u>201,017</u>	<u>199,801</u>	<u>176,547</u>
Net income (loss) per share applicable to common stockholders - diluted	<u>\$ 0.10</u>	<u>\$ 0.36</u>	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>

The following potentially dilutive securities outstanding as of September 30, 2022 and 2021 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Warrants	55	55	199	199

Stock options	16,182	11,273	16,202	15,511
RSUs and PSUs	4,232	—	4,695	—
<b>Total</b>	<b>20,469</b>	<b>11,328</b>	<b>21,096</b>	<b>15,710</b>

#### 14. SHARE-BASED COMPENSATION

The following table sets forth the amount of share-based compensation expense recognized by Merger, the Company by line item on its Condensed Consolidated Statements of Operations for assumed the three Legacy Carisma Plan and nine months ended September 30, 2022 the outstanding and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 863	\$ 152	\$ 1,838	\$ 536
General and administrative	1,305	1,016	4,026	2,849
<b>Total Share Based Compensation</b>	<b>\$ 2,168</b>	<b>\$ 1,168</b>	<b>\$ 5,864</b>	<b>\$ 3,385</b>

*unexercised options issued thereunder, and ceased granting awards under the Legacy Carisma Plan.*

#### 2014 Stock Incentive Plan

The Company's Sesen Bio, Inc. Amended and Restated 2014 Stock Incentive Plan, as amended (the "2014 Plan"), was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The Sesen Bio 2014 Plan became effective immediately prior to the closing of the Company's IPO in February 2014 and Plan), provides for the grant of incentive and non-qualified stock options, restricted stock awards and restricted stock units, ("RSU"), stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants, and advisors, with amounts and terms of grants determined by the Company's Company's board of directors at the time of grant, to the Company's employees, officers, directors, consultants and advisors.

At the Annual Meeting of the Company's stockholders in June 2019, the Company's stockholders approved an amendment to the 2014 Plan that (i) increased by 7.9 million the number of shares of common stock reserved for issuance under the 2014 Plan and (ii) eliminated the "evergreen" or automatic replenishment provision of the 2014 Plan, pursuant to which the number of shares of common stock authorized for issuance under the 2014 Plan was automatically increased on an annual basis. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 Plan that increased by 12 million the number of shares of common stock reserved for issuance under the 2014 Plan. There were approximately 3.7 million shares of common stock available for issuance under the 2014 Plan as of September 30, 2022.

grant.

Stock options outstanding under the Sesen Bio 2014 Plan generally vest over a four-year four-year period at the rate of 25% of the grant vesting on the first anniversary of the date of grant and 6.25% of the grant vesting at the end of each successive three-month period thereafter. Stock

options granted under the Sesen Bio 2014 Plan are exercisable for a period of ten years from the date of grant. There were approximately 13.0 million stock options outstanding under

On March 7, 2023, the Company amended and restated the Sesen Bio 2014 Plan as of September 30, 2022.

On September 9, 2021, to (i) change the Company's board of directors and the compensation committee name of the board of directors (the "Compensation Committee") approved a retention program for all then-current employees, except for the Chief Executive Officer, pursuant to which the Company will provide certain incentives designed to retain such employees (the "2021 Retention Program"). Pursuant plan to the 2021 Retention Program Carisma Therapeutics Inc. 2014 Amended and effective as Restated Stock Incentive Plan (the 2014 Plan) and (ii) adopt a new form of October 1, 2021, the Company's non-executive employees received a combination of a cash bonus award stock option agreement and a one-time RSU award which vested in full on September 30, 2022, subject to continued employment through September 30, 2022. Each RSU represents a contingent right to receive one share new form of the Company's common stock.

Also pursuant to the 2021 Retention Program and effective as of October 1, 2021, the Company's executive officers, except for the Chief Executive Officer, were granted a one-time performance-based restricted stock unit ("PSU") award equal to the value of approximately fifty percent of then-current base salary. The fair value of PSUs at the grant date was \$0.4 million. Each PSU represents a contingent right to receive one share of the Company's common stock upon the satisfaction of pre-determined performance criteria. Subject to continued employment, such awards vest on September 30, 2023 upon the determination by the Compensation Committee of the level of achievement of certain key milestones consisting of a clinical trial milestone, an employee retention milestone and cash management milestones. As of September 30, 2022, achievement was deemed probable for only the cash management milestone, representing \$87,000, 20% of the PSU awards. Therefore, \$11,000 and \$44,000 have been expensed during the three and nine months ended September 30, 2022, respectively and \$43,000 remains measured but unrecognized.

#### **2009 Stock Incentive Plan**

The Company maintains a 2009 Stock Incentive Plan, as amended and restated (the "2009 Plan"), which provided agreement for the grant of incentive and non-qualified stock options and restricted stock awards and restricted stock units with amounts and terms of grants determined by the Company's board of directors at the time of grant, to its employees, officers, directors, consultants and advisors. Upon the closing of its IPO in February 2014, the Company ceased granting awards under the 2009 Plan and all shares (i) available for issuance under the 2009 Plan at such time and (ii) subject to outstanding awards under the 2009 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued were carried over to the 2014 Plan. Stock options granted under the 2009 Plan are exercisable for a period of ten years from the date of grant. There were approximately 0.1 million fully vested stock options outstanding under the 2009 Plan as of September 30, 2022.

#### **Out-of-Plan Inducement Grants**

From time to time, the Company has granted equity awards to its newly hired employees, including executives, in accordance with Nasdaq employment inducement grant exemption (Nasdaq Listing Rule 5635(c)(4)). Such grants are made outside of the 2014 Plan and act as an inducement material to the employee's acceptance of employment with the Company. There were approximately 3.1 million stock options outstanding which were granted as employment inducement awards outside of the 2014 Plan as of September 30, 2022.

#### **Stock Options**

The following table sets forth a summary of the Company's total stock option activity, including awards granted under the 2014 Plan and the 2009 Plan and inducement grants made outside of

stockholder approved plans, for the nine months ended September 30, 2022:

	Number of Shares under Option (in thousands)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	15,703	\$1.93	8.03	\$ 82
Granted	1,510	\$0.72		
Exercised	—	—		
Canceled or forfeited	(1,011)	2.10		
Outstanding at September 30, 2022	16,202	\$1.81	7.41	DM
Exercisable at September 30, 2022	10,494	\$1.72	6.94	DM

The Company recognized share-based compensation expense, related to stock options, of \$1.0 million and \$3.5 million for the three and nine months ended September 30, 2022, respectively and \$1.2 million and \$3.4 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022 March 31, 2023, there was \$6.4 million approximately 6.2 million shares of total unrecognized compensation cost related to unvested common stock options which the Company expects to recognize over a weighted-average period of 2.09 years. The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2022 and 2021 were \$0.46 and \$2.20, respectively. No stock options were exercised during the nine months ended September 30, 2022.

For the nine months ended September 30, 2022 and 2021, the grant-date fair value of stock options was determined using the following weighted-average inputs and assumptions in the Black-Scholes option pricing model:

	September 30, 2022	September 30, 2021
Fair market value	\$0.72	\$3.40
Grant exercise price	\$0.72	\$3.40
Expected term (in years)	6.0	6.03
Risk-free interest rate	2.1%	0.9%
Expected volatility	71.8%	74.6%
Dividend yield	—%	—%

#### **Restricted Stock Units and Performance Stock Units**

The following table sets forth a summary of the Company's RSU and PSU activity remained available for the nine months ended September 30, 2022:

issuance.

	Restricted Stock Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	3,041	\$0.80
Granted RSU	4,160	\$0.68
Cancelled RSU	(217)	\$0.75



Released RSU	(3,293)	\$0.76
Granted PSU	1,004	\$0.67
Unvested at September 30, 2022	<u>4,695</u>	\$0.68

The Company did not grant any RSUs or PSUs during the nine months ended September 30, 2021.

The share-based compensation expense related to RSUs and PSUs for the three and nine months ended September 30, 2022 was \$1.2 million and \$2.4 million, respectively. There was no shared-based compensation expense related to RSUs and PSUs for the three and nine months ended September 30, 2021. As of September 30, 2022, there was \$1.8 million of total unrecognized compensation cost related to unvested RSUs and PSUs.

## 15. EMPLOYEE BENEFIT PLANS

### 2014 Employee Stock Purchase Plan

The Company's Sesen Bio 2014 Employee Stock Purchase Plan ("the Sesen Bio 2014 ESPP") was adopted by its board of directors in December 2013 and subsequently approved by its stockholders in January 2014. The 2014 ESPP became effective immediately prior to the closing of the Company's IPO in February 2014 and established an initial reserve of 0.2 million shares of the Company's common stock for issuance to participating employees. At the Annual Meeting of the Company's stockholders in May 2021, the Company's stockholders approved an amendment to the 2014 ESPP that increased by 2.3 million the number of shares of common stock reserved for issuance under the 2014 ESPP. The purpose of the 2014 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2014 ESPP ESPP provides employees with the opportunity to purchase shares of common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. The Company estimates the number of shares to be issued at the end of an offering period and recognizes expense over the requisite service period. Shares purpose of the common stock issued and sold pursuant to the Sesen Bio 2014 ESPP are shown on is to enhance employee interest in the condensed consolidated statements success and progress of changes in stockholders' equity (deficit); the Company by encouraging employee ownership of common stock. On March 7, 2023, the Company amended and restated the Sesen Bio 2014 ESPP to (i) change the name of the plan to Carisma Therapeutics Inc. 2014 Employee Stock Purchase Plan (the 2014 ESPP) and (ii) restate and integrate all prior amendments thereto. As of September 30, 2022 March 31, 2023, there were 2.3 million 0.2 million shares of common stock remained available for sale issuance.

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## CARISMA THERAPEUTICS INC.

### Notes to the Interim Consolidated Financial Statements



The following is a summarizes of stock option activity for the three months ended March 31, 2023:

	Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	3,356,937	\$ 1.01		
Sesen Bio options assumed in the Merger	765,223	27.94		
Exercised	—	—		
Granted	144,352	5.64		
Forfeited	(82,427)	1.46		
Expired	(38)	1.46		
Outstanding as of March 31, 2023	4,184,047	\$ 6.11	5.9	\$ 6,798
Exercisable as of March 31, 2023	3,015,084	\$ 5.58	3.6	\$ 5,057
Vested and expected to vest at March 31, 2023	4,184,047	\$ 6.11	5.9	\$ 6,798

The weighted-average grant-date per share fair values of options granted during the three months ended March 31, 2023 and 2022 were \$2.64 and \$0.75, respectively. The fair values in the three months ended March 31, 2023 and 2022 were estimated using the Black-Scholes option-pricing model based on the following assumptions:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	2.92% - 4.03%	2.40% - 2.41 %
Expected term	6 years	6 years
Expected volatility	57.77% - 62.65 %	54.54% - 54.58 %
Expected dividend yield	—	—

#### ***Stock-Based Compensation Expense***

The Company recorded stock-based compensation expense in the following expense categories in its accompanying unaudited consolidated statements of operations:

	Three months ended March 31,	
	2023	2022
Research and development	\$ 10	\$ 41
General and administrative	255	48
	<u>\$ 265</u>	<u>\$ 89</u>

The Company recognized stock-based compensation expense of \$0.2 million related to the modification of Sesen Bio options assumed in connection with the Merger. Compensation cost for awards not vested as of March 31, 2023 was \$1.1 million and will be expensed over a weighted-average period of 2.3 years.

#### (8) Income Taxes

Based on taxable income projections for 2023, the Company expects to have federal and state income tax liabilities for the year. For tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 (TCJA) eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the U.S. and 15 years for research activities performed outside the U.S. pursuant to Internal Revenue Code Section 174. In addition, the Company is required to recognize tax revenue of \$45.0 million in 2023, related to cash received under the 2014 ESPP, collaboration and license agreement with Moderna in 2022, for tax purposes in advance of GAAP recognition. The Company did not sell any shares also expects limitations on utilization of net operating losses and tax credits under TCJA and/or IRC Sections 382 and 383. These requirements temporarily increase the ESPP during Company's U.S. federal and state cash tax payments and reduces cash flows in 2023.

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### CARISMA THERAPEUTICS INC.

#### Notes to the nine Interim Consolidated Financial Statements

#### (9) Related-Party Transactions

The Company has outstanding licensing and scientific research agreements with Penn, a significant shareholder (Note 5). The Company recognized \$0.4 million and \$0.2 million of research and development expense for the three months ended September 30, 2022 March 31, 2023 and 2021.

##### **Defined Contribution Plans**

##### *United States - 401(k) Plan*

2022, respectively, related to the Penn License Agreement.

The Company's collaboration and license agreement is with Moderna, a significant shareholder (Note 10). The Company maintains recognized revenue of \$3.2 million and \$0.8 million for the three months ended March 31, 2023 and 2022, respectively, related to the Moderna License Agreement.

## (10) Moderna Collaboration and License Agreement

In January 2022, the Company entered into a 401(k) defined contribution retirement plan which covers all Collaboration and License Agreement with Moderna (Moderna License Agreement), to develop and commercialize *in vivo* engineered CAR-M therapeutics for different forms of its US employees. Employees are eligible cancer. The Moderna License Agreement allows Moderna to participate on the first of the month following their date of hire. Under the 401(k) plan, participating employees may defer develop and commercialize product candidates for up to 100% of their pre-tax salary, subject to certain statutory limitations. Employee contributions vest immediately. twelve research targets. The plan allows Company is responsible for a discretionary match per participating employee up to a maximum of \$4,000 per year. The expenses incurred discovering and optimizing development candidates, and Moderna is responsible for the periods presented were de minimis amount for each of the nine months ended September 30, 2022 and 2021, respectively.

### Canada - Defined Contribution Plan

The Company maintains a defined contribution plan for its Canadian employees. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company contributes up clinical development thereafter. Pursuant to the first 4% of eligible compensation for its Canadian-based employees to Moderna License Agreement, the retirement plan. The expenses incurred Company and Moderna formed a joint steering committee (JSC) that is responsible for the periods presented were de minimis amount coordination and oversight of all research activities to which the Company is responsible for each of the nine months ended September 30, 2022 and 2021, respectively.

## 16. INCOME TAXES

providing. The following table sets forth the components of the Company's loss before income taxes by country (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Country:		
United States	\$ (32,083)	\$ (38,864)
Canada	15,898	21,311
<b>Total loss before income taxes</b>	<b>\$ (16,185)</b>	<b>\$ (17,553)</b>

The Company's tax benefit (provision) JSC is comprised of three representatives each from the following components (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Current tax benefit (provision)		
Federal	\$ —	\$ 8,559
State	—	—
Foreign	3,875	(286)

<b>Total current benefit</b>	<b>\$ 3,875</b>	<b>\$ 8,273</b>
------------------------------	-----------------	-----------------

The Company's deferred tax liability is comprised Company and Moderna and with Moderna having final decision-making authority, subject to customary exclusions.

During the research term of the following:

	<b>September 30, 2022</b>	<b>December 31, 2021</b>
Deferred tax liabilities		
IPR&D	\$ —	\$ (3,969)
<b>Total deferred tax liabilities</b>	<b>\$ —</b>	<b>\$ (3,969)</b>

For the nine months ended September 30, 2022, Moderna License Agreement, the Company recorded has granted Moderna an exclusive worldwide royalty free license to the Company's intellectual property associated with the product candidates that permits Moderna to conduct its research and development activities. Upon Moderna's election of a benefit development target (and payment of a related development target designation milestone) for commencement of pre-clinical development of a product candidate, the Company will grant Moderna an exclusive worldwide, sublicensable royalty bearing license to develop, manufacture and commercialize the product candidate.

Upon execution of the Moderna License Agreement, Moderna made an upfront non-refundable payment of \$45.0 million to the Company. Moderna also will reimburse the Company for all costs incurred by the Company in connection with its research and development activities under the Moderna License Agreement plus a reasonable margin for the respective services performed (with a minimum commitment to reimburse \$10.0 million in research and development costs over the first three years from income taxes execution of \$3.9 million the Moderna License Agreement). In the second quarter of 2022, addition, assuming Moderna develops and commercializes 12 products, each directed to a different development target, the Company determined that the fair value is eligible to receive up to between \$247.0 million and \$253.0 million per product in development target designation, development, regulatory and commercial milestone payments. The Company is also eligible to receive tiered mid-to-high single digit royalties of the Vicineum EU rights was zero, which resulted in an impairment charge of \$14.7 million, net product sales, subject to adjustment. In connection with this impairment charge, addition, Moderna will repay the Company reversed the associated deferred tax liability by \$4.0 million as an income tax benefit, partially offset by \$0.1 million income tax paid to foreign jurisdictions for certain development, regulatory and commercial milestone payments and certain royalty payments pursuant to the Qilu License Agreement.

During the nine months ended September 30, 2021, the Company recorded a benefit from income taxes of \$8.3 million. In the third quarter of 2021, the Company determined that the fair value of the Vicineum US rights was zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, the Company wrote-down the associated deferred tax liability by \$8.6 million as a benefit.

## 17. LICENSE AGREEMENTS

### ***In-License Agreements***

#### ***License Agreement with Zurich***

The Company has a Company's license agreement with the University of Zurich ("Zurich") which grants Pennsylvania. The Moderna License Agreement terminates on a product-by-product basis upon the Company exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to the Company's targeting agent, including an EpCAM chimera and related immunoconjugates and methods latest of use and manufacture expiration of the same (the "Zurich License Agreement"). These applicable product patents, cover some key aspects expiration of Vicineum. The Company's receipt of the Complete Response Letter ("CRL") regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC triggered a \$0.5 million milestone payment to Zurich. Under the Zurich License Agreement, as of September 30, 2022, the Company is also obligated to pay up to a 4% royalty on the net product sales for products covered by or manufactured using a method covered by a valid claim in the Zurich patent rights, which includes Vicineum. Royalties owed to Zurich will be reduced if the total royalty rate owed by the Company to Zurich and any other third party is 10% or greater, provided that the royalty rate to Zurich may not be less than 2% of net sales. The obligation to pay royalties in a particular country expires upon the expiration or termination of the last of the Zurich patent rights that covers the manufacture, use or sale of a product. There is no obligation to pay royalties in a country if there is no valid claim that covers the product or a method of manufacturing the product. The Company recorded an expense of \$0.3 million and \$0.5 million related to meeting a development milestone, the submission of the Company's BLA with the FDA in December 2020, in the fourth quarter of 2020, and a regulatory milestone, the Company's receipt of the CRL from the FDA in August 2021, in the third quarter of 2021, respectively.

#### *License Agreement with Micromet*

The Company has a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants it nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the "Micromet License Agreement"). These patents cover some key aspects of Vicineum. Under the terms of the Micromet License Agreement, as of September 30, 2022, the Company may be obligated to pay up to €2.4 million in milestone payments for the first product candidate that achieves applicable regulatory and sales-based development milestones (approximately \$2.4 million at exchange rates in effect on September 30, 2022). The Company is also required to pay up to a 3.5% royalty on the net sales for products covered by the agreement, which includes Vicineum. The royalty rate owed to Micromet in a particular country will be reduced to 1.5% if there are no valid claims covering the product in that country. The obligation to pay royalties in a particular country expires upon the later of the expiration date of the last valid claim covering the product exclusivity and the tenth anniversary of the first commercial sale, unless terminated earlier by the Company or Moderna.

At commencement, the Company identified several potential performance obligations within the Moderna License Agreement, including research and development services on research targets, option rights held by Moderna, a non-exclusive royalty-free license to use the Company's intellectual property to conduct research and development activities and participation on the JSC. The Company determined that there were two performance obligations comprised of (i) research and development services and (ii) option rights.

For the research and development services, the stand-alone selling price was determined considering the expected passthrough costs and cost of the product in such country. Finally, research and development services and a reasonable margin for the Company respective services. The material rights from the option rights were valued based on the estimated discount at which the option is required to pay to Micromet an annual license maintenance fee priced and the Company's estimated probability of €50,000 (approximately \$48,987 at exchange rates in effect the options' exercise as of September 30, 2022), the time of the agreement. The transaction price allocated to research and development services is recognized as collaboration revenues as

the research and development services are provided to satisfy the underlying obligation related to the research

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**CARISMA THERAPEUTICS INC.**  
**Notes to the Interim Consolidated Financial Statements**

and development target. The transfer of control occurs over this period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

The transaction price allocated to the options rights, which are considered material rights, will be recognized in the period that can be credited towards any royalty payment Moderna elects to exercise or elects to not exercise its option right to license and commercialize the Company owes to Micromet. underlying research and development target.

The Company recorded an expense included the \$45.0 million upfront payment and \$73.9 million of €0.7 million (\$0.9 million) related variable consideration for expected research and development services to achievement be performed during the five-year contract term, inclusive of a development milestone passthrough costs, in the transaction price as of the outset of the arrangement. During the three months ended December 31, 2020 March 31, 2023, the Company recognized \$3.2 million of research and development services as collaboration revenues as the Company is the principal in providing such services. The Company recognized \$13.1 million of collaboration revenues since inception of the Moderna License Agreement through March 31, 2023. The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied as of March 31, 2023 (in thousands):

	Transaction price unsatisfied
Performance obligations:	
Research and development	\$ 61,376
Option rights	45,000
Total performance obligations	\$ 106,376

Amounts due to the submission of Company for satisfying the Company's BLA for Vicineum with the FDA in December 2020. The Company recorded an expense of €0.5 million (\$0.6 million) related to the submission of marketing authorization application (the "MAA") to the European

Medicines Agency (the "EMA") for Vysyrium™ in the first quarter of 2021. Vysyrium is the proprietary brand name revenue recognition criteria or that was conditionally approved by the EMA for oportuzumab monatox in the EU.

#### License Agreement with XOMA

The Company has a license agreement with XOMA Ireland Limited ("XOMA") which grants it non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems (the "XOMA License Agreement"). These patents and related know-how cover some key aspects of Vicineum. Under are contractually due based upon the terms of the XOMA License Agreement, collaboration agreements are recorded as accounts receivable in the Company's consolidated balance sheet. Contract liabilities consist of amounts received prior to satisfying the revenue recognition criteria, which are recorded as deferred revenue in the Company's consolidated balance sheet.

The following table summarizes the changes in deferred revenue (in thousands):

	Three months ended March 31,	
	2023	2022
Balance at the beginning of the period	\$ 47,459	\$ —
Deferral of revenue	2,920	46,441
Recognition of unearned revenue	(3,243)	(822)
Balance at the end of the period	<u>\$ 47,136</u>	<u>\$ 45,619</u>

The current portion of deferred revenue represents advanced payments received from Moderna for costs expected to be incurred by the Company within the next twelve months. The noncurrent portion of deferred revenue represents the \$45.0 million upfront, non-refundable and non-creditable payment allocated to customer option right which is required not expected to pay up to \$0.25 million in milestone payments for a product candidate that incorporates know-how under be recognized within the license and achieves applicable clinical development milestones. The Company is also required to pay a 2.5% royalty on the net sales for products incorporating XOMA's technology, which includes Vicineum. next 12 months.

#### (11) Subsequent Events

The Company has evaluated subsequent events from the right to reduce balance sheet date through May 11, 2023, the amount of royalties owed to XOMA on a country-by-country basis by the amount of royalties paid to other third parties, provided that the royalty rate to XOMA may not be less than 1.75% of net sales. In addition, the foregoing royalty rates are reduced by 50% with respect to products that are not covered by a valid patent claim in the country of sale. The obligation to pay royalties in a particular country expires upon the later of the expiration issuance date of the last valid claim covering the product these unaudited interim consolidated financial statements and the tenth anniversary of the first commercial sale of the product in such country. has not identified any requiring disclosure.

#### Out-License Agreements

#### ***Roche License Agreement***

In June 2016, the Company entered into the license agreement with Roche (the “Roche License Agreement”), pursuant to which the Company granted Roche an exclusive, worldwide license, including the right to sublicense, to its patent rights and know-how related to the Company’s monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company (collectively, the “Roche Licensed Intellectual Property”). Under the Roche License Agreement, Roche was required to continue developing, at its cost, EBI-031 and any other product made from the Roche Licensed Intellectual Property that contains an IL-6 antagonist monoclonal antibody and pursue ongoing patent prosecution, at its cost. For additional information regarding the Roche License Agreement, see Note 17. “License Agreements” in the Notes to Condensed Consolidated Financial Statements in the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

On July 15, 2022, the Company entered into an asset purchase agreement with Roche (the “Roche Asset Purchase Agreement”) pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by the Company for up to \$70 million. As a result of the Roche Asset Purchase Agreement, the Roche License Agreement was terminated resulting in no further diligence, milestone or royalty payment obligations under the Roche License Agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40 million payment to the Company upon execution of the Roche Asset Purchase Agreement, which was recorded as license revenue in the third quarter of 2022. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30 million payment to the Company upon Roche’s initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026. Pursuant to ASC 606, the variable consideration of \$30 million is constrained. Therefore, the amount was not recorded as revenue during the third quarter of 2022.

Additionally, at or prior to the effective time of the Merger, the Company will enter into a Contingent Value Rights Agreement (the “CVR Agreement”) with a rights agent (“Rights Agent”) pursuant to which the Company intends to declare a dividend payable to the Company’s stockholders of record as of a date agreed to by the Company and Carisma prior to the effective time of the Merger with respect to the receipt of one contingent value right (each, a “CVR”) for each outstanding share of the Company’s common stock held by such stockholders on such date. Each CVR will represent the contractual right to receive contingent cash payments upon the receipt by the Company of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche of a specified milestone set forth in the Roche Asset Purchase Agreement, subject to certain customary deductions, including for expenses and taxes. The contingent payments under the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

#### **OUS Business Development Partnership Agreements**

##### ***Qilu License Agreement***

On July 30, 2020, the Company and its wholly-owned subsidiary, Viventia Bio, Inc., entered into the Qilu License Agreement pursuant to which the Company granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to develop, manufacture and commercialize Vicineum (the “Qilu Licensed Product”) for the treatment of NMIBC and other types of cancer (the “Field”) in China, Hong Kong, Macau and Taiwan (“Greater China”). The Company also granted Qilu a non-exclusive, sublicensable, royalty-



bearing sublicense, under certain other intellectual property licensed by the Company to develop, manufacture and commercialize the Qilu Licensed Product in Greater China. The Company retains (i) development, and commercialization rights in the rest of the world, excluding Greater China and (ii) manufacturing rights with respect to Vicineum in the rest of the world, excluding China.

In consideration for the rights granted by the Company, Qilu agreed to pay to the Company a one-time upfront cash payment of \$12 million, and milestone payments totaling up to \$23 million upon the achievement of certain technology transfer, development and regulatory milestones. All payments were to be inclusive of VAT, which can be withheld by Qilu upon payment, and for which future recovery of such taxes may be available.

Qilu also agreed to pay the Company a 12% royalty based upon annual net sales of Qilu Licensed Products in Greater China. The royalties are payable on a Qilu Licensed Product-by-Licensed Product and region-by-region basis commencing on the first commercial sale of a Qilu Licensed Product in a region and continuing until the latest of (i) twelve years after the first commercial sale of such Qilu Licensed Product in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of such Qilu Licensed Product in such region, and (iii) the expiration of regulatory or data exclusivity for such Qilu Licensed Product in such region (collectively, the "Royalty Terms"). The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers a Qilu Licensed Product in a particular region or no data or regulatory exclusivity of a Qilu Licensed Product in a particular region.

Qilu is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the Qilu Licensed Products in the Field in Greater China. Qilu is required to use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize at least one Qilu Licensed Product in the Field in Greater China. A joint development committee was established between the Company and Qilu to coordinate and review the development, manufacturing and commercialization plans with respect to the Qilu Licensed Products in Greater China. The Company and Qilu also executed the terms and conditions of a supply agreement and related quality agreement pursuant to which the Company will manufacture or have manufactured and supply Qilu with all quantities of the Qilu Licensed Product necessary for Qilu to develop and commercialize the Qilu Licensed Product in the Field in Greater China until the Company has completed manufacturing technology transfer to Qilu and approval of a Qilu manufactured product by the National Medical Products Administration in China ("NMPA") for the Qilu Licensed Product has been obtained.

The Qilu License Agreement will expire on a Qilu Licensed Product-by-Licensed Product and region-by-region basis on the date of the expiration of all applicable Royalty Terms. Either party may terminate the Qilu License Agreement for the other party's material breach following a cure period or upon certain insolvency events. Qilu has the right to receive a refund of all amounts paid to the Company in the event the Qilu License Agreement is terminated under certain circumstances. The Qilu

License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The Qilu License Agreement is subject to the provisions of ASC Topic 606, *Revenue*. In 2020, the initial transaction price was estimated to be \$11.2 million and was based on the up-front fixed consideration of \$12 million less amounts withheld for VAT. The Company concluded that its agreements under the Qilu License Agreement represented one bundled performance obligation that had been achieved as of September 30, 2020. As such, \$11.2 million of the total \$11.2 million transaction price was considered earned and the Company recorded \$11.2 million of revenue during the three-month period ended September 30, 2020.

The Investigational New Drug application for Vicineum submitted by Qilu to the Center for Drug Evaluation of the NMPA was accepted for review in January 2021 and approved in March 2021, resulting in a \$3 million milestone payment from Qilu, the first milestone payment out of the

\$23 million in potential milestone payments. The Company recorded \$2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021. The Company received the payment in 2021.

In June 2021, the Qilu License Agreement was recognized by Shandong Province, Bureau of Science and Technology as a "Technology Transfer". An agreement that is designated as a Technology Transfer shall be entitled to a tax incentive of VAT recovery. As such, the Company recorded \$0.9 million of revenue during the three months ended June 30, 2021 for additional purchase price resulting from Qilu's obligation to pay Sesen Bio an amount equal to its recovery of VAT.

#### **MENA License Agreement**

On November 30, 2020, the Company entered into a license agreement with a third party pursuant to which the Company granted an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by the Company, to commercialize Vicineum in the Middle East and North Africa region ("MENA") (the "MENA License Agreement"). In consideration for the rights granted by the Company, the counterparty to the MENA License Agreement agreed to pay to the Company an upfront payment of \$3 million, which would be subject to certain tax withholdings. In addition, the counterparty agreed to pay to the Company milestone payments upon the achievement of certain sales-based milestones as well as a royalty based upon annual net sales in the MENA region for the term of the MENA License Agreement.

On July 20, 2022, the Company provided notice of termination of the MENA License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the US.

#### **EIP License Agreement**

On August 5, 2021, the Company entered into an exclusive license agreement with EIP Eczacıbaşı İlaç Pazarlama A.Ş., ("EIP") pursuant to which it granted EIP an exclusive license to register and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC in Turkey and Northern Cyprus (the "EIP License Agreement"). Under the terms of the EIP License Agreement, the Company was entitled to receive an upfront payment of \$1.5 million. The Company and EIP have amended the license agreement to defer EIP's payment of the upfront payment to coincide with the potential FDA approval of Vicineum. The Company would be eligible to receive additional regulatory and commercial milestone payments of \$2.0 million and also to receive a 30% royalty on net sales in Turkey and Northern Cyprus.

On July 20, 2022, the Company provided notice of termination of the EIP License Agreement as a result of the Company's strategic decision to voluntarily pause further development of Vicineum in the US. The EIP License Agreement was terminated on October 20, 2022.

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## **18. RESTRUCTURING AND RELATED ACTIVITIES**

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**On July 15, 2022, the Company approved a restructuring plan to reduce operating expenses and better align its workforce with the needs of its business following the decision to voluntarily pause further development of Vicineum in the US (the "2022 Restructuring Plan"). Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing,**

**November 7, 2022. The 2022 Restructuring Plan includes an incremental reduction in the Company's workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the Merger with Carisma and while the Company seeks a potential partner for the further development of Vicineum.**

The Company also incurred one-time cash costs associated with the termination of certain contracts and all other activities under the 2022 Restructuring Plan. The following is a summary of accrued restructuring costs related to the 2022 Restructuring Plan, (in thousands):

	2022 Restructuring Plan
Severance and benefits costs	\$ 6,944
Contract termination and other associated costs	4,003
Total restructurings costs	10,947
Cash payments	(4,582)
<b>Balance at September 30, 2022</b>	<b>\$ 6,365</b>

Restructuring costs related to the Restructuring Plan were recorded in operating expenses in the Company's Condensed Consolidated Statements of Income (Operations) and Comprehensive Income (Loss) in the three months ended September 30, 2022. The Company expects that substantially all of the accrued restructuring costs as of September 30, 2022 will be paid in cash in connection with the closing of the Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022.

## 19. SUBSEQUENT EVENTS

On October 21, 2022, the Company received two separate letters and on November 4, 2022, the Company received one letter from purported stockholders demanding that the Company amend the Registration Statement filed with the SEC on October 14, 2022 to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by the Company's financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. The Company believes that these demands are without merit and intends to vigorously defend against them. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company.

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

*The following discussion and analysis of our financial condition and results of operations as well as other sections in should be read together with our unaudited consolidated financial statements and the related notes appearing elsewhere this Quarterly Report on Form 10-Q, should be read in conjunction with our unaudited interim condensed consolidated financial statements and related notes thereto appearing elsewhere herein and our audited annual consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations"*

for the year ended December 31, 2021, included in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on February 28, 2022. In addition to historical financial information, some of the information contained in the following 10-Q. This discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), that involve risks and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, the proposed merger with CARISMA Therapeutics Inc. ("Carisma"), the impact of the COVID-19 pandemic, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions.

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

- our ability to complete, on a timely basis or at all, the proposed merger with Carisma announced on September 21, 2022, pursuant to the terms and conditions of the Merger Agreement (as defined below);
- the receipt of any potential future payments to our stockholders under the CVR Agreement (as defined below);
- the strategy or future operations of the combined company following the closing of the proposed merger with Carisma;
- advancement of the combined company's product candidates and product pipeline, clinical development of the combined company's product candidates, including expectations regarding timing of initiation and results of clinical trials of the combined company;
- our intentions to seek a partner for the further development of Vicineum;
- the expected timing of implementing and completing our restructuring plan following the decision to voluntarily pause further development of Vicineum in the US (the "2022 Restructuring Plan");
- the expected timing for incurring costs associated with the 2022 Restructuring Plan;
- our ability to preserve capital during the pendency of the proposed merger with Carisma and while we seek a potential partner for the further development of Vicineum;
- the potential impact of the COVID-19 pandemic on our ability to consummate the proposed merger with Carisma and seek a partner for the further development of Vicineum;
- our projected financial position;
- our ability to obtain and maintain intellectual property protection for our product candidates and our proprietary technology;
- our beliefs regarding key advantages of our targeted fusion protein therapeutics ("TFPT") platform; and
- our expectations regarding the amount of future milestone payments pursuant to our Asset Purchase Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La

Roche Inc. (collectively, "Roche"), (the "Roche Asset Purchase Agreement").

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, among others, the following:

- the risk that the conditions to the closing of the proposed merger with Carisma are not satisfied, including the failure to obtain stockholder approval of matters related to the proposed merger in a timely manner or at all;
- uncertainties as to the timing of the consummation of the proposed merger with Carisma and the ability of each of us and Carisma to consummate the proposed merger, including Carisma's completion the Carisma Pre-Closing Financing (as defined below);
- risks related to our ability to correctly estimate our expected net cash at closing and our ability to correctly estimate and manage our respective operating expenses and expenses associated with the proposed merger;
- risks related to our continued listing on The Nasdaq Stock Market ("Nasdaq") until closing of the proposed merger;
- the risk that as uncertainties. As a result of adjustments to the exchange ratio, many factors, such as defined those set forth in the Merger Agreement, our stockholders could own less of the combined company than is currently anticipated;
- the risk that the conditions to payment under the CVR Agreement will not be met and may never deliver any value to our stockholders;
- risks associated with the possible failure to realize certain anticipated benefits of the proposed merger, including with respect to future financial and operating results;
- uncertainties regarding the impact any delay section titled "Risk Factors" in the closing of the proposed merger would have on the anticipated cash resources of the combined company upon closing of the proposed merger and other events and unanticipated spending and costs that could reduce the combined company's cash resources;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the effect of the announcement, pendency or completion of the proposed merger on our or Carisma's business relationships, operating results and business generally;
- costs related to the proposed merger;
- the outcome of any legal proceedings that may be instituted against us or any of our directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- the ability of us or Carisma to protect our and their intellectual property rights, as applicable;
- competitive responses to the proposed merger and changes in expected or existing competition;
- the success and timing of regulatory submissions and pre-clinical and clinical trials;

- regulatory requirements or developments;
- changes to clinical trial designs and regulatory pathways;
- changes in capital resource requirements;
- risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- legislative, regulatory, political and economic developments, among other risks and uncertainties;
- the risk that we may not be successful in identifying a partner for the further development of Vicineum;
- the risk that we may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of Vicineum, in connection with our decision to voluntarily pause further development of Vicineum in the US;
- the risk that we may not be able to implement the 2022 Restructuring Plan as currently anticipated or within the timing currently anticipated;
- we may incur unanticipated charges as a result of the 2022 Restructuring Plan;
- the risk that the respective courts may not grant final approval of the settlements agreed to by the parties to the ongoing securities litigation and the derivative litigation;
- we may be unable to obtain, maintain, defend and enforce patent claims and other intellectual property rights;
- we may be unable to defend against pending or threatened litigation, which may be costly and time-consuming; and
- such other factors described throughout Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Part II, Item 1A. Risk Factors in this Quarterly Report on Form 10-Q and throughout Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2021.

The events December 31, 2022, in Exhibit 99.3 to our Current Report on Form 8/K dated March 7, 2023 and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q, to the "Company," "Sesen Bio," "we," "us," and "our" include Sesen Bio, Inc. and its subsidiaries.

**our actual results may differ materially from those anticipated by these forward-looking statements.**

## Overview

We are a late-stage clinical stage cell therapy company focused on advancing utilizing our proprietary macrophage and monocyte cell engineering platform to develop transformative immunotherapies to treat cancer and other serious diseases. We have



created a comprehensive cell therapy platform to enable the therapeutic use of engineered macrophages and monocytes, which belong to a subgroup of white blood cells called myeloid cells. Macrophages and monocytes are part of the innate immune system and can detect and degrade harmful substances through a process referred to as phagocytosis, in which the harmful substance is engulfed and destroyed and in turn leads to the activation of a broad immune response. With our lead product candidate from our proprietary Chimeric Antigen Receptor Macrophage, or CAR-M, cell therapy platform in the clinic and the potential for multiple clinical and preclinical data updates over the next 18 months, we believe that we are poised to deliver on the potential of our platform and to expand the opportunity for effective gene delivery, tunable phenotypes, multiple payloads and applications in oncology and beyond.

Our platform harnesses the powerful immunologic functions of macrophages against cancer, through our proprietary CAR-M platform technology. Chimeric antigen receptors, or CARs, are synthetically engineered receptors that are designed to bestow immune cells with the ability to target specific antigens on the surface of cancer cells. By introducing CARs into macrophage and monocyte cells, we aim to redirect their potent innate immune functions against cancer. Our CAR-M platform technology incorporates proprietary tumor targeting constructs, vectors to deliver CARs to macrophages and monocytes and novel manufacturing processes. Our CAR-M therapeutics are designed to infiltrate the solid tumor microenvironment, kill cancer cells via targeted fusion phagocytosis, and activate other immune cells, such as T-cells, to initiate a robust anti-tumor immune response. Our initial product candidates, CT-0508 and CT-0525, are *ex vivo* autologous cell therapy product candidates, wherein immune cells from blood drawn from a patient are engineered outside of the body and reinfused into the same patient. We also have research programs to develop allogeneic and *in vivo* cell therapy macrophage products.

Our lead product candidate CT-0508, is the first CAR-M to be evaluated in a human clinical trial and is intended to treat solid tumors that overexpress HER2, a protein therapeutics that is overexpressed on the surface of a variety of solid tumors, including breast cancer, gastric cancer, esophageal cancer, salivary gland cancer, and numerous others. It has been granted "Fast Track" status for the treatment of patients with cancer.

Our most advanced product candidate, Vicineum, also known as VB4-845, HER2 overexpressing solid tumors by the FDA. CT-0508 is currently being studied in a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule ("EpCAM") antibody fragment tethered to a truncated form of *Pseudomonas* *exotoxin A* for the treatment of non-muscle invasive bladder cancer ("NMIBC").

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum multi-center open label Phase 1 clinical trial in the United States. The decision U.S. This ongoing first-in-human study primarily evaluates the safety, tolerability and manufacturing feasibility of CT-0508 along with several customary exploratory secondary end points. We have completed enrollment of the first group of patients in this trial, with nine patients having been successfully dosed over a five-day dosing schedule. In November 2022, we presented preliminary clinical results from the first group of patients. CT-0508 was based on a thorough

reassessment of Vicineum following recent discussions successfully manufactured using macrophages obtained from heavily pre-treated, advanced solid tumor patients and has shown high CAR expression, viability, and purity. In addition, CT-0508 has been generally well-tolerated after infusion with no dose-limiting toxicities reported to date from the United States Food and Drug Administration ("FDA"), which had implications on nine patients enrolled in the size, timeline and costs of an additional Phase 3 first group. While the results from this early clinical trial which data are both preliminary and limited, we believe the FDA previously confirmed would results indicate that CT-0508 can be required for detected within the tumor microenvironment, or TME, lead to remodeling and activation of the TME, and potentially induce anti-tumor adaptive immunity. In addition to the first group of patients in this study, we have initiated a potential resubmission second group to evaluate bolus dosing of a biologics license application ("BLA") for Vicineum for the treatment of NMIBC. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company anticipate data from this group in the second half of 2023. We have also initiated several additional sub studies evaluating CT-0508 in the clinical setting. In addition to monotherapy treatment, we have observed synergistic potential of CT-0508 with a larger infrastructure, and as such, intend to seek a partner that can execute further development to realize the full potential of Vicineum. PD1 blocking T-cell checkpoint inhibitor in multiple preclinical models. As a result of those studies and the preliminary results from group 1 in our clinical trial, we initiated a sub study to evaluate at least nine patients with the co-administration of CT-0508 and pembrolizumab in the first quarter of 2023. We anticipate the initial data from this decision, sub study in the second half of 2023.

Our second product candidate, CT-0525, is also intended to treat solid tumors that overexpress HER2, is in preclinical development and is advancing to an IND filing. CT-0525 utilizes a novel approach to CAR-M therapy to accelerate the manufacturing process, increase the cell yield, and improve upon the potential anti-tumor effect by engineering patients' monocytes directly, without *ex vivo* differentiation into macrophages, as we currently do for CT-0508. We refer to this CAR-Monocyte approach as CAR-Mono. By increasing the cell yield, the CAR-Mono approach enables a larger potential dose and improved trafficking, which may improve tumor

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**control. The CAR-Mono approach reduces manufacturing time and leverages an automated, closed-system manufacturing process. CT-0525 is our first CAR-Mono product candidate and is currently in the pre-clinical process development stage. We expect to submit an IND to the FDA for CT-0525 in the second half of 2023, initiate clinical development shortly thereafter, and treat our first patient in the first half of 2024.**



Beyond CT-0508 and CT-0525, we have turned our primary focus a broad pipeline of cell therapy assets in various stages of pre-clinical development. In addition to the careful assessment development of potential strategic alternatives with *ex vivo* CAR-M cell therapies, we are also developing *in vivo* CAR-M gene therapies, wherein immune cells are directly engineered within the goal of maximizing shareholder value.

#### ***Anticipated Merger with CARISMA Therapeutics Inc.***

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for patient's body. To advance our *in vivo* CAR-M therapeutics, we established a strategic transaction, collaboration with Moderna TX Inc., or Moderna, focused on September 20, 2022, the development and potential commercialization of up to 12 product candidates, of which four have already been nominated. In collaboration with Moderna, we Seahawk Merger Sub, Inc., have established an approach that uses Moderna's LNP/mRNA technology, together with our CAR-M platform technology, to create novel *in vivo* oncology gene therapies. We believe this approach has the potential to enable a Delaware corporation series of off-the-shelf product candidates to target a patient's own myeloid cells against cancer cells directly within their body. As part of the agreement with Moderna, we received a \$45.0 million up-front cash payment and our wholly-owned subsidiary ("Merger Sub"), and Carisma, entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth investment by Moderna in the Merger Agreement, Merger Sub will merge with and form of a \$35.0 million convertible promissory note, which converted into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the merger (the "Merger"). Our board of directors unanimously approved the Merger Agreement and resolved to recommend that our stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

The Merger is expected to close approximately two to three months from the date of this form 10-Q filing, November 7, 2022. In connection with the Merger, we will seek the approval of our stockholders to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger under the rules of Nasdaq, and (b) amend our certificate of incorporation to effect a reverse stock split of the outstanding shares of our common stock at a ratio as mutually agreed to by us and Carisma and approved by our board of directors prior to the closing of the Merger (clauses (a) and (b), collectively, the "Sesen Bio Voting Proposals").

Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the Sesen Bio Voting Proposals as described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (d) the effectiveness of a registration statement on Form S-4 to register the shares of our common stock to be issued in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than or equal to \$100.0 million.

The Merger Agreement contains certain termination rights of each of us and Carisma. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each then outstanding share of Carisma common stock and Carisma preferred stock (collectively, "Carisma capital stock") (including shares of Carisma's common stock issued in connection with the pre-closing financing described below) will be converted into the right to receive a number of the shares of our common stock calculated in accordance with the Merger Agreement (the "Exchange Ratio"), and (b) each then outstanding Carisma stock option to purchase Carisma's common stock will be assumed by us, subject to adjustment as set forth in the Merger Agreement.

Concurrently with the execution and delivery of the Merger Agreement, Carisma entered into a subscription agreement with certain investors named therein, pursuant to which such investors have agreed, subject to the terms and conditions of such subscription agreement, to purchase prior to the consummation of the Merger shares of Carisma's common stock for an aggregate purchase price of approximately \$30.6 million (the "Carisma Pre-Closing Financing"). The consummation of the Carisma Pre-Closing Financing is conditioned on the satisfaction **merger with Sesen Bio**, or **waiver of the conditions set forth in the Merger Agreement**.

Shares of Carisma's common stock issued pursuant to the Carisma Pre-Closing Financing will be converted into shares of our common stock in the Merger, in **accordance** **addition to future research funding and the opportunity for milestone payments and royalties**.

**Through our robust internal discovery engine, we are building upon our platform to enhance and expand the utility of macrophage cell and gene therapies, leading to the creation of multiple product candidates with the Exchange Ratio.**

**Additionally, at or prior** **potential to treat cancer and other serious diseases. By replacing the effective time** **targeting domain of the Merger, CAR, we can reprogram the target antigen specificity of the CAR-M cell product and develop candidates against a range of cancer indications and therapeutic areas beyond oncology. As a result, we believe the flexibility of our macrophage and monocyte cell engineering platform will enter into** **allow us to generate new product candidates suitable for clinical development in a Contingent Value Rights Agreement (the "CVR Agreement") with cost-efficient manner to expand our pipeline. In addition to acting as a rights agents (the "Rights Agent") pursuant to which** **first line of defense in the innate immune system, macrophages are found in all tissues in the body where they serve key regulatory functions such as wound healing, termination of immune responses and tissue regeneration. Using our macrophage and monocyte ex vivo and in vivo engineering platform, we intend to declare a dividend payable** **are pursuing early research and development of multiple assets for the potential treatment of diseases beyond oncology, including liver fibrosis, neurodegeneration, and other immunologic and inflammatory diseases.**

**By investing in early platform research and accessing key enabling technologies, we are enhancing and expanding our platform capabilities and reinforcing our leadership position in the engineered macrophage field. We have developed proprietary CAR-M platform enhancements directed toward key product parameters that are important for efficacy, safety and patient access to our stockholders CAR-M therapies. We plan to apply these technology enhancements to future CAR-M product candidates. In addition to our platform, we have invested in establishing scalable clinical manufacturing capabilities to deliver on potential of record as our products. In the first**

quarter of a 2023, we completed technology transfer for manufacturing HER2 targeted CAR-M cell therapies and have begun to manufacture CT-0508 at their facility.

To date, agreed to by us we have not yet commercialized any products or generated any revenue from product sales and Carisma prior to the effective time have financed our operations primarily with proceeds from sales of our preferred stock, proceeds from our collaboration with Moderna, research tax credits, convertible debt financing, closing of pre-closing financing, and completion of the Merger with respect Merger. Our operations to date have been limited to organizing and staffing the receipt company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of one contingent value right (each, a "CVR"), product candidates, conducting drug discovery activities, undertaking pre-clinical studies, manufacturing process development studies, conducting early-stage clinical trials, and providing general and administrative support for each outstanding share these operations. We have devoted substantially all of our common stock held by such stockholders on such date. Each CVR will represent the contractual right financial resources and efforts to receive contingent cash payments upon the receipt by us pursuing discovery, research and development of certain proceeds payable by Roche, if any, pursuant to the Roche Asset Purchase Agreement, upon the achievement by Roche our product candidates. We only recently initiated clinical development of a specified milestone set forth our lead product candidate, CT-0508, and are in the Roche Asset Purchase Agreement, subject to certain customary deductions, including pre-clinical testing stages for expenses our other product candidates.

Our net losses were \$24.6 million and taxes. The contingent payments under \$11.3 million for the CVR Agreement, if they become due, will be payable to the Rights Agent for subsequent distribution to the holders three months ended March 31, 2023 and 2022, respectively. As of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any cash payment will be made or that any holders of CVRs will receive any amounts with respect thereto.

Our future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the event that we do not complete the Merger with Carisma, we may continue to explore strategic alternatives, including, without limitation, another strategic transaction and/or pursue a liquidation and dissolution of our company.

#### **Other Recent Events**

##### *2022 Restructuring Plan*

On July 15, 2022 March 31, 2023, we approved a restructuring plan had \$139.0 million in cash, cash equivalents and marketable securities and an accumulated deficit of \$182.9 million. We expect to reduce operating expenses devote substantial financial resources to our ongoing and better align planned activities, particularly as we conduct our workforce with the needs ongoing clinical trial of CT-0508 and pursue related combination strategies, prepare for, initiate and conduct our business following the decision to voluntarily pause further planned clinical trials of CT-0525 and CT-1119 and

advance our discovery programs and continues our product development of Vicineum efforts. In addition, if we obtain marketing approval for CT-0508 or any other product candidate we are developing or develop in the United States. Execution future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

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[Table of the 2022 Restructuring Plan is expected to be substantially completed](#) [Contents](#)

On March 7, 2023 in connection with the closing of the Merger, with we issued 29,880,394 shares of common stock to Legacy Carisma which is expected stockholders (including 5,059,338 shares issued to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendencyholder of the Merger convertible promissory note that was entered into concurrently with the Moderna License Agreement (as defined below) and 3,730,608 shares issued in exchange for shares sold in the pre-closing financing). Former Sesen Bio stockholders continued to hold 10,374,272 shares of our common stock, reflective of the 1-for-20 reverse stock split that was effected immediately prior to the closing of the Merger.

We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our discovery and product development efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to

become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand business, maintain discovery and product development efforts, diversify our pipeline of product candidates or even continue operations.

#### Moderna Collaboration and License Agreement

In collaboration with Moderna, we have established an approach that uses Moderna's LNP/mRNA technology, together with our CAR-M platform technology, to create novel *in vivo* oncology gene therapies. We believe this approach has the potential to enable a series of off-the-shelf product candidates to target a patient's own myeloid cells against cancer cells directly within their body.

In January 2022, Legacy Carisma and while we seek Moderna established this collaboration by entering into a potential partner Collaboration and License Agreement (Moderna License Agreement), which provides for the further development of Vicineum. We also incurred one-time cash costs associated a broad strategic collaboration with the termination of certain contracts Moderna to discover, develop and all other activities under the 2022 Restructuring Plan.

#### Sale of Legacy Technology to Roche

On July 15, 2022, we executed the Roche Asset Purchase Agreement pursuant to which Roche purchased all patent rights and know-how related to the monoclonal antibody EBI-031 and all other IL-6 antagonist monoclonal antibody technology owned by us commercialize *in vivo* engineered CAR-M therapeutics for up to \$70 million. As a result of 12 oncology programs. Under the Roche Asset Purchase Agreement, the exclusive license agreement between Roche and us was terminated resulting in no further diligence, milestone or royalty payment obligations under such license agreement. Pursuant to the Roche Asset Purchase Agreement, Roche made a \$40 million payment to us upon execution of the Roche Asset Purchase Agreement. The Roche Asset Purchase Agreement also provides that Roche will make an additional \$30 million payable to us upon Roche's initiation of a Phase 3 clinical trial with EBI-031 for a defined indication if initiated prior to December 31, 2026.

#### 2022 Retention Program

On August 28, 2022, our board of directors and the compensation committee of the board of directors approved a retention program for certain employees pursuant to which we will provide a cash incentive designed to retain such employees. Pursuant to this retention program, certain of our employees, including certain executive officers, will receive a cash bonus award, which vests in full upon the earlier of the completion of a strategic transaction and termination without cause, subject to continued employment through that time.

#### Regulatory Update

In December 2020, we submitted our completed BLA for Vicineum for the treatment of BCG-unresponsive NMIBC to the FDA, which was accepted for filing by the FDA in February 2021. The FDA granted Priority Review for the BLA and set a target PDUFA date for a decision on the BLA of August 18, 2021. On August 13, 2021, we received the Complete Response Letter ("CRL") from the FDA indicating that the FDA had

determined that it could not approve the BLA for Vicineum in its present form and provided recommendations specific to additional clinical/statistical data and analyses in addition to chemistry, manufacturing and controls (“CMC”) issues pertaining to a recent pre-approval inspection and product quality. On August 20, 2021, we withdrew our marketing authorization application (“MAA”) to the European Medicines Agency (the “EMA”) for Vysyrium for the treatment of BCG-unresponsive NMIBC in order to pause our plans to pursue regulatory approval of Vysyrium in the EU until there is more clarity from the FDA on next steps for Vicineum in the United States. Vysyrium is the proprietary brand name that was conditionally approved by the EMA for oportuzumab monatox in the EU. In October 2021, the

EMA issued its Withdrawal Assessment Report relating to our MAA for Vysyrium, as is consistent with the EMA’s standard practice when an MAA is withdrawn. The EMA Withdrawal Assessment Report reflects the initial assessment and corresponding questions from the EMA and identifies major objections in the areas of quality, good clinical practice, efficacy and safety.

In October 2021 and December 2021, we participated in a CMC Type A meeting and a Clinical Type A meeting, respectively, with the FDA to discuss issues raised in the CRL and design elements of an additional Phase 3 clinical trial for Vicineum, which the FDA confirmed would be required for a potential resubmission of a BLA. In March 2022, we participated in a Type C meeting with the FDA. During the Type C meeting, the FDA agreed to a majority of our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial. On July 11, 2022, we participated in a Type B meeting with the FDA to discuss outstanding items related to our proposed protocol and statistical analysis plan design elements for an additional Phase 3 clinical trial.

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial which the FDA previously confirmed would be required for a potential resubmission of a BLA for Vicineum for the treatment of NMIBC. As a result of this decision, we no longer plan to pursue regulatory approval of Vysyrium for NMIBC in the EU. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we intend to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, we have turned our primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value.

#### **Prior Phase 3 Clinical Trial – VISTA Trial**

In the third quarter of 2015 in the United States and Canada, through our subsidiary Vivintia, we commenced our single-arm, multi-center, open-label Phase 3 clinical trial (“VISTA Trial”) in patients with BCG-unresponsive NMIBC who have received adequate BCG and whose disease is now BCG-unresponsive, and for whom the then-current standard of care was a radical cystectomy. Based on safety and efficacy data observed with the longer 12-week induction in our Phase 2 clinical trial, the FDA agreed to our plan to employ more frequent dosing in the VISTA Trial, in which the primary endpoints were complete response (“CR”) and duration of response (“DoR”) in patients with CIS whose disease is BCG-unresponsive. In November 2016, the FDA issued draft guidance regarding appropriate clinical trial design for new drugs and biologics for BCG-unresponsive NMIBC, including the use of single-arm trials. The FDA finalized this guidance in February 2018 and retained many of the recommendations from the 2016

draft guidance regarding clinical trial design, including the use of single-arm trials. We believe that our VISTA Trial design was consistent with these aspects of the FDA's guidance. In May 2022, we completed the follow-up phase of the VISTA Trial.

The VISTA Trial completed enrollment in April 2018 with a total of 133 patients across three cohorts based on histology and time to disease recurrence after adequate BCG treatment:

- Cohort 1 (n=86): Patients with CIS with or without papillary disease that was determined to be refractory or recurred within six months of their last course of adequate BCG;
- Cohort 2 (n=7): Patients with CIS with or without papillary disease that recurred after six months, but less than 11 months, after their last course of adequate BCG; and
- Cohort 3 (n=40): Patients with high-risk (Ta or T1) papillary disease without CIS that recurred within six months of their last course of adequate BCG.

The primary endpoints of the VISTA Trial were CRR at 3 months in patients with CIS (with or without papillary disease) whose disease is BCG-unresponsive and DoR for BCG-unresponsive CIS patients who experience a CR.

As of the May 29, 2019 data cutoff date, preliminary primary and secondary endpoint data for each of the trial cohorts were as follows:

**Cohort 1 (n=86) Evaluable Population (n=82) Complete Response Rate, for CIS:**

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=82	39% (28%-50%)
6-months	n=82	26% (17%-36%)
9-months	n=82	20% (12%-30%)
12-months	n=82	17% (10%-27%)

*\*Response evaluable population includes any mITT patient who completed the induction phase.*

**Cohort 2 (n=7) Evaluable Population (n=7) Complete Response Rate, for CIS:**

Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=7	57% (18%-90%)
6-months	n=7	57% (18%-90%)
9-months	n=7	43% (10%-82%)
12-months	n=7	14% (0%-58%)

*\*Response-evaluable population includes any mITT patient who completed the induction phase.*

**Pooled Cohorts 1 and 2 (n=93) Evaluable Population (n=89) Complete Response Rate, for CIS:**



Time Point	Evaluable Patients*	Complete Response Rate (95% Confidence Interval)
3-months	n=89	40% (30%-51%)
6-months	n=89	28% (19%-39%)
9-months	n=89	21% (13%-31%)
12-months	n=89	17% (10%-26%)

\*Response-evaluable population includes any mITT patient who completed the induction phase.

#### Phase 3 Pooled Complete Response Rate vs. Phase 2 Pooled Complete Response Rate:

Time Point	Phase 3 Pooled CRR (95% Confidence Interval)	Phase 2 Pooled CRR (95% Confidence Interval)
3-months	40% (30%-51%)	40% (26%-56%)
6-months	28% (19%-39%)	27% (15%-42%)
9-months	21% (13%-31%)	18% (8%-32%)
12-months	17% (10%-26%)	16% (7%-30%)

#### Cohort 3 (n=40) Evaluable Population (n=38) Recurrence-Free Rate†:

Time Point	Evaluable Patients*	Recurrence-Free Rate (95% Confidence Interval)
3-months	n=38	71% (54%-85%)
6-months	n=38	58% (41%-74%)
9-months	n=38	45% (29%-62%)
12-months	n=38	42% (26%-59%)

†Recurrence-free rate is defined as the percentage of patients that are recurrence-free at the given assessment time point.

\*Response-evaluable population includes any mITT patient who completed the induction phase.

**Duration of Response:** The median DoR for patients in Cohort 1 and Cohort 2 combined (n=93) is 287 days (95% CI, 154-NE), using the Kaplan-Meier method. Additional *ad hoc* analysis of pooled data for all patients with CIS (Cohorts 1 and 2, n=93) shows that among patients who achieved a complete response at 3 months, 52% remained disease-free for a total of 12 months or longer after starting treatment, using the Kaplan-Meier method. DoR is defined as the time from first occurrence of complete response to documentation of treatment failure or death.

We have conducted additional analyses for secondary endpoints. These additional data include the following:

- **Time to Cystectomy:** Across all 133 patients treated with Vicineum in the VISTA Trial, greater than 75% of all patients are estimated to remain cystectomy-free at 3 years, using the Kaplan-Meier method. Additional *ad hoc* analysis shows that approximately 88% of responders are estimated to remain cystectomy-free at 3 years. Time to cystectomy is defined as the



time from the date of first dose of study treatment to surgical bladder removal. The first 2018 FDA guidance on treatment of BCG-unresponsive NMIBC patients states that the goal of therapy in

such patients is to avoid cystectomy. Therefore, time to cystectomy was a key secondary endpoint in the VISTA Trial.

- **Time to Disease Recurrence:** High-grade papillary (Ta or T1) NMIBC is associated with high rates of progression and recurrence. The median time to disease recurrence for patients in Cohort 3 (n=40) is 402 days (95% CI, 170-NE), using the Kaplan-Meier method. Time to disease recurrence is defined as the time from the date of the first dose of study treatment to the first occurrence of treatment failure or death on or prior to treatment discontinuation.
- **Progression-Free Survival ("PFS"):** 90% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to remain progression-free for 2 years or greater, using the Kaplan-Meier method. PFS is defined as the time from the date of first dose of study treatment to the first occurrence of disease progression (e.g., T2 or more advanced disease) or death on or prior to treatment discontinuation.
- **Event-Free Survival:** 29% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to remain event-free at 12 months, using the Kaplan-Meier method. Event-free survival is defined as the time from the date of first dose of study treatment to the first occurrence of disease recurrence, progression or death on or prior to treatment discontinuation.
- **Overall Survival ("OS"):** 96% of all 133 patients treated with Vicineum in the VISTA Trial are estimated to have an overall survival of 2 years or greater, using the Kaplan-Meier method. OS is defined as the time from the date of first dose of study treatment to death from any cause.

Data is as of the May 29, 2019 data cut from the Phase III VISTA Trial. The clinical data shown are based on the data submitted in the BLA on December 18, 2020. On August 13, 2021, the FDA issued a CRL for the BLA that included requests for additional clinical and statistical data.

### **Safety Results**

As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5 or death). There were no age-related increases in adverse events observed in the VISTA Trial.

### **Manufacturing**

In October 2018, we entered into a Master Bioprocessing Services Agreement with Fujifilm Diosynth Biotechnologies U.S.A., Inc. ("Fujifilm") (the "Fujifilm MSA") for the manufacturing process and technology transfer of Vicineum drug substance production.

In November 2019, we entered into a Commercial Manufacturing and Supply Agreement with Baxter (the "Baxter CMSA") for the manufacturing process and technology transfer of Vicineum drug product production.

In June 2021, we entered into a Global Supply Agreement with Qilu pursuant to which Qilu will be part of the manufacturing network for, if approved, global commercial supply of Vicineum drug substance and drug product.

In connection with our decision to voluntarily pause further development of Vicineum, we terminated the Fujifilm MSA and Baxter CMSA and requested that Fujifilm and Baxter cease all work under the respective agreements and refrain from incurring any additional costs or expenses.

### **In-License Agreements**

We have a license agreement with the University of Zurich ("Zurich") which grants us exclusive license rights, with the right to sublicense, to make, have made, use and sell under certain patents primarily directed to our targeting agent, including an EpCAM chimera and related immunoconjugates and methods of use and manufacture of the same (the "Zurich License Agreement"). These patents cover some key aspects of Vicineum.

We have a License Agreement with Micromet AG ("Micromet"), now part of Amgen, Inc., which grants us nonexclusive rights, with certain sublicense rights, for know-how and patents allowing exploitation of certain single chain antibody products (the "Micromet License Agreement"). These patents cover some key aspects of Vicineum.

We have a license agreement with XOMA Ireland Limited ("XOMA") which grants us non-exclusive rights to certain XOMA patent rights and know-how related to certain expression technology, including plasmids, expression strains, plasmid maps and production systems (the "XOMA License Agreement"). These patents and related know-how cover some key aspects of Vicineum.

Notwithstanding our decision to voluntarily pause further development of Vicineum in the United States, we have not taken steps to terminate the Zurich Moderna License Agreement, the Micromet parties initiate research programs during a research term, focused on the discovery and research of products directed to biological targets. Either party may nominate a target for inclusion in a research program, subject to certain exclusions. We refer to a target included in a research program pursuant to designated procedures as a research target. Moderna may replace research targets pursuant to designated procedures. Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. The first four research targets have been nominated and all programs are currently in the discovery phase.

The collaboration is managed by a joint steering committee, or JSC, which is comprised of representatives from us and Moderna. Decisions of the JSC are made by consensus, with each party having one vote. If the JSC is unable to agree, and the parties' executives are not able to resolve the dispute, then Moderna has final decision-making authority, subject to specified limitations.

Under the terms of the Moderna License Agreement, or the XOMA License Agreement as we intend to seek a partner for the further development of Vicineum.

### **OUS Business Development Partnering**

In connection with our decision to voluntarily pause further development of Vicineum in the United States, we have terminated our OUS business development partnerships in the Middle East and North Africa region ("MENA") and Turkey by providing notice of termination for the MENA License Agreement and EIP License Agreement on July 20, 2022.

#### Greater China

On July 30, 2020, we and our wholly-owned subsidiary, Viventia Bio, Inc., entered into an exclusive license agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu") (the "Qilu License Agreement") pursuant to which we granted Qilu an exclusive, sublicensable, royalty-bearing license, under certain intellectual property owned or exclusively licensed by us, to develop, manufacture and commercialize Vicineum for the treatment of BCG-unresponsive NMIBC and other types of cancer in China, Hong Kong, Macau and Taiwan ("Greater China"). We also granted Qilu a non-exclusive, sublicensable, royalty-bearing sublicense, under certain other intellectual property licensed by us to develop, manufacture and commercialize Vicineum in Greater China. We retain (i) development and commercialization rights in the rest of the world excluding Greater China and (ii) manufacturing rights with respect to Vicineum in the rest of the world excluding Greater China.

During 2020, we received a total of \$10 million in net proceeds associated with the Qilu License Agreement. We received \$45.0 million up-front cash payment. Assuming Moderna develops and commercializes 12 products, each directed to a different development target, we are also entitled to receive up to an additional \$23 million upon the achievement of certain technology transfer, between \$247.0 million and \$253.0 million per product in development target designation, development, regulatory and regulatory milestones, as well as a 12% royalty based upon annual commercial milestone payments. In addition, we are eligible to receive mid to high single digit tiered royalties on net sales of Vicineum any products that are commercialized under the agreement, which may be subject to reductions. Moderna has also agreed to cover the cost of certain milestone payments and royalties we owe to a licensor under one of our intellectual property in-license agreements that we are sublicensing to Moderna under the Moderna License Agreement, which royalties Moderna may deduct in Greater China. The part from any royalties are payable upon owed to us.

### **Financial Operations Overview**

#### **Revenues**

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the first commercial sale of Vicineum products for the foreseeable future. Our revenues to date have been generated from the Moderna License Agreement. Moderna reimburses us for all costs incurred by it in a region connection with its research and continuing until development activities under the latest of (i) twelve years after the first commercial sale of Vicineum in such region, (ii) the expiration of the last valid patent claim covering or claiming the composition of matter, method of treatment, or method of manufacture of Vicineum in such region, and (iii) the expiration of regulatory or data exclusivity for Vicineum in such region. The royalty rate is subject to reduction under certain circumstances, including when there is no valid claim of a licensed patent that covers Vicineum in a particular region or no data or regulatory exclusivity of Vicineum in a particular region.

The Investigational New Drug application ("IND") for Vicineum submitted by Qilu to the Center for Drug Evaluation of the China National Medical Products Administration was accepted for review in January 2021 and approved in March 2021, resulting in a \$3 million milestone payment from Qilu, the first milestone payment out of the \$23 million in potential milestone payments. We recorded \$2.8 million (net of VAT) as license revenue during the three-month period ended March 31, 2021.

In June 2021, the Qilu Moderna License Agreement was recognized by Shandong Province, Bureau of Science and Technology as "Technology Transfer". An agreement plus a reasonable margin for the respective services performed. We expect that is designated as a Technology Transfer shall be entitled to a tax incentive of value-added tax ("VAT") recovery. As such, we recorded \$0.9 million of our revenue during for at least the three months ended June 30, 2021, for additional purchase price resulting from Qilu's obligation to pay us an amount equal to its recovery of VAT.

On July 20, 2021 we and Qilu announced the enrollment of the first patient in China in a Phase 3 clinical trial to assess the efficacy and safety of Vicineum in patients with BCG-unresponsive NMIBC. The open-label, single-arm, multi-center bridging trial will evaluate the efficacy and safety of Vicineum in approximately 53 patients with carcinoma in situ (CIS) with or without papillary disease, high-grade Ta papillary disease or T1 papillary disease of any grade. Patients next several years will be required to have failed previous treatment with BCG for inclusion derived primarily

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from Moderna License Agreement, other current collaboration agreements and any additional collaborations that we may enter into in the trial. The primary endpoints are future. To date, we have not received any royalties under the complete response rate (for CIS patients) and the recurrence-free rate (for papillary patients) at six months, with the complete response rate and the recurrence-free rate at three months, safety and tolerability as the secondary endpoints. Based on the Qilu Moderna License Agreement, the trial is being run at the sole cost of Qilu.

We and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, we will regain the rights to develop, manufacture and commercialize Vicineum in Greater China.

## **Components of Our Results of Operations**

### ***License and Related Revenue***

License revenue consists of revenue recognized pursuant to our OUS business development partnership agreements, including the Qilu License Agreement, and the Roche Asset Purchase Agreement, which is assessed under ASC Topic 606, Revenue. We have terminated all of our OUS business development partnership agreements other

than the Qilu License Agreement, of which we and Qilu are in the process of negotiating a termination.

## **Research and Development**

### **Expense**

Research and development expenses consist primarily of costs incurred for our research activities, including discovery efforts and the development of Vicineum for the treatment of NMIBC, which product candidates, and include:

- expenses incurred to conduct the necessary pre-clinical studies and clinical trials required to obtain regulatory approval;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our pre-clinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations, or CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical study and clinical trial materials;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring materials for pre-clinical studies;
- facility-related expenses, which include direct depreciation costs of equipment and expenses for rent and maintenance of facilities and other operating costs; and
- third-party licensing fees.

employee-related expenses, including salaries, benefits, travel and share-based compensation expense;

- expenses incurred under agreements with contract resource organizations ("CROs") and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities;
- expenses associated with transferring manufacturing capabilities to contract manufacturing organizations ("CMOs") for commercial-scale production;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies;
- expenses associated with regulatory activities; and
- expenses associated with license milestone fees.

### **We expense research**

Research and development costs as incurred. We recognize external activities are central to our business model. Product candidates in later stages of clinical development will generally have higher development costs based on an

evaluation than those in earlier stages of clinical development, primarily due to the progress to completion increased size and duration of specific tasks using information and data provided to us by our vendors and our later-stage clinical sites.

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, costs related to manufacturing or purchasing clinical trial materials and technology transfer and license milestone fees, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs may be deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for Vicineum for the treatment of NMIBC and other expenses by category. trials. We expect to significantly reduce our research and development expenses during to increase significantly over the pendency of the proposed Merger with Carisma.

We did not allocate next several years as we increase personnel costs, including stock-based compensation, conduct ongoing and planned clinical trials for CT-0508, conduct research and development expenses activities under the Moderna License Agreement and conduct other clinical and pre-clinical activities for other product candidates and prepare regulatory filings for any of our product candidates.

The successful development of our current or future product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidates. The success of CT-0508 and our other specific product program during candidates will depend on several factors, including the periods presented (in thousands): following:

- successfully completing pre-clinical studies;
- successfully initiating future clinical trials;
- successfully enrolling patients in and completing clinical trials;
- scaling up manufacturing processes and capabilities to support clinical trials of CT-0508 and any other product candidate;
- applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for CT-0508 and any other product candidates it is developing or may develop in the future;
- making arrangements with third-party manufacturers, or establishing commercial manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of CT-0508 and any other product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;

- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization activities of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Programs:				
Vicineum for the treatment of NMIBC	\$ 813	\$ 2,989	\$ 29,705	\$ 10,888
Total direct program expenses	813	2,989	29,705	10,888
Personnel and other expenses:				
Employee and contractor-related expenses	1,840	1,732	6,920	6,392
Platform-related lab expenses	5	19	100	133
Facility expenses	150	124	428	392
Other expenses	123	103	483	468
Total personnel and other expenses	2,118	1,978	7,931	7,385
<b>Total Research and Development</b>	<b>\$ 2,931</b>	<b>\$ 4,967</b>	<b>\$ 37,636</b>	<b>\$ 18,273</b>

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of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we could be required to expend



significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years, and we expect to spend a significant amount in development costs.

#### **General and Administrative**

##### **Expense**

General and administrative expenses consist expense consists primarily of personnel expenses, including salaries, benefits and related costs stock-based compensation expense for personnel, including share-based compensation and benefits, employees in executive, operational, finance, legal, accounting, business development and human resource functions. Other general General and administrative expenses include facility-related expense also includes corporate facility costs, professional including rent, utilities, depreciation and maintenance, and costs not otherwise included in research and development expense, legal fees related to intellectual property and corporate matters as well as fees for legal, estimated payments to settle litigation, insurance, investment banking fees, patent, accounting and consulting and accounting services, and pre-commercial United States market research. services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Increased costs associated with being a public company will also include expenses related to increase due to increases in professional and advisory fees during services associated with maintaining compliance with the pendency requirements of the proposed Merger Nasdaq Stock Market and the Securities and Exchange Commission, or the SEC, insurance and investor relations costs. If any of our current or future product candidates obtains marketing approval, we expect that we would incur significantly increased expenses associated with Carisma.

##### **sales and marketing efforts.**

##### **Interest Expense**

**Interest expense consisted of interest on our convertible promissory note that was entered into concurrently with the Moderna License Agreement including non-cash interest expense associated with the amortization of the debt discount. The convertible promissory note was converted into common stock upon the closing of the Merger.**

##### **Change in Fair Value of Contingent Consideration**

In connection with the Viventia Acquisition in September 2016, we recorded contingent consideration pertaining to the amounts potentially payable to Viventia's shareholders pursuant to the terms of the Share Purchase Agreement among us, Viventia and the other signatories thereto and are based on regulatory approval in certain markets and



future revenue levels. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized in earnings (or loss) for the period.

#### **Other Income, Net**

Other income, net consists primarily of interest income earned on cash and cash equivalents and, to a lesser extent, any gains or losses on foreign exchange.

#### **Provision for Income Taxes**

Benefit for income taxes is driven by the intangible impairment charge, changing the value of deferred tax liabilities. Provision for income taxes consists of income taxes incurred to non-US jurisdictions pursuant to our OUS business development partnership agreements, including the Qilu License Agreement.

### **Our Results of Operations**

#### **Comparison of the three months ended September 30, 2022 and 2021**

	Three Months Ended September 30,		Increase/(Decrease)	
	2022	2021	Dollars	Percentage
(in thousands, except percentages)				
Revenue:				
License and related revenue	\$ 40,000	\$ —	\$ 40,000	—
Total revenue	40,000	—	40,000	—
Operating expenses:				
Research and development	\$ 2,931	\$ 4,967	\$ (2,036)	(41) %
General and administrative	8,141	8,699	(558)	(6) %
Restructuring charge	10,947	5,522	5,425	98 %
Intangibles impairment charge	—	31,700	(31,700)	(100) %
Change in fair value of contingent consideration	(1,800)	(114,000)	112,200	(98) %
Total operating expenses	20,219	(63,112)	83,331	(132) %
Income from Operations	19,781	63,112	(43,331)	(69) %
Other income:				
Other income, net	676	1	675	67,500 %
<b>Income Before Taxes</b>	<b>\$ 20,457</b>	<b>\$ 63,113</b>	<b>\$ (42,656)</b>	<b>(68) %</b>
Benefit from income taxes	—	8,561	(8,561)	(100) %
<b>Net Income After Taxes</b>	<b>\$ 20,457</b>	<b>\$ 71,674</b>	<b>\$ (51,217)</b>	<b>(71) %</b>

#### **License Revenue**

Revenue for the three months ended September 30, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement for EBI-031 and all other IL-6 antagonist monoclonal antibody technology. We did not record any revenue for the three months ended September 30, 2021.

#### **Research and Development**

Research and development expenses were \$2.9 million for the three months ended September 30, 2022, compared to \$5.0 million for the three months ended September

30, 2021. The decrease of \$2.0 million was primarily due to a decrease in costs associated with manufacturing (\$1.9 million) and a decrease in other R&D related costs (\$0.1 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the US in the third quarter of 2022.

#### *General and Administrative*

General and administrative expenses were \$8.1 million for the three months ended September 30, 2022, compared to \$8.7 million for the three months ended September 30, 2021. The decrease of \$0.6 million was primarily due to a decrease in marketing and commercialization expenses, which were incurred in the third quarter of 2021 in preparation for potential commercial launch of Vicineum but were discontinued as a result of the Complete Response Letter from the FDA received in August 2021 (\$2.3 million) and a decrease in professional fees for accounting services (\$0.4 million). This was partially offset by an increase in legal expense (\$1.3 million), driven by legal fees associated with our assessment of strategic alternatives incurred in the third quarter of 2022 (\$2.2 million), partially offset by a decrease in legal fees associated with the internal review (\$0.4 million) and other legal expenses (\$0.5 million). Additionally, financial advisor fees increased due to financial advisor fees associated with our assessment of strategic alternatives incurred in the third quarter of 2022 (\$0.8 million).

#### *Restructuring Charge*

Restructuring charges were \$10.9 million for the three months ended September 30, 2022 compared to \$5.5 million for the three months ended September 30, 2021. The expense for the third quarter of 2022 consisted of severance and other employee-related costs (\$6.9 million) and termination of certain contracts and other associated costs (\$4.0 million) associated with our 2022 Restructuring Plan following the decision to voluntarily pause further development of Vicineum in the United States. The expense for the third quarter of 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) associated with the restructuring plan we approved on August 30, 2021 to reduce operating expenses and better align our workforce with the needs of our business following the receipt of the CRL in August 2021.

#### *Intangibles impairment*

Intangibles impairment charge for three months ended September 30, 2022 was zero compared to \$31.7 million in the three months ended September 30, 2021. In August 2021, we received a CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. As a result an impairment analysis was conducted, which concluded that the carrying value of our intangible asset of Vicineum US rights was fully impaired as of September 30, 2021.

#### *Derivative Liability*

##### *Change in Fair Value of Contingent Consideration*

The non-cash change in fair value of contingent consideration was a gain of \$1.8 million the derivative liability for the three months ended September 30, 2022, compared to a gain redemption feature of \$114.0 million our convertible promissory note reflected the non-cash charge for the three months ended September 30, 2021. The decrease in the fair value of contingent consideration of \$1.8 million for the three months ended September 30, 2022 was due to our conclusion that we no longer expect to owe any future earnout payments related to the Greater China region. Accordingly, we reduced our remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

The change in fair value of contingent consideration was a gain of \$114.0 million for the three months ended September 30, 2021. This was primarily driven by the receipt of a CRL from the FDA, in which the FDA determined that it cannot approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at the time, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value of contingent consideration was based. The most significant and impactful assumptions in our revenue projection models are timing of product launch and probabilities of clinical and regulatory success ("POS"); we expected delays in the start of commercialization and estimated lower POS as a direct result of the CRL. We anticipated needing to conduct an additional clinical trial, which would lead to delays in the start of commercialization globally. We had assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we assumed a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The milestone payments constitute debt-like obligations, and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value was 7.5% as of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues was derived from our estimated weighted-average cost of capital ("WACC"), and this WACC-derived discount rate was 8.6% as of September 30, 2021.

#### *Benefit (Provision) from Income Taxes*

We did not record a benefit or loss for the three months ended September 30, 2022. In the third quarter of 2021, we determined that the fair value of the Vicineum US rights was zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, we reduced the associated deferred tax liability which resulted in an \$8.6 million income tax benefit.

#### *Net income*

For the three months ended September 30, 2022, net income was \$20.5 million, compared to \$71.7 million for the three months ended September 30, 2021. In the third quarter of 2022, we recorded revenue of \$40.0 million related to the execution of the Roche Asset Purchase Agreement and non-cash income of \$1.8 million related to changes in the fair value of contingent consideration, partially offset by operating the derivative liability that was subject to re-measurement at each balance sheet date through the settlement of the convertible promissory note upon the closing of the Merger at which time the redemption feature was derecognized.

#### *Income Taxes*

For tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017, or the TCJA, eliminates the option to currently deduct research and development expenses of \$22.0 million. In the third quarter of 2021 we recorded non-cash income of \$90.9 million, which includes changes and requires taxpayers to capitalize and amortize them over five years for research activities performed in the fair value U.S. and 15 years for research activities performed outside the U.S. pursuant to IRC Section 174. In addition, we are required to recognize tax revenue of contingent consideration, income \$45.0 million in 2023, related to Moderna cash received in 2022, for tax benefit purposes in advance of GAAP recognition. We also expect limitations on utilization of net operating losses and intangible impairment charge. Additionally, we recorded R&D, G&A tax credits under TCJA and/or IRC Sections 382 and restructuring charges of \$19.2 million.<sup>383</sup> These requirements temporarily increase our U.S. federal

and state cash tax payments and reduces cash flows in 2023. Cash tax payments are expected to be funded from existing cash balances and cash flows from operations.

Our

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Results of Operations

Comparison of the **nine** Three Months Ended March 31, 2023 and 2022

	Three Months Ended March 31,	
	2023	2022
<b>Collaboration revenues</b>	<b>\$ 3,243</b>	<b>\$ 822</b>
<b>Operating expenses:</b>		
<b>Research and development</b>	<b>16,641</b>	<b>8,767</b>
<b>General and administrative</b>	<b>9,574</b>	<b>2,211</b>
<b>Total operating expenses</b>	<b>26,215</b>	<b>10,978</b>
<b>Operating loss</b>	<b>(22,972)</b>	<b>(10,156)</b>
<b>Change in fair value of derivative liability</b>	<b>(84)</b>	<b>(557)</b>
<b>Interest (expense) income, net</b>	<b>(1,477)</b>	<b>(599)</b>
<b>Pre-tax loss</b>	<b>(24,533)</b>	<b>(11,312)</b>
<b>Income tax expense</b>	<b>(109)</b>	<b>—</b>
<b>Net loss</b>	<b>\$ (24,642)</b>	<b>\$ (11,312)</b>

Collaboration Revenues

Collaboration revenues were \$3.2 million and \$0.8 million for the three months ended **September 30, 2022** March 31, 2023 and **2021**

	Nine Months Ended September 30,		Increase/(Decrease)	
	2022	2021	Dollars	Percentage
	(in thousands, except percentages)			
Revenue:				
License and related revenue	\$ 40,000	\$ 6,544	\$ 33,456	511 %
Total revenue	40,000	6,544	33,456	511 %
Operating expenses:				

Research and development	\$ 37,636	\$ 18,273	\$ 19,363	106 %
General and administrative	32,705	20,797	11,908	57 %
Restructuring charge	10,947	5,522	5,425	98 %
Intangibles impairment charge	27,764	31,700	(3,936)	(12) %
Change in fair value of contingent consideration	(52,000)	(52,240)	240	— %
Total operating expenses	57,052	24,052	33,000	137 %
Loss from Operations	(17,052)	(17,508)	456	(3) %
Other income (expense), net	867	(45)	912	(2,027) %
<b>Loss Before Taxes</b>	<b>\$ (16,185)</b>	<b>\$ (17,553)</b>	<b>\$ 1,368</b>	<b>(8) %</b>
Benefit from income taxes	3,875	8,273	(4,398)	(53) %
<b>Net Loss After Taxes</b>	<b>\$ (12,310)</b>	<b>\$ (9,280)</b>	<b>\$ (3,030)</b>	<b>33 %</b>

2022, respectively. The increase was related to the research and development activities completed under the Moderna License Revenue

Revenue Agreement that we executed in January 2022 with activities starting in second half of the quarter.

#### Research and Development Expenses

We track outsourced development, outsourced personnel costs and other external research and development costs of our CT-0508 program. We do not track internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the nine three months ended September 30, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement. Revenue for the nine months ended September 30, 2021 was \$6.5 million, which was due to achieving the IND milestone in China pursuant to the Qilu License Agreement, clinical supply revenue resulting from the delivery of drug product to Qilu March 31, 2023 and license revenue for additional purchase price due to the recovery of VAT by Qilu.

#### Research and Development

2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
CT-0508	\$ 1,832	\$ 2,327
CT-0525	1,675	—
Personnel costs, including stock-based compensation	4,954	3,020
Other clinical and pre-clinical development expenses	1,622	475
Facilities and other expenses	6,558	2,945
Total research and development expenses	\$ 16,641	\$ 8,767

Research and development expenses were \$37.6 million for the nine three months ended September 30, 2022 March 31, 2023 were \$16.6 million, compared to \$18.3 million \$8.8 million for the nine three months ended September 30, 2021 March 31,

2022. The increase of \$19.4 million was primarily due to the expense of prepaid balances related to consumables and manufacturing reservations as the balances were deemed to have no future value (\$25.2 million) in the second quarter of 2022. Additionally, employee-related compensation increased, primarily due to the retention programs implemented in the fourth quarter of 2021 and third quarter of 2022 (\$2.6 million). The increase was partially offset by decreased costs associated with manufacturing (\$6.1 million), clinical and manufacturing related consulting fees (\$2.0 million), and other individually immaterial R&D costs (\$0.3 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the US in the third quarter of 2022.

#### General and Administrative

General and administrative expenses were \$32.7 million for the nine months ended September 30, 2022, compared to \$20.8 million for the nine months ended September 30, 2021. The increase of \$11.9 million \$7.8 million was primarily due to an increase in legal expense (\$14.6 million) driven by the preliminary settlements our facilities and other expenses of the securities \$3.6 million resulting from increased lab space and derivative litigation net of expected insurance recovery (\$8.2 million) lab supplies from expanded clinical and legal fees pre-clinical work, a \$1.9 million increase in personnel costs due to growth in research and development employee headcount, a \$1.7 million increase due to costs associated with our assessment growth and expansion of strategic alternatives (\$2.6 million). Additionally, legal fees related to pre-clinical activities towards submission an IND for of CT-0525, and a \$1.1 million increase of other clinical and pre-clinical development expenses associated with the internal review (\$2.8 million), securities litigation counseling (\$0.9 million) and other legal expenses (\$0.1 million) increased during the nine months ended September 30, 2022. In addition, employee-related compensation increased, primarily driven by the retention programs implemented in the fourth quarter of 2021 and third quarter of 2022 (\$1.3 million). This was Moderna License Agreement, partially offset by decreases a \$0.5 million decrease in marketing direct costs associated with CT-0508.

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#### General and commercial Administrative Expense

The following table summarizes our general and administrative expenses (\$4.0 million) for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended	
	March 31,	
	2023	2022
Personnel costs, including stock-based compensation	\$ 5,826	\$ 628
Legal and professional fees	2,904	1,340

Facilities and supplies	109	107
Other expenses	735	136
Total general and administrative expense	\$ 9,574	\$ 2,211

General and administrative expenses for the three months ended March 31, 2023 were \$9.6 million, compared to \$2.2 million for the three months ended March 31, 2022. The increase of \$7.4 million was primarily attributable to \$3.4 million of severance costs associated with the Merger, \$1.8 million of higher personnel costs as a result of an increase in headcount, a \$1.6 million increase in legal and professional fees in support of our patent portfolio and expanding infrastructure in preparation of operating as a public company as well as a \$0.6 million increase in other expenses due to an increase in public relation expenditures.

#### *Interest (Expense) Income, net*

We recognized \$1.5 million in interest (expense) income, net for the three months ended March 31, 2023, which were incurred during was attributable primarily to the first half accelerated amortization of 2021 in preparation for potential commercial launch of Vicineum but were discontinued the debt discount as a result of the CRL received settlement of the convertible promissory note at the closing of the Merger, interest expense on the outstanding principal balance associated with the convertible promissory note issued to Moderna through March 7, 2023, offset by interest income of \$0.4 million.

We recognized \$0.6 million in August 2021.

#### *Restructuring Charge*

Restructuring charges were \$10.9 million interest (expense) income, net for the nine three months ended September 30, 2022 compared March 31, 2022, which was attributable primarily to \$5.5 million for interest expense on the nine months ended September 30, 2021. The outstanding principal balance associated with the convertible promissory note issued to Moderna, including non-cash interest expense for associated with the nine months ended September 30, 2022 consisted of severance and other employee-related costs (\$6.9 million) and termination of certain contracts and other associated costs (\$4.0 million) following the decision to pause further development of Vicineum in the US. The expense for the nine months ended September 30, 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) following the receipt amortization of the CRL in August 2021.

#### *debt discount.*

#### *Change in Fair Value of Contingent Consideration Derivative Liability*

We recognized a \$0.1 million non-cash charge for the three months ended March 31, 2023, for the increase in fair value of the derivative liability associated with the redemption feature

of the convertible promissory note with Moderna through settlement in connection with the Merger.

We recognized a \$0.6 million non-cash charge for the three months ended March 31, 2022, for the increase in fair value of the derivative liability associated with the redemption feature of the convertible promissory note with Moderna, which was attributable to the timing in which we estimated the accrued settlement event to occur as of March 31, 2023.

#### **Income Tax Expense**

We recorded \$0.1 million of income tax expense for the three months ended March 31, 2023 based on projected taxable income for the year ending December 31, 2023.

### **Liquidity and Capital Resources**

#### **Sources of Liquidity**

As of March 31, 2023, we had \$139.0 million in cash, cash equivalents and marketable securities and an accumulated deficit of \$182.9 million. To date, we have not yet commercialized any products or generated any revenue from product sales and have financed operations primarily with proceeds from sales of preferred stock, proceeds from our collaboration with Moderna, research tax credits and convertible debt financing. Under the terms of the Moderna License Agreement, assuming Moderna develops and commercializes 12 products, each directed to a different development target, we are eligible to receive up to between \$247.0 million and \$253.0 million per product in development target designation, development, regulatory and commercial milestone payments. In addition, we are eligible to

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receive mid to high single digit tiered royalties on net sales of any products that are commercialized under the agreement, which may be subject to reductions.

In addition to the upfront \$45.0 million payment received, the Moderna License Agreement includes variable consideration which we estimate to be \$73.9 million over the life of the contract for expected research and development services to be performed, inclusive of passthrough costs, in the transaction price as of the outset of the arrangement to be billed quarterly. Through March 31, 2023, we have recognized \$13.1 million of research and development services as collaboration revenues.

#### **Cash Flows**



The following table shows a summary of our cash flows for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended	
	March 31,	
	2023	2022
Cash provided by (used in)		
Operating activities	\$(25,534)	\$ 34,604
Investing activities	(3,595)	(64,251)
Financing activities	67,742	35,000
Net change in cash, cash equivalents and restricted cash	\$ 38,613	\$ 5,353

#### *Cash Flows from Operating Activities*

During the three months ended March 31, 2023, we used \$25.5 million of net cash in operating activities. Cash used in operating activities reflected our net loss of \$24.6 million that was offset by \$3.5 million of non-cash charges related to depreciation and amortization expense, stock-based compensation, reductions in the operating right of use, or ROU assets, amortization of the debt discount on the convertible promissory note, change in fair value of contingent consideration was the derivative liability, accretion on marketable securities, and non-cash interest on the finance liability from the failed sale-leaseback and a gain of \$52.0 million \$4.4 million net change in our operating assets and liabilities attributable to the timing in which we pay our vendors for research and development activities.

During the nine three months ended September 30, 2022 March 31, 2022, compared we provided \$34.6 million of net cash in operating activities. Cash provided by our operating activities reflected our net loss of \$11.3 million that was offset by \$1.9 million of non-cash charges related to a gain of \$52.2 million for the nine months ended September 30, 2021. The decrease depreciation and amortization expense, stock-based compensation, reductions in the fair value of contingent consideration of \$52.0 million for the nine months ended September 30, 2022 was driven by our strategic decision to voluntarily pause further development of Vicineum in the US and our conclusion that we no longer expect to owe any future earnout payments related to the Greater China region. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications for the size, timeline and costs for an additional Phase 3 clinical trial for the treatment of NMIBC. Additionally, during the second quarter of 2022, we observed an evolution operating ROU assets, amortization of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during debt discount on the ongoing BCG shortage. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a

larger infrastructure, and as such, intend to seek a partner that can execute further development to realize the full potential of Vicineum. We expect that any partner who acquires Vicineum from us will be obligated to make any payments to the former shareholders of Viventia under the Share Purchase Agreement

The convertible promissory note, change in fair value of contingent consideration the derivative liability and the accretion on marketable securities, and a \$44.0 million net change in our operating assets and liabilities which was a gain of \$52.2 million for primarily attributable to the nine \$45.0 million upfront nonrefundable payment received from Moderna pursuant to the Moderna License Agreement.

#### *Cash Flows from Investing Activities*

During the three months ended September 30, 2021. This was primarily driven by the receipt March 31, 2023, we used \$3.6 million of a CRL net cash in August 2021, investing activities. Cash used in which the FDA determined that it could not approve the BLA for Vicineum in its present form. Due to the inherent uncertainty in the path forward for Vicineum at the time, we reassessed the underlying assumptions used to develop the revenue projections upon which the fair value investing activities reflected purchases of its contingent consideration is based. The most significant and impactful assumptions in our revenue projection models are timing marketable securities of product launch and POS; we expected delays in the start of commercialization and estimate lower POS as a direct result of the CRL. We anticipated needing to conduct an additional clinical trial, which would lead to delays in the start of commercialization globally. We had assessed a range of commercialization timeline assumptions and applied a probability to each outcome based on management's best estimate. In addition, we assumed a lower POS in achieving certain clinical and regulatory milestones in the range of approximately 45% to 55% globally. The milestone payments constitute debt-like obligations, \$34.5 million and the high-yield debt index rate applied to the milestones in order to determine the estimated fair value was 7.5% as purchase of September 30, 2021. The discount rate applied to the 2% earnout payment due on forecasted Vicineum revenues was derived from our estimated WACC, property and this WACC-derived discount rate was 8.6% as equipment of September 30, 2021.

#### *Provision for Income Taxes*

For the nine months ended September 30, 2022 \$0.1 million, we recorded a benefit from income taxes of \$3.9 million. In the second quarter of 2022, we determined that the fair value of the Vicineum EU rights was zero, which resulted in an impairment charge of \$14.7 million. In connection with this impairment charge, in the second quarter of 2022, we reduced the associated deferred tax liability to zero, which resulted in a \$4.0 million income tax benefit, partially offset by \$0.1 million income tax paid to foreign jurisdictions pursuant \$31.0 million of proceeds from the sale of marketable securities.

During the three months ended March 31, 2022, we used \$64.3 million of net cash in investing activities. Cash used in investing activities reflected purchases of marketable securities of \$63.2 million and the purchase of property and equipment of \$1.0 million.

## Cash Flows from Financing Activities

During the three months ended March 31, 2023, we received \$67.7 million of net cash from financing activities, primarily attributable to the Qilu License Agreement. Please refer to Note 8, "Intangible Assets and Goodwill," \$37.9 million in the Notes to Condensed Consolidated Financial Statements cash and cash equivalents acquired in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 for further information regarding the impairment charge.

For the nine months ended September 30, 2021, we recorded a benefit from income taxes of \$8.3 million. In the third quarter of 2021, we determined that the fair value of the Vicineum United States rights were zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, the Merger and \$30.6 million in proceeds from the third quarter issuance of 2021, we reduced the associated deferred tax liability which resulted common stock in an \$8.6 million income tax benefit.

## Net Loss

For the nine months ended September 30, 2022 net loss was \$12.3 million, compared to net loss of \$9.3 million, for the nine months ended September 30, 2021. The increase of \$3.0 million was due to an increase in operating expense (\$33.0 million), primarily driven by the reduction of our prepaid balances related to consumables and manufacturing reservations in the second quarter of 2022 (\$25.2 million) and the preliminary settlements of the securities and derivative litigation net of expected insurance recovery (\$8.2 million). Additionally, the benefit from income taxes decreased (\$4.4 million) in 2022 compared to

2021. This was pre-closing financing, partially offset by increased revenue (\$33.5 million) primarily driven by \$1.7 million in payments of financing costs.

During the execution three months ended March 31, 2022, we received \$35.0 million of net cash from financing activities attributable to the Roche Asset Purchase agreement, proceeds from convertible promissory note.

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## Liquidity

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## Funding Requirements

**We expect to devote substantial financial resources to our ongoing and Capital Resources**

## Overview

planned activities, particularly as we conduct our ongoing clinical trial of CT-0508 and pursue related combination strategies, prepare for, initiate and conduct our planned clinical trials of CT-0525, CT-1119 and CT-0729 and advance our discovery programs and continue our product development efforts. As of September 30, 2022, March 31, 2023, we had cash, cash equivalents and marketable securities of \$184.9 million, net working capital of \$157.7 million and an accumulated deficit of \$328.6 million. We incurred cash flows from operating activities of \$22.2 million for the nine months ended September 30, 2022, compared to negative cash flows of \$56.3 million for the nine months ended September 30, 2021 \$139.0 million. We believe that based on our current operating plans and financial forecasts, our cash, cash equivalents and marketable securities of \$184.9 million as of September 30, 2022, are sufficient to fund sustain our current operating plan for expenses and capital expenditure requirements at least twelve months from through the date end of this Form 10-Q filing, November 7, 2022.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on September 20, 2022, we entered into the Merger Agreement with Carisma and Merger Sub, pursuant 2024.

We expect our expenses to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub will merge with and into Carisma, with Carisma continuing as our wholly-owned subsidiary and the surviving corporation of the Merger. Our board of directors unanimously approved the Merger Agreement and resolved to recommend that our stockholders approve the proposals described in the Merger Agreement. If the Merger is completed, the business of Carisma will continue as the business of the combined company.

The Merger is expected to close approximately two to three months from the date of this form 10-Q filing, November 7, 2022. Consummation of the Merger is subject to certain closing conditions, including, among other things, (a) approval by our stockholders of the proposals described in the Merger Agreement, (b) approval by Carisma's stockholders of, among other things, the adoption of the Merger Agreement, (c) Nasdaq's approval of the listing of the shares of our common stock to be issued increase substantially in connection with our ongoing activities, particularly as we advance our pre-clinical activities and clinical trials. In addition, if we obtain marketing approval for CT-0508 or any other product candidate we are developing or develop in the Merger, (d) the effectiveness of future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. In addition, we expect to incur additional costs associated with operating as a registration statement on Form S-4 public company. Accordingly, we will need to register the shares of our common stock to be issued obtain substantial additional funding in connection with the Merger, and (e) our having net cash as of closing of the Merger greater than continuing operations. If we are unable to raise capital or equal to \$100.0 million.

The Merger Agreement contains certain termination rights of each of us and Carisma. Upon termination of the Merger Agreement under specified circumstances, obtain adequate funds when needed or on acceptable terms, we may be required to pay Carisma a termination fee of \$7.6 million and/ delay, limit, reduce or reimburse Carisma's expenses up terminate our discovery and product development programs or any future commercialization efforts or grant rights to a maximum of \$1.75 million, develop and Carisma may be required to pay us a termination fee of \$5.49 million and/or reimburse our expenses up to a maximum of \$1.75 million.

Our future operations are highly dependent on the success of the Merger and there can be no assurances that the Merger will be successfully consummated. In the

event market product candidates that we do not complete would otherwise prefer to develop and market ourself. In addition, attempting to secure additional financing may divert the Merger with Carisma, we may continue to explore strategic alternatives, including, without limitation, another strategic transaction and/or pursue a liquidation time and dissolution attention of our company.

Since our inception, we have received no revenue management from sales of our products, day-to-day activities and we anticipate that operating losses will continue for the foreseeable future. We have financed our operations to date primarily through private placements of our common stock, preferred stock, common stock warrants and convertible bridge notes, venture debt borrowings, our IPO, follow-on public offerings, sales effected in ATM offerings, our OUS business development partnerships and license agreements, sale of assets, and, to a lesser extent, from a collaboration.

We have entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies") dated November 29, 2019, as amended by Amendment No. 1 dated October 30, 2020, Amendment No. 2 dated February 17, 2021 and Amendment No. 3, dated June 1, 2021 (as amended, the "Sale Agreement"), under which we may issue and sell shares of our common stock, par value \$0.001 per share from time to time through Jefferies (the "ATM Offering"). In June and July 2021, we filed prospectus supplements with the SEC in connection with the offer and sale of up to an aggregate of \$200 million of our common stock pursuant to the Sale Agreement of which \$97.8 million of common shares remain available for future issuance as of September 30, 2022. Sales of common stock under the Sale Agreement are made by any method that is deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act of 1933, including but not limited to sales made directly on or through the Nasdaq Stock Market or any other existing trading market for our common stock. We may sell shares of our common stock efficiently from time to time but have no obligation to sell any of our common stock and may at any time suspend offers under the Sale Agreement or terminate the Sale Agreement. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell common stock from time to time, as the sales agent, based upon our instructions, which include a prohibition on sales below a minimum price set by distract us from time to time. We have provided Jefferies with customary indemnification rights, discovery and Jefferies is entitled to a commission at a fixed rate equal to 3.0% of the gross proceeds for each sale of common stock under the Sale Agreement. We did not sell any shares of common stock pursuant to the Sale Agreement during the nine months ended September 30, 2022. We raised \$175.0 million of net proceeds from the sale of 56.9 million shares of common stock at a weighted-average price of \$3.17 per share during the nine months ended September 30, 2021,

including \$38.2 million of net proceeds from the sale of 9.8 million shares of common stock at a weighted-average price of \$4.01 per share during the three months ended September 30, 2021. Share issue costs, including sales agent commissions, related to the ATM Offering totaled \$1.2 million and \$5.4 million for the three and nine months ended September 30, 2021, respectively.

### **Funding Requirements**

Our future funding requirements will depend on the outcome of the proposed Merger with Carisma.

We are subject to a number of risks similar to other clinical companies that have determined to focus primarily on pursuing a strategic transaction, including, but not limited to, those which are described under Part II Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

We will incur substantial expenses if and as we:

- address our ongoing securities litigation and derivative litigation;
- maintain, expand and protect our intellectual property portfolio;
- reduce our personnel and incur related severance and employee-related costs;
- wind down activities with our CMOs;
- terminate our property leases; and
- explore, evaluate and pursue any strategic alternatives if the Merger is not completed.

product development efforts.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our ongoing clinical trial of CT-0508 and other planned and future clinical trials;
- the scope, progress, costs and results of pre-clinical testing and clinical trials of CT-0508 for additional combinations, targets and indications;
- the number of and development requirements for additional indications for CT-0508 or for any other product candidates;
- the success of our collaborations with Moderna or others;
- our ability to scale up our manufacturing processes and capabilities to support clinical trials of CT-0508 and other product candidates we are developing and develop in the future;
- the costs, timing and outcome of regulatory review of CT-0508 and other product candidates we are developing and may develop in the future;
- potential changes in the regulatory environment and enforcement rules;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment of license fees and other costs of our technology license arrangements;
- the progress, costs and results of our ongoing preclinical studies of CT-0525 and other planned and future preclinical studies;
- The costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for CT-0508, CT-0525 and other product candidates we are developing and may develop in the future for which we may receive marketing approval;
- our ability to obtain and maintain acceptance of any approved products by patients, the medical community and third-party payors;
- the amount and timing of revenue, if any, received from commercial sales of CT-0508 and any other product candidates we are developing or develop in the future for which we receive marketing approval;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the availability of raw materials for use in production of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire additional technologies or product candidates.

Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if

approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. For example, market volatility resulting from the COVID-19 pandemic, any other future infectious diseases, epidemics or pandemics or general U.S. or global economic or market conditions could also adversely impact our ability to access capital as and when needed.

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• the outcome and the timing [Table of the proposed Merger with Carisma](#); [Contents](#)

• the outcome and timing of any pending

Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future [litigation involving us or our business](#);

- the costs and timing of maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our obligation to make milestone, royalty and other payments to third-party licensors under our licensing agreements.

operating plans.

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or government or other third-party funding, licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the your ownership interests of existing stockholders interest will be diluted, and the terms of these those securities may include liquidation or other preferences that adversely affect the your rights as a holder of existing stockholders, our common stock. Debt financing and preferred equity financing, if available, would increase our fixed payment obligations and may involve agreements that include liens or other restrictive covenants limiting or restricting our operations and ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, Merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our assessment of strategic alternatives. If we do not successfully consummate the proposed Merger with Carisma, our board of



directors may decide to explore other strategic alternatives, including, without limitation, another strategic transaction and/or a liquidation and dissolution of our company

### **Contractual and Other Obligations**

For information related to our cash requirements from known contractual and other obligations, see the description of Contingent Consideration in Note 5 “Fair Value Measurement and Financial Instruments,” the information in Note 10 “Commitments and Contingencies”, our leases in Note 11 “Leases”, and the description of our license agreements in Note 17, “License Agreements” of Part I - Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements.

### **Cash Flows**

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Net Cash Provided by (Used in) Operating Activities	\$ 22,214	\$ (56,278)
Net Cash Used in Investing Activities	(113,733)	(4)
Net Cash Provided by Financing Activities	—	176,129
<b>Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash</b>	<b>\$ (91,519)</b>	<b>\$ 119,847</b>

#### **Net Cash Used in Operating Activities**

Net cash provided by operating activities was \$22.2 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$12.3 million, adjusted for non-cash items including, a decrease in the fair value of contingent consideration (\$52.0 million), intangible impairment charge (\$27.8 million), share-based compensation (\$5.9 million), and a net increase in operating assets and liabilities (\$52.9 million).

Net cash used in operating activities was \$56.3 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$9.3 million, which includes \$6.5 million of revenue recognized pursuant to certain of our out-license agreements, adjusted for non-cash items, including share-based compensation (\$3.4 million), a decrease in the fair value of contingent consideration (\$52.2 million), increase in impairment charge (\$31.7 million), and a net decrease in operating assets and liabilities of (\$29.9 million).

#### **Net Cash Used in Investing activities**

Net cash used in investing activities was \$113.7 million for the nine months ended September 30, 2022 and consisted of marketable security purchases.

Net cash used in investing activities consisted of de minimis purchases and sales of property and equipment during the nine months ended September 30, 2021.

#### **Net Cash Provided by Financing activities**

Net cash provided by financing activities was zero for the nine months ended September 30, 2022.

Net cash provided by financing activities was \$176.1 million for the nine months ended September 30, 2021 and consisted primarily of \$175.0 million net proceeds from the



sale of common stock under the ATM Offering.

### **Critical Accounting Policies and Use of Estimates**

The preparation of our condensed consolidated financial statements in accordance with GAAP and the rules and regulations of the SEC require the use of estimates and assumptions, based on complex judgments considered reasonable, and affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Our critical accounting policies are those policies which involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. Management has determined **restrictions** that our most critical accounting policies are those relating to the fair value of indefinite-lived intangible assets, goodwill; contingent consideration; revenue recognition; development and regulatory milestone payments and other costs; and research and development costs.

### **Fair Value of Indefinite-Lived Intangible Assets**

Our intangible assets consist of indefinite-lived, acquired IPR&D worldwide product rights to Vicineum as a result of the acquisition of Viventia in 2016. IPR&D assets acquired in a business combination are considered indefinite-lived until the completion or abandonment of the associated research and development efforts.

Indefinite-lived intangible assets are quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of indefinite-lived intangible assets requires management to estimate the future discounted cash flows of an asset using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. We recognize an impairment loss when and to the extent that the estimated fair value of an intangible asset is less than its carrying value. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could indicate that the carrying value of our intangible assets was not recoverable. If an impairment indicator is identified, an interim impairment assessment is performed.

During the second quarter of 2022, we observed an evolution of the current market treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage. We have also experienced a sustained decline in share price and a resulting decrease in our market capitalization. On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. Management updated the discounted cash flow model using the market participant approach and considered preliminary terms of potential partnering deal to conclude the fair value of our intangible asset of Vicineum EU rights. We concluded that the carrying value of our intangible asset of Vicineum EU rights of \$14.7 million was fully impaired as of June 30, 2022 and was reduced to zero in the second quarter of 2022.

### **Goodwill**

Goodwill on our condensed consolidated balance sheets is the result of our acquisition of Viventia in September 2016 and represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets acquired under the acquisition method of accounting. Goodwill is not amortized; rather than

recording periodic amortization, goodwill is quantitatively tested for impairment at least annually during the fourth quarter of the fiscal year, or more often if indicators of impairment are present. Impairment testing of goodwill requires management to estimate the future discounted cash flows of a reporting unit using assumptions believed to be reasonable, but which are unpredictable and inherently uncertain. Actual future cash flows may differ from the estimates used in impairment testing. If the fair value of the equity of a reporting unit exceeds the reporting unit's carrying value, including goodwill, then goodwill is considered not to be impaired. We recognize a goodwill impairment when and to the extent that the fair value of the equity of a reporting unit is less than the reporting unit's carrying value, including goodwill. We have only one reporting unit. In addition, on a quarterly basis, we perform a qualitative review of our business operations to determine whether events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of each reporting unit and thus indicate a potential impairment of the goodwill carrying value. If an impairment indicator is identified, an interim impairment assessment is performed.

During the second quarter of 2022, we observed continued trends in our market capitalization as compared to the carrying value of our single reporting unit as well as changes in certain assumptions in the fair value of the business including market share, size, length and cost of a clinical trial, and time to potential market launch. We identified these changes as potential impairment indicators and performed a quantitative impairment analysis in advance of our typical annual assessment date of October 1. We reassessed the underlying assumptions used to develop our revenue projections, which were then used as significant inputs to determine the fair value of equity. We updated our revenue forecast models based on further expected launch delays in both US and OUS regions. We also recently observed an evolution of the current treatment paradigm in NMIBC, with substantial uptake of intravesical chemotherapy (monotherapy and combination therapy) during the ongoing BCG shortage resulting in lower projected peak market share for Vicineum. We also considered other factors including the preliminary valuations of strategic alternatives during the fair value assessment. As a result of the interim impairment test, we concluded that the carrying value of our goodwill of \$13.1 million was fully impaired as of June 30, 2022.

### **Contingent Consideration**

Contingent consideration on our condensed consolidated balance sheets is the result of our acquisition of Viventia in September 2016 and represents the discounted present value of future commercial launch milestones and net sales earnout payments due to the former shareholders of Viventia pursuant to the Share Purchase Agreement. Contingent consideration is measured at its estimated fair value on a recurring basis at each reporting period, with fluctuations in value resulting in a non-cash charge to earnings (or loss) during the period. The estimated fair value measurement is based on significant unobservable inputs (Level 3 within the fair value hierarchy), including internally developed financial forecasts, probabilities of success and timing of certain milestone events and achievements, which are unpredictable and inherently uncertain. Actual future cash flows may differ from the assumptions used to estimate the fair value of contingent consideration. The valuation of contingent consideration requires the use of significant assumptions and judgments, which management believes are consistent with those that would be made by a market participant. Management reviews its assumptions and judgments on an ongoing basis as additional market and other data is obtained, and any future changes in the assumptions and judgments utilized by management may cause the estimated fair value of contingent consideration to fluctuate materially, resulting in earnings volatility.

The estimated fair value of our contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales were expected to be achieved through 2033, the level of commercial sales of Vicineum forecasted for the US, Europe, Japan, China and other potential markets. Earnouts were determined using an earnout rate of 2% on all commercial net sales of Vicineum through December 2033. The discount rate applied to the 2% earnout was derived from our estimated weighted-average cost of capital, which has fluctuated from 9.3% as of December 31, 2021. Milestone payments constitute debt-like obligations, and therefore a high-yield debt index rate was applied to the milestones in order to determine the estimated fair value. This index rate was 8.0% as of December 31, 2021.

On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial for the treatment of NMIBC. We continue to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, we intend to seek a partner for the further development of Vicineum. Accordingly, during the second quarter of 2022, we concluded that we are no longer expected to pay related milestone and earnout payments to the former shareholders of Viventia, with the exception of the potential 2% earnout payment related to the Greater China region since those territory rights had been out-licensed. Qilu held the exclusive license to develop Vicineum in the Greater China

region, and accordingly, the \$1.8 million estimated earnout payment in the Greater China region remained as long-term contingent consideration as of June 30, 2022.

We and Qilu are in the process of negotiating a termination of the Qilu License Agreement. Upon the termination of the Qilu License Agreement, we will regain the rights to develop, manufacture and commercialize Vicineum in Greater China. However, we do not plan to develop or commercialize Vicineum in that region or any other, as we are pursuing the Merger with Carisma. We are also seeking to sell or out-license Vicineum and all the related obligations related to Vicineum. We expect that any partner who acquires or licenses Vicineum from us will be obligated to make any payments, including those related to sales in the Greater China region (if any), that become payable to the former shareholders of Viventia under the Share Purchase Agreement. If a sale or license of Vicineum has not occurred at the time the Merger is completed, Carisma has indicated it may continue to seek a sale or license of Vicineum and has no plans to develop Vicineum. Accordingly, as of September 30, 2022, we concluded that we no longer expect to owe any future earnout payments related to the Greater China region and reduced our remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022.

### **Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the

extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize accrued interest and penalties related to uncertain tax positions as income tax expense in our condensed consolidated statements of operations. As of September 30, 2022 and December 31, 2021, we did not have any uncertain tax positions.

#### **Research and Development Costs**

Research and development activities are expensed in the period incurred. Research and development expenses consist of both internal and external costs associated with all basic research activities, clinical development activities and technical efforts required to develop a product candidate. Internal research and development consist primarily of personnel costs, including salaries, benefits and share-based compensation, facilities leases, research-related overhead, pre-approval regulatory and clinical trial costs, manufacturing and other contracted services, license fees and other external costs.

In certain circumstances, we are required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are recorded as prepaid assets and expensed when the activity has been performed or when the goods have been received.

#### **Recently Issued Accounting Standards**

Recently issued accounting standards are discussed in "Item 1. Financial Statements - Notes to Condensed Consolidated Financial Statements - Note 4. Recent Accounting Pronouncements" of this Quarterly Report on Form 10-Q.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

The information under this item is not required to be provided by smaller reporting companies.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), that are designed to ensure information required to be disclosed by us in reports 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 and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as the end of the period covered by this Quarterly Report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

## Limitations on Effectiveness of Controls and Procedures

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore, the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company 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. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon 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; over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies and procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of controls, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our system of controls to enhance, where necessary, our control policies and procedures.

## Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2022, there were no changes in our internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f), which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings.

On August 19, 2021, August 31, 2021, and October 7, 2021, three substantially identical securities class action lawsuits captioned Bibb v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07025, Cizek v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-07309 and Markman v. Sesen Bio, Inc. et al., Case No. 1:21-cv-08308 were filed against us and certain of our officers in the US District Court for the Southern District of New York. The three complaints alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder based on statements made by us concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The three complaints sought compensatory damages and costs and expenses, including attorneys' fees. On October 29, 2021, the court consolidated the three cases under the caption In re Sesen Bio, Inc. Securities Litigation, Master File No. 1:21-cv-07025-AKH (the "Securities Litigation"), and appointed Ryan Bibb, Rodney Samaan, Lionel Dreshaj and Benjamin Dreshaj (collectively, the "Lead Plaintiffs") collectively as the lead plaintiffs under the Private Securities Litigation Reform Act. On November 1, 2021, two stockholders filed motions to reconsider asking the court to appoint a different lead plaintiff. On November 24, 2021, defendants filed a motion to transfer venue to the US District Court for the District of Massachusetts. That motion was fully briefed as of December 13, 2021, but the court has not ruled on that motion. On December 6, 2021, the Lead Plaintiffs filed an amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges the same violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the same theory as the prior complaints. The defendants moved to

dismiss the Amended Complaint on March 7, 2022, and that motion was fully briefed on May 6, 2022. On June 3, 2022, before the court ruled on the motion to dismiss, the parties requested that the court hold any decision on the motion to dismiss in abeyance to provide the parties with an opportunity to engage in mediation. On June 30, 2022 and July 6, 2022, we and the plaintiffs engaged in mediation sessions in an attempt to resolve the Securities Litigation and continued to discuss a potential settlement over the following weeks. On July 19, 2022, the parties reached an agreement in principle to settle the Securities Litigation. Pursuant to that agreement, we and the individual defendants will pay or cause to be paid to members of the class who submit timely and valid proofs of claims. In exchange, the Lead Plaintiffs will dismiss the action and all class members who do not timely and validly opt-out of the settlement will provide broad customary releases to us and the individual defendants. On August 3, 2022, the parties entered into a Stipulation and Agreement of Settlement to settle the Securities Litigation, which was filed with the court on August 17, 2022. The Stipulation and Agreement of Settlement related to the Securities Litigation provides for a settlement payment of \$21.0 million to the class and the dismissal of all claims against us and the other defendants. The settlement payment is being funded by us and our insurance carriers. On September 1, 2022, the US District Court for the Southern District of New York issued an order denying the motions to appoint a different lead plaintiff. On September 28, 2022, the court issued an order granting preliminary approval of the proposed settlement of the Securities Litigation. The court has set a final settlement approval hearing for January 23, 2023 at 10:00 a.m. local time.

On September 20, 2021 and September 24, 2021, two substantially similar derivative lawsuits captioned Myers v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11538 and D'Arcy v. Sesen Bio, Inc., et. al., Case No. 1:21-cv-11577 were filed against our board of directors and certain of our officers in the US District Court for the District of Massachusetts, with us named as nominal defendant. On January 12, 2022, a third derivative complaint captioned Tang v. Sesen Bio, Inc., et al., was filed in Superior Court in Massachusetts against our board of directors and certain of our officers (the "State Derivative Litigation"). The three derivative complaints allege breach of fiduciary duties, waste of corporate assets, and violations of federal securities laws based on statements made by us concerning the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. The D'Arcy complaint further alleges unjust enrichment, abuse of control, gross mismanagement and aiding and abetting thereof. The three derivative complaints seek unspecified damages, restitution and disgorgement of profits, benefits and compensation obtained by the defendants and costs and expenses, including attorneys' fees. On October 18, 2021, the court consolidated the two federal court cases under the caption In re Sesen Bio, Inc. Derivative Litigation, Lead Case No. 1:21-cv-11538 (the "Federal Derivative Litigation"). On December 22, 2021, the court entered a joint stipulation among the parties to stay the Federal Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On May 1, 2022, the plaintiffs filed a verified consolidated shareholder derivative complaint in the Federal Derivative Litigation. On May 18, 2022, the court entered a joint stipulation among the parties to stay the State Derivative Litigation until after a ruling on any motion to dismiss filed by defendants in the Securities Litigation. On July 6, 2022, we and the plaintiffs to the Federal Derivative Litigation and the State Derivative Litigation engaged in mediation in an attempt to resolve the litigation, with settlement discussions continuing over the following days. On July 19, 2022, the parties reached an agreement in principle to settle the Federal Derivative Litigation, the State Derivative Litigation and other potential related derivative claims (collectively, the "Derivative Litigation"). Pursuant to that agreement, the individual defendants will cause us to adopt certain enhancements to our corporate governance policies and procedures. In exchange, plaintiffs will dismiss the Derivative Litigation and, on behalf of us, provide broad customary releases to the individual defendants. On August 22, 2022, the parties



entered into a Stipulation of Settlement to settle the Derivative Litigation, which was filed with the court on August 30, 2022. The Stipulation of

Settlement related to the Derivative Litigation confirms that we previously adopted certain corporate governance enhancements in response to, among other things, the filing of the Derivative Litigation, and that, subject to final court approval, we will adopt additional corporate governance enhancements. The Stipulation of Settlement also provides for a \$630,000 payment for plaintiffs' attorneys fees due to the benefits the corporate governance enhancements are intended to provide to us. The payment of plaintiffs' attorneys fees is being funded by us. On September 2, 2022, the court issued an order granting preliminary approval of the Stipulation of Settlement related to the Derivative Litigation. The court has set a final settlement approval hearing for November 8, 2022 at 2:00 p.m. local time.

We, our board of directors and the individual defendants continue to deny all allegations of any wrongdoing, but are seeking to settle the Securities Litigation and the Derivative Litigation to avoid the uncertainty, risk, expense and distraction of protracted litigation.

On October 21, 2022, we received two separate letters and on November 4, 2022, we received one letter from purported stockholders demanding that we amend the Registration Statement filed with the SEC on October 14, 2022 (the "Registration Statement") to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. We believe that these demands are without merit and intend to vigorously defend against them. At this time, no assessment can be made as to the likely outcome or whether the outcome will be material to us.

#### **Item 1A. Risk Factors.**

During the nine months ended September 30, 2022, other than as set forth below, there were no material changes to the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2021. You should carefully consider the information described therein and in this Quarterly Report on Form 10-Q, which could materially affect our financial condition, results of operations and cash flows.

#### **Risks Related to the Merger with CARISMA Therapeutics Inc.**

***The Exchange Ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing of the Merger and not the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.***

The Merger Agreement has set the calculation of the Exchange Ratio for the Carisma capital stock, and the Exchange Ratio is based on the fully-diluted capitalization of Carisma and us, in each case immediately prior to the closing of the Merger (after giving effect to the Carisma Pre-Closing Financing). The Merger Agreement does not include a price-based termination right. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Carisma's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Carisma's stockholders could receive merger consideration with substantially greater value than the value of such merger

consideration on the date of the Merger Agreement. Because the Exchange Ratio does not adjust as a direct result of changes in the market price of our common stock, changes in the market price of our common stock will change the value of the total merger consideration payable to Carisma's stockholders pursuant to the Merger Agreement.

Stock price changes may result from a variety of factors, including changes in our or Carisma's respective businesses, operations and prospects, reductions or changes in US government spending or budgetary policies, market assessments of the likelihood that the Merger will be completed, interest rates, federal, state and local legislation, governmental regulation, legal developments in the industry segments in which we or Carisma operate, the timing of the Merger, and general market, industry and economic conditions, including pandemics and other public health emergencies. Recent events surrounding the global economy, geopolitics and the COVID-19 pandemic continue to evolve and have introduced unusually high levels of volatility into financial and stock markets, and may affect the value of our common stock.

***Our stockholders and Carisma's stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Carisma Pre-Closing Financing and the conversion of the Carisma convertible note.***

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders and Carisma's stockholders will have experienced substantial dilution of their ownership interests in their respective companies, including as a result of the Carisma Pre-Closing Financing and the conversion of Carisma's \$35.0 million outstanding convertible note, without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger and the Carisma Pre-Closing Financing.

***Failure to complete the Merger may result in either us or Carisma paying a termination fee to the other party and could significantly harm the market price of our common stock and negatively affect the future business and operations of each company.***

If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million, and Carisma may be required to pay Sesen Bio a termination fee of \$5.49 million and/or reimburse Sesen Bio's expenses up to a maximum of \$1.75 million. Even if a termination fee or reimbursement of expenses of the other party are not payable in connection with a termination of the Merger Agreement, each of us and Carisma will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that we will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement.

***The issuance of our common stock to Carisma's stockholders pursuant to the Merger Agreement and the resulting change in control from the Merger must be approved by our stockholders, and the Merger Agreement and transactions contemplated thereby must be approved by the Carisma stockholders. Failure to obtain these approvals would prevent the closing of the Merger.***



Before the Merger can be completed, our stockholders must approve, among other things, the issuance of our common stock to Carisma's stockholders pursuant to the Merger Agreement and the resulting change in control from the Merger, and Carisma's stockholders must adopt the Merger Agreement and approve the Merger and the related transactions. Failure to obtain the required stockholder approvals may result in a material delay in, or the abandonment of, the Merger. Any delay in completing the Merger may materially adversely affect the timing and benefits that are expected to be achieved from the Merger.

***Some of our executive officers and directors have interests in the Merger that are different from our stockholders and that may influence them to support or approve the Merger without regard to the interests of our stockholders.***

Certain of our executive officers and directors participate in arrangements that provide them with interests in the Merger that are different from the interests of our stockholders, including, among others, severance benefits, the acceleration of equity vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined company in accordance with Rule 144 under the Securities Act. Further, Thomas R. Cannell, D.V.M., our President and Chief Executive Officer and a current member of our board of directors, is expected to continue as a member of the combined company's board of directors following the Merger. These interests, among others, may influence our executive officers and directors to support or approve the Merger.

***Our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in our company.***

If the proposed Merger is completed, our current stockholders will own a smaller percentage of the combined company than their ownership in our company prior to the Merger. Immediately after the Merger, our pre-Merger stockholders are expected to own approximately 41.7% of the outstanding shares of capital stock of the combined company and Carisma's pre-Merger stockholders, excluding shares of Carisma common stock purchased in connection with the Carisma Pre-Closing Financing and the conversion of Carisma's \$35.0 million outstanding convertible note, are expected to own approximately 58.3% of the outstanding shares of capital stock of the combined company, subject to certain assumptions, including our net cash as of the closing of the Merger being \$125.0 million.

***During the pendency of the Merger, we may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect our business prospects.***

Covenants in the Merger Agreement impede impact our ability to make acquisitions during the pendency of the Merger, subject to specified exceptions. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors during such period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating or knowingly encouraging, inducing or facilitating any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to our stockholders, but we may be unable to pursue them.

***Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to result in a superior takeover proposal and that failure to cooperate with the proponent of the proposal is reasonably likely to be inconsistent with our board's fiduciary duties. Any such transactions could be favorable to our stockholders. In addition, if we terminate the Merger Agreement under certain circumstances, including terminating because of a decision of ours to enter into a definitive agreement with respect to a superior offer, we would be required to pay a termination fee of \$7.6 million to Carisma and/or reimburse Carisma's expenses up to a maximum of \$1.75 million. This termination fee described above may discourage third parties from submitting alternative takeover proposals to our stockholders, and may cause our board of directors to be less inclined to recommend an alternative takeover proposal.

***Because the lack of a public market for Carisma common stock makes it difficult to evaluate the value of Carisma common stock, the Carisma stockholders may receive shares of our common stock in the Merger that have a value that is less than, or greater than, the fair market value of Carisma common stock.***

The outstanding common stock of Carisma is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Carisma. Because the percentage of our common stock to be issued to Carisma's stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be received by Carisma's stockholders will be less than the fair market value of Carisma, or that the value of our common stock to be received by Carisma's stockholders may be more than the aggregate fair market value for Carisma.

***If the conditions to the Merger are not satisfied or waived, the Merger will not occur.***

Even if the transactions contemplated by the Merger Agreement are approved by our stockholders and Carisma's stockholders, certain other specified conditions set forth in the Merger Agreement must be satisfied, to the extent permitted by applicable law, or waived to complete the Merger, including approval from Nasdaq to maintain the listing of our common stock on the Nasdaq Capital Market following the Merger and the listing of the shares of our common stock being issued in the Merger and upon the conversion of the Carisma convertible note. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

***Lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.***

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us and our board of directors in connection with the transactions contemplated by the Merger Agreement. For example, on October 21, 2022, we received two separate letters and on November 4, 2022, we received one letter from purported stockholders demanding that we amend the Registration Statement filed with the SEC on October 14, 2022 to provide additional disclosures that such stockholders allege were improperly omitted from the Registration Statement, including information regarding the financial projections for Carisma, the financial analyses performed by our financial advisor in support of its fairness opinion, and the background and process leading to the execution of the Merger Agreement. We believe that these demands are without merit and intends to vigorously defend against them. The outcome of such demands or any future demands that we may receive or any

litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us and our board of directors, could delay or prevent the Merger, divert the attention of our management team and employees from our day-to-day business and otherwise adversely affect our business and financial condition.

***If the Merger is not completed, our board of directors may decide to pursue a liquidation and dissolution of our company. In such an event, there can be no assurances as to the amount or timing of available cash left, if any, to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.***

While we have entered into the Merger Agreement with Carisma, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits we expect or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay Carisma a termination fee of \$7.6 million and/or reimburse Carisma's expenses up to a maximum of \$1.75 million. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, we will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

If, for any reason, the Merger does not close, our board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of ours or resume our research and development activities and continue to operate our conduct business. Any of these alternatives would be costly and time-consuming and would require that we obtain additional funding. We expect that it would be difficult to secure financing in a timely manner, on favorable terms or at all. We can make no assurances that we would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the

Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that we seek and are able to raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic transactions alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research discovery programs or product candidates, or to grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments at March 31, 2023 (in thousands):

		Less			More
	Total	than	1 to 3	4 to 5	than
		1 Year	Years	Years	5 Years
Contractual obligations:					
Operating lease commitments <sup>(1)</sup>	\$ 4,027	\$ 2,766	\$ 664	\$ 235	\$ 362
Finance lease commitments	2,088	1,300	788	—	—
Manufacturing commitments <sup>(2)</sup>	5,000	1,000	3,000	1,000	—
Total contractual obligations	<u>\$11,115</u>	<u>\$ 5,066</u>	<u>\$ 4,452</u>	<u>\$ 1,235</u>	<u>\$ 362</u>

(1) Reflects obligations pursuant to our office and laboratory leases in Philadelphia, Pennsylvania.

(2) Reflects obligations pursuant to a manufacturing and supply agreement pursuant to which we will pay \$1.0 million per calendar year, payable in quarterly payments, for reserved capacity starting on the date on which the manufacturing site is declared ready to produce CT-0508 as determined by us.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. Our contracts with CMOs, CROs and other third parties for the manufacture of our product candidates and to support pre-clinical research studies and clinical testing are generally cancelable by us upon prior notice and do not contain any minimum purchase commitments. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation are not included in the table above as the amount and timing of such payments are not known.

The table above does not include any potential milestone or royalty payments that we may be required to make under license agreement with Penn and under licensing agreements with other third parties not considered material. We excluded these milestone and royalty payments given that the timing and likelihood of any such payments cannot be reasonably estimated at this time.

### University of Pennsylvania License

In November 2017, we entered into a license agreement with the Trustees of the University of Pennsylvania (Penn) for certain intellectual property licenses, which was amended in February 2018, January 2019, March 2020 and June 2021. We are responsible for paying Penn an annual license maintenance fee in the low tens of thousands of dollars, payable until our first payment of a royalty. We are required to

pay Penn up to \$10.9 million per product in development and regulatory milestone payments, up to \$30.0 million per product in

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commercial milestone payments, and up to an additional \$1.7 million in development and regulatory milestone payments for the first CAR-M product directed to mesothelin. While the agreement remains in effect, we are required to pay Penn low to mid-single digit percentage tiered royalties on annual net sales of licensed products, which may be subject to reductions. Penn is guaranteed a minimum royalty payment amount in the low hundreds of thousands of dollars for each year after the first commercial sale of a licensed product. We must also pay Penn a percentage in the mid-single digits to low double digits of certain types of income we receive from sublicensees. In addition, we are required to pay Penn an annual alliance management fee in the low tens of thousands of dollars, ending after several years, unless we provide funding to Penn for research and development activities that extend beyond a specified date, in which case we will continue to owe the alliance management fee for each year in which we continue to fund such activities. We also paid Penn an upfront fee in the low hundreds of thousands of dollars for the license to the patents related to the mesothelin binder that is incorporated into the CAR design for our mesothelin product candidate. We are responsible for a pro rata share of costs relating to the prosecution and maintenance of the licensed patents.

#### Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited interim consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our unaudited interim consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our unaudited interim consolidated financial statements. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing

basis. Our actual results may differ from these estimates under different assumptions or conditions.

During the three months ended March 31, 2023, there were no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" which was filed as Exhibit 99.5 to our Current Report on Form 8-K/A filed with the SEC on April 4, 2023.

#### Recent Accounting Pronouncements

See Note 3 to our unaudited interim consolidated financial statements found elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents and marketable securities. Interest income earned on these assets was \$0.4 million and \$49,500 for the three months ended March 31, 2023 and 2022, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2023 and 2022.

#### Item 4. Controls and Procedures.

##### Evaluation of disclosure controls and procedures

Our management, with the participation of our principal executive officer and our principal financial officer have evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of March 31, 2023. The term "disclosure controls and procedures," as defined in the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal

financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of

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achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### Changes in internal control over financial reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this quarterly report on Form 10-Q, we were not a party to any material legal matters or claims.

### Item 1A. Risk Factors.

*Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section of this Quarterly Report on Form 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase our securities. The risks and uncertainties we describe below and in the documents mentioned above are not the only ones we face. Additional risks and uncertainties not presently known to us could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.*

#### Summary of Risk Factors

- We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have never generated revenue from product sales and may never achieve or maintain profitability.
- We are heavily dependent on the success of our lead product candidate, CT-0508, and our follow on HER2 product candidate, CT-0525, which will both require significant clinical testing before we can seek marketing approval and potentially launch commercial sales. If CT-0508 or CT-0525 do not receive marketing approval or are not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.
- We will need substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our discovery or product development programs or commercialization efforts.
- Cell therapy is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates by utilizing genetically modified macrophages is novel and may never lead to approved or marketable products.
- Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.



- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.
- If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected and we may not be able to compete effectively in our market.
- The regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.
- The market price of our common stock may be volatile, and the market price of our common stock may drop in the future.
- We incur and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.
- Once we are no longer a “smaller reporting company” or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

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#### **Risks Related to Our Financial Position and Need for Additional Capital**

*We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability.*

Since inception, we have incurred significant operating losses. Our net losses were \$24.6 million and \$11.3 million for the three months ended March 31, 2023 and 2022, respectively. To date, we have not yet commercialized any products or generated any revenue from product sales and have financed our operations primarily with proceeds from sales of our preferred stock, proceeds from our collaboration with Moderna, research tax credits and convertible debt financing. We have devoted substantially all of our financial resources and efforts to pursuing discovery, research and development of our product candidates. We are still in the early stages of development of our lead product candidate, CT-0508, and initiated our first clinical trial in 2021.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, including costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- enhance the capabilities of our CAR-M platform;
- conduct our ongoing Phase 1 clinical trial of CT-0508;
- prepare for, initiate and conduct a planned clinical trial utilizing CT-0508 in combination with pembrolizumab;
- develop other CT-0508 combination studies;
- advance CT-0508 for additional indications or any other product candidate into clinical development;
- prepare for, initiate and conduct a planned clinical trial of CT-0525 for solid tumors that overexpress HER2;
- prepare for, initiate and conduct a planned clinical trial of CT-1119 for advanced mesothelin-positive solid tumors;
- prepare for, initiate and conduct a planned clinical trial of CT-0729 for prostate-specific membrane antigen positive castrate resistant prostate cancer;
- conduct discovery and pre-clinical testing of the development of *in vivo* CAR-M therapeutics for up to twelve oncology targets, as well as multiple other targets and indications;
- conduct discovery and pre-clinical testing of our autologous cell therapy pipeline to gather information to apply to the development of off-the-shelf engineered macrophage therapeutics;
- develop iPSC-derived iCAR-M, and other macrophage therapies;
- develop *in vivo* reprogrammed LNP/mRNA CAR-M therapies for cancer;
- develop viral vectors to effectively engineer human monocytes and macrophages, including the Vpx lentiviral vector and our Ad5f35 vector;
- conduct discovery and pre-clinical testing of our other product candidates;
- seek marketing approval for CT-0508 or any other product candidate if we successfully complete clinical trials;
- scale up our external manufacturing capabilities and capabilities to support clinical trials of CT-0508 or any other of our product candidates and for commercialization of any product candidate for which we may obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- in-license or acquire additional technologies or product candidates;

- make any payments under our existing or future strategic collaboration agreements, global exclusive rights licensing agreements or sponsored research agreements, including with Moderna, University of Pennsylvania and New York University;
- maintain, expand, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory, manufacturing, quality control, development and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our discovery, product development and planned future commercialization efforts and our operations as a public company.

**Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond our expectations if, among other things:**

- we are required by regulatory authorities in the United States, Europe or other jurisdictions to perform trials or studies in addition to, or different than, those that we currently expect;

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- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or our needs to defend against any intellectual property-related claim.

**Even if we obtain marketing approval for and are successful in commercializing one or more of our product candidates, we expect to incur substantial additional discovery and product development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.**

***We have never generated revenue from product sales and may never achieve or maintain profitability.***

**We recently initiated clinical development of our lead product candidate, CT-0508, and are in the pre-clinical testing stages for our other product candidates.**

We expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in completing development of, obtaining marketing approval for and eventually commercializing, one or more products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing clinical development of CT-0508, completing discovery, pre-clinical testing and clinical development of CT-0508 in the combination setting and for additional indications, timely filing and receiving acceptance of our Investigational New Drug applications, or INDs, in order to commence our planned or future clinical trials, including for CT-0525, CT-1119 and, CT-0729, successfully enrolling subjects in, and completing, our ongoing and planned clinical trials, scaling up our manufacturing processes and capabilities to support clinical trials of CT-0508 or of other product candidates, obtaining marketing approval for CT-0508 or any other product candidates, manufacturing, marketing and selling any products for which we may obtain marketing approval and maintaining a continued acceptable safety profile of our products following approval. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our discovery and product development efforts, diversify our pipeline of product candidates or even continue our operations.

*We are heavily dependent on the success of our lead product candidate, CT-0508, and our follow on HER2 product candidate, CT-0525, which will both require significant clinical testing before we can seek marketing approval and potentially launch commercial sales. If CT-0508 or CT-0525 do not receive marketing approval or are not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.*

We recently initiated our first clinical trial, have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures for the foreseeable future will be devoted to CT-0508 and related combination sub-studies of the synergistic potential and utility of CT-0508. Our business currently depends heavily on the successful development, marketing approval and commercialization of CT-0508 and the success of related combination sub-studies. We cannot be certain that CT-0508 or any combination therapy will achieve success in ongoing or future clinical trials, receive marketing approval or be successfully commercialized. We are also currently in the pre-clinical stage for another product candidate, CT-0525, which is also intended to treat solid tumors that overexpress HER2. By leveraging our discovery engine and

preliminary clinical data from our Phase 1 clinical trial of CT-0508, we are building upon our CAR-M platform to generate next-generation therapeutics that may increase potential efficacy and patient access.

If we were required to discontinue development of CT-0508 or CT-0525, or if CT-0508 or CT-0525, do not receive marketing approval for one or more of the indications we pursue, fail to achieve significant market acceptance, or fail to receive adequate reimbursement, we may be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

*We will need substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our discovery or product development programs or commercialization efforts.*

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our ongoing clinical trial of CT-0508 and pursue related combination strategies, prepare for, initiate and conduct our planned clinical trials of CT-0525,

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CT-1119 and CT-0729, advance our discovery programs and continue our product development efforts. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our pre-clinical activities and clinical trials. In addition, if we obtain marketing approval for CT-0508 or any other product candidate we are developing or develop in the future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our discovery and product development efforts.

- Our future capital requirements will depend on many factors, including:
- the progress, costs and results of our ongoing clinical trial of CT-0508 and other planned and future clinical trials;
- the scope, progress, costs and results of pre-clinical testing and clinical trials of CT-0508 for additional combinations, targets and indications;
- the number of and development requirements for additional indications for CT-0508 or for any other product candidates;
- the success of our collaborations with Moderna or others;
- our ability to scale up our manufacturing processes and capabilities to support clinical trials of CT-0508 and other product candidates we are developing and develop in the future;
- the costs, timing and outcome of regulatory review of CT-0508 and other product candidates we are developing and may develop in the future;
- potential changes in the regulatory environment and enforcement rules;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment of license fees and other costs of our technology license arrangements;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for CT-0508 and other product candidates we are developing and may develop in the future for which we may receive marketing approval;
- our ability to obtain and maintain acceptance of any approved products by patients, the medical community and third-party payors;
- the amount and timing of revenue, if any, received from commercial sales of CT-0508 and any other product candidates we are developing or develop in the future for which we receive marketing approval;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the availability of raw materials for use in production of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire additional technologies or product candidates.

**As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$139.0 million. We believe that we have cash, cash equivalents and marketable securities sufficient to sustain our operating expenses and capital expenditure requirements at least through the end of 2024. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect. In addition, because the successful development of CT-0508, CT-0525, CT-1119, CT-0729 and any combination studies or other product candidates that we pursue is highly uncertain, at this time we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate.**

Identifying potential product candidates and conducting pre-clinical and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and we may be impacted by the economic climate and market conditions. For

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example, market volatility resulting from the COVID-19 pandemic, any other future infectious diseases, epidemics or pandemics or general U.S. or global economic or market conditions could also adversely impact our ability to access capital as and when needed. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

*Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.*

We were formed as Carma Therapeutics LLC, a Pennsylvania limited liability company, in April 2016 and converted to a Delaware corporation in May 2017. In connection with the Merger, CARISMA Therapeutics Inc. merged with and into a wholly-owned subsidiary of Sesen Bio and was renamed "CTx Operations, Inc." Sesen Bio's name was changed to "Carisma Therapeutics Inc." Following the completion of the Merger, the business conducted by the public company became primarily the business conducted by us. We are a clinical-stage cell therapy company with a limited operating history. Cell therapy product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations prior to the Merger have been limited to organizing and staffing the company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of product candidates, conducting drug discovery activities, undertaking pre-clinical studies, manufacturing process development studies, conducting early-stage clinical trials, and providing general and administrative support for these operations. Our prospects must be considered in light of the

uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition at some point from a company with a discovery and pre-clinical and clinical focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

As we continue to build our business, we expect our financial condition and operating results to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

*The COVID-19 pandemic may affect our pre-clinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations.*

The COVID-19 pandemic has caused many governments to implement measures to slow the spread of the virus through quarantines, travel restrictions, heightened border scrutiny and other measures. The pandemic and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

We and the third-party manufacturers and clinical research organizations that we engage may face disruptions that could affect our ability to initiate and complete pre-clinical studies or clinical trials, including disruptions in procuring items that are essential for our discovery and product development activities, such as, for example, raw materials used in the manufacturing of our product candidates, laboratory supplies for our ongoing and planned pre-clinical studies and clinical trials, or animals that are used for pre-clinical testing, in each case, for which there may be shortages because of ongoing



**efforts to address the pandemic, or disruptions in our ability to obtain necessary site approvals or other delays at clinical trial sites.**

**As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, including:**

- disruptions related to our ongoing and planned clinical trials or future clinical trials arising from delays in completing pre-clinical studies required to begin clinical development;
- manufacturing disruptions;
- our inability to obtain necessary site approvals or other delays at clinical trial sites;

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- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by foreign, federal or state governments, employers and others;
- interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the United States Food and Drug Administration, or the FDA, or other regulatory authorities, which may impact review and approval timelines;
- limitations on employee resources that would otherwise be focused on the conduct of our pre-clinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- difficulties recruiting or retaining patients for our clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the virus; and
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events and refusal of the FDA, to accept data from clinical trials in these affected geographies.

**The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to pursue marketing approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.**

Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, contract research organizations and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

On January 30, 2023, the Biden Administration announced that it will end the public health emergency declarations related to COVID-19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would soon issue a Federal Register notice describing how the termination of the public health emergency will impact the FDA's COVID-19 related guidance, including the clinical trial guidance and updates thereto. On March 13, 2023, the FDA announced that it will end twenty two COVID-19-related policies when the public health emergency ends on May 11, 2023, and allow twenty two to continue for 180 days. The FDA plans to retain twenty four COVID-19-related policies with appropriate changes and four whose duration is not tied to the end of the public health emergency. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates.

The COVID-19 pandemic continues to evolve and has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will further significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business, and it has the potential to materially and adversely affect our business, financial condition, results of operations and prospects. To the extent the COVID-19 pandemic adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

*Changes in tax law may adversely affect us or our investors.*

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued,

which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our common stock.

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*Our ability to use our net operating loss carryforwards, or NOLs, and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.*

Prior to the Merger, we have a history of cumulative losses and anticipates that we will continue to incur significant losses in the foreseeable future. As a result, we do not know whether or when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards. As of December 31, 2022, Legacy Carisma had federal, state and local NOLs of \$94.2 million, \$94.2 million and \$74.3 million, respectively, and federal research and development tax credit carryforwards totaling \$5.6 million.

In general, under Section 382 of the Internal Revenue Code and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three year period, is subject to limitations on our ability to utilize our pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future (which may be outside our control). As a result, if and to the extent we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

**Risks Related to Our Discovery Programs and Research and Development of Our Product Candidates**

*Cell therapy is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates by utilizing genetically modified macrophages is novel and may never lead to approved or marketable products.*

Cell therapy has yet to be broadly applied to solid tumors, inflammatory disease, fibrotic disease or neurodegeneration. The discovery, research and development of engineered macrophages to treat disease is an emerging field and our CAR-M platform, which is the first CAR-M to be evaluated in a human clinical trial, is a relatively new technology. Our future success depends on the successful development of this novel therapeutic approach. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. We have only preliminary results from our Phase 1 clinical trial of CT-0508 and expect clinical updates in the next 18 months. As such, there may be adverse effects or limited favorable results from treatment with any of our current or future product candidates that we cannot predict at this time.

Our success also depends on our successful application of our proprietary macrophage engineering platform in the combination setting and to other indications by reprogramming the target specificity of our CAR-M cell product and developing product candidates against a plethora of tumor associated antigens, including in therapeutic areas beyond oncology. However, our macrophage engineering platform may not allow us to generate new INDs to expand our pipeline on our anticipated timeline or in a cost-efficient manner or at all, which could cause the potential value of our business to decline and materially harm our business prospects.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of macrophage engineering platform will result in the development and marketing approval of any products. Any development problems we experience in the future related to our macrophage engineering platform or any of our discovery programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our clinical trials or pre-clinical studies or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

*We are early in our development efforts. If we are unable to commercialize our product candidates or experiences significant delays in doing so, our business will be materially harmed.*

We are early in our development efforts. We initiated our first Phase 1 clinical trial of CT-0508 in 2021 and expect to evaluate a combination of CT-0508 with pembrolizumab in an ongoing Phase 1 clinical trial and expect to receive initial

data in the second half of 2023. We expect to submit INDs for CT-0525 in the second half of 2023 and for CT-1119 in 2025. CT-0729 is still in the discovery stage.

Our ability to generate revenues from product sales, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of CT-0508, including in the combination setting, or one or more of our other product candidates, which may never occur. The success of CT-0508 and our other product candidates will depend on several factors, including the following:

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- successfully completing pre-clinical studies;
- successfully initiating future clinical trials;
- successfully enrolling patients in and completing clinical trials;
- scaling up manufacturing processes and capabilities to support clinical trials of CT-0508 and any other product candidate;
- applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for CT-0508 and any other product candidates we are developing or may develop in the future;
- making arrangements with third-party manufacturers, or establishing commercial manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of CT-0508 and any other product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

**If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business. As a company, we have limited experience in clinical development, having only recently advanced CT-0508 into an early-stage clinical trial. Any**

predictions about the future success or viability of CT-0508 or any product candidates we are developing or may develop in the future may not be as accurate as they could be if we had a history of conducting clinical trials.

*Drug development involves a lengthy and expensive process, with an uncertain outcome. The results of pre-clinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of CT-0508 or our other product candidates.*

We only recently initiated our first clinical trial of CT-0508 and our other product candidates are in pre-clinical development. The risk of failure for CT-0508 and our other product candidates is high. It is impossible to predict when or if CT-0508 or any of our other product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of a product candidate, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Clinical trials may fail to demonstrate that CT-0508 or any of our other product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive pre-clinical testing and studies, manufacturing process development studies, and analytical development studies that support our planned INDs and other applications to regulatory authorities in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our pre-clinical testing and studies and cannot predict if the outcome of our pre-clinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. As a result, we may not be able to submit applications to initiate clinical development of product candidates on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued pre-clinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. We cannot

guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, among other things, flaws in

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study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or at all;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may determine that the planned design of our clinical trials is flawed or inadequate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;
- pre-clinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional pre-clinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain marketing approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our clinical investigators, regulators or IRBs to suspend or terminate the trials;
- regulators may withdraw their approval of a product or impose restrictions on its distribution; and
- business interruptions resulting from the COVID-19 pandemic may result in adverse effects on our business and operations.

**If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:**

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;

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- obtain approval for indications or patient populations that are not as broad as intended or desired;



- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in pre-clinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses or delays. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. 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. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

Similarly, the regulatory landscape related to clinical trials in the European Union recently evolved. The European Union Clinical Trials Regulation, or the EU-CTR, which was adopted in April 2014 and repeals the European Union Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate Clinical Trial Application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the EU-CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The EU-CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by

each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized European Union portal. Once the CTA is approved, clinical study development may proceed. If we are not able to adapt to these and other changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for second-line or third-line use. When cancer is detected early enough, first-line therapy, usually hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. For any of our products that prove to be sufficiently beneficial, we would expect to seek approval potentially as a first-line therapy, but any product candidates we develop, even if approved, may not be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

*The results of early-stage clinical trials and pre-clinical studies may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.*

The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our ongoing early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of our Phase 1 clinical trial of CT-0508 may not be predictive of the results of further clinical trials of CT-0508 or any of our other product candidates. Our product candidates may also fail to show the desired safety and efficacy in clinical development despite positive results in pre-clinical studies or having successfully advanced through initial clinical trials.

Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates and we cannot assure you that any clinical trials that we may conduct will demonstrate

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consistent or adequate efficacy and safety to support marketing approval. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in pre-clinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Any such setbacks in our clinical development could materially harm our business and results of operations.

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

From time to time, we may announce or publish interim or preliminary results from our clinical trials, including our Phase 1 clinical trial of CT-0508. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. 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 evaluate all data. Preliminary or interim results 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 and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

*If we experience delays or difficulties in the enrollment of patients in our clinical trials for CT-0508 or any of our other product candidates, our receipt of necessary marketing approvals could be delayed or prevented.*

Identifying and qualifying patients to participate in clinical trials for CT-0508 and any other product candidates in the future is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In particular, group 2 for our Phase 1 clinical trial of CT-0508 is currently open for enrollment with an additional nine

patients to be dosed in the study. We are preparing to advance other products into clinical development. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols;
- the availability of existing treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to identify specific patient populations based on specific genetic mutations or other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the impact of the ongoing COVID-19 pandemic.

**Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary marketing approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our business to decline and limit our ability to obtain additional financing.**

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***If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of CT-0508 or any of our other product***

*candidates, we may need to abandon or limit our further clinical development of those product candidates.*

Enrollment in group 1 of our first in human Phase 1 clinical trial of CT-0508 has been completed with nine patients successfully dosed and group 2 is currently open for enrollment with nine additional patients to be dosed in the trial. If CT-0508 or any other product candidate is associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or pre-clinical testing, we may need to abandon development of such product candidate or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or unexpected characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound. For example, while CT-0508 has been generally well tolerated based on preliminary clinical results from our Phase 1 clinical trial, such results may not be predictive or indicative of the successful development, marketing approval and eventual commercialization of CT-0508.

Additionally, if results of our clinical trials reveal undesirable side effects, we, regulatory authorities or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials, regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications or we could be forced to materially modify the design of our clinical trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenues from sales of such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

*If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.*

We only recently initiated clinical development of our lead product candidate, CT-0508, and are in the pre-clinical testing stages for our other product candidates. Clinical trials will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is

possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label;
- requirement that we implement a risk evaluation and mitigation strategy or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

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*We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*

Because we have limited financial and managerial resources, we focus on discovery programs and product candidates that we identify for specific indications. 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. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market

opportunities. Our spending on current and future discovery and product development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

*We may develop CT-0508 in combination with other drugs. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs, revoke their approval of such drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with CT-0508, we may be unable to obtain approval of CT-0508 or market CT-0508.*

In September 2022, we submitted a clinical protocol amendment to the CT-0508 IND for a CAR-M / anti-PD-1 (CT-0508 and pembrolizumab) combination strategy.

We did not develop or obtain marketing approval for, nor have we manufactured or sold, any of the currently approved drugs that we may study in combination with CT-0508. If the FDA or similar regulatory authorities outside of the United States revoke their approval of any drug or drugs in combination with which we determine to develop CT-0508, we will not be able to market CT-0508 in combination with such revoked drugs.

If safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays, and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate the applicable clinical trials. If the drugs we use are replaced as the standard of care for the indications we choose for CT-0508, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with CT-0508, we may not be able to complete clinical development of CT-0508 on our current timeline or at all.

Even if CT-0508 were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the drug used in combination with CT-0508 or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our other product candidates for use in combination with other drugs or for indications

other than cancer. This could result in our own products being removed from the market or being less successful commercially.

*We may not be successful in our efforts to identify or discover additional potential product candidates.*

A key element of our strategy is to apply our macrophage engineering platform to address a broad array of indications and targets to generate next-generation therapeutics, including three programs for indications outside of oncology. The discovery efforts that we are conducting may not be successful in identifying product candidates that are useful in treating cancer or other diseases. Our discovery engine may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

Discovery programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify additional suitable product candidates for pre-clinical and clinical development, it will limit our potential to obtain revenues from sale

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of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

*Adverse public perception of genetic medicine, and gene therapy in particular, may negatively impact regulatory approval of, or demand for, our potential products.*

The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical



trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates that we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

#### Risks Related to the Commercialization of Our Product Candidates

*Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.*

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as chemotherapy and radiation therapy, are well established in the medical community and doctors may continue to rely on these and similar treatments. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- our ability to offer our products, if approved, for sale at competitive prices;
- the clinical indications for which the product is approved;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- product labeling or product insert requirements of the FDA, the European Medical Agency, or the EMA, or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects;
- support from patient advocacy groups; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and studies. 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. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be

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inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

*If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates if and when they are approved.*

We do not have a sales or marketing infrastructure and have no experience as a company in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any product for which we may obtain marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

We currently expect that we would build our own focused, specialized sales and marketing organization to support the commercialization in the United States of product candidates for which we receive marketing approval and that

can be commercialized with such capabilities. There are risks involved with us establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In general, the cost of establishing and maintaining a sales and marketing organization may exceed the cost-effectiveness of doing so.

**Factors that may inhibit our efforts to commercialize our products on our own include:**

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials;
- our inability to effectively manage a geographically dispersed sales and marketing team;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our revenues from product sales and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

*We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, thus rendering our products non-competitive, obsolete or reducing the size of our market.*

The biopharmaceutical industry, and in particular the cell therapy field, is characterized by intense investment and competition aimed at rapidly advancing new technologies. Our platform and therapeutic product candidates are expected to face substantial competition from multiple technologies, marketed products and numerous other therapies being developed by third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition is likely to come from multiple sources, including biopharmaceutical companies, academic research institutions, governmental agencies and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and

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commercialization. The competition is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions.

We are aware of a number of companies generally pursuing the development of myeloid cell therapies, including, among others Myeloid Therapeutics, Shoreline Biosciences, Inceptor Bio, Thunder Bio, Resolution Therapeutics, CellOrigin, SIRPant Therapeutics, and others. We are also facing competition from companies pursuing autologous T-cell therapies, allogenic T-cell therapies, NK and other cell therapies, direct *in vivo* reprogrammed cell therapies and other macrophage-targeted oncology therapeutics.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. 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 development programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Technology in the biopharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development.

Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We have pursued and may in the future pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. However, we may be unable to in-license or acquire any additional technologies or product candidates from third parties. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.

*Even if we are able to pursue commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.*

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively

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impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as alternatives, as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products, including our product candidates. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and

elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers its costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs 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 drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance

that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

There can be no assurance that our product candidates, even if they are approved for sale in the United States, in the European Union or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

*Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.*

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves

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against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- withdrawal of marketing approval, recall, restriction on the approval or a "black box" warning or contraindication for an approved drug;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;



- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- reduced resources of our management to pursue our business strategy;
- distraction of management's attention from our primary business; and
- the inability to commercialize any products that we may develop.

We currently hold \$10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if it commences commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

#### Risks Related to Our Dependence on Third Parties

*We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.*

We rely, and expect to continue to rely, on third-party clinical research organizations, in addition to other third parties such as research collaboratives, clinical data management organizations, medical institutions and clinical investigators, to conduct our ongoing Phase 1 clinical trial of CT-0508 and related combinations studies, our planned clinical trials of CT-0525, CT-1119 and CT-0729 and any other clinical trials we conduct. We do not plan to independently conduct clinical trials of our product candidates or any other product candidates that we may develop. These contract research organizations and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. These third-party arrangements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities might be delayed.

Our reliance on these third parties for discovery and product development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that

each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities in Europe and other jurisdictions have similar requirements. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our contract research organizations or trial sites fail to comply with applicable GCPs, 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 are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing

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approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional contract research organizations, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. The COVID-19 pandemic and government measures taken in response have also had a significant impact on many contract research organizations. Although we plan to carefully manage our relationships with our contract research organizations, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

*We rely on third-party contract manufacturing organizations for the manufacture of both drug substance and finished drug product of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.*

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third-party contract manufacturing organizations for both drug substance and finished drug product, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also currently rely on these third parties for the manufacture of plasmid and viral vectors, patient leukapheresis material logistics, as well as packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the potential failure to manufacture our product candidate or product according to our specifications;
- the potential failure to manufacture our product candidate or product according to our schedule or at all;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. Our or our third-party manufacturers failure to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If any of our current contract manufacturers cannot perform

as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. In addition, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our product candidates. The extent of this impact will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

*We expect to depend on collaborations with third parties for the research, development and commercialization of certain of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.*

We anticipate seeking third-party collaborators for the research, development and commercialization of certain of our product candidates. For example, we entered into a strategic collaboration with Moderna in January 2022 focused on the development of *in vivo* CAR-M therapeutics for up to twelve product candidates. In collaboration with Moderna, we have established a myeloid tropic LNP/mRNA *in vivo* CAR-M platform for oncology targets, which enables an off-the-shelf approach wherein the patient's own myeloid cells are engineered directly within their body via the administration of a myeloid-tropic LNP encapsulating macrophage reprogramming mRNA CAR constructs, removing the requirement for *ex vivo* cell manufacturing entirely. We expect to nominate additional targets under the Moderna collaboration in 2023. As part of the collaboration, we received a \$45.0 million up-front cash payment from Moderna, in addition to future research funding, milestone payments and royalties. Concurrent with entering into the collaboration agreement, Moderna made an investment in our company in the form of a \$35.0 million convertible promissory note.

Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies and biotechnology companies.

Any such arrangements with third parties will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform

the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our discovery programs or any product candidates we may develop, including our collaboration with Moderna, pose the following risks to us:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations; for example, our collaboration with Moderna is managed by a joint steering committee, which is comprised of representatives from the company and Moderna, with Moderna having final decision-making authority, subject to specified limitations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;
- collaborators may not pursue development and commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

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- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis; for example, data, results and know-how generated in the performance of the Moderna collaboration is deemed the confidential information of Moderna, which we may not disclose except under limited circumstances;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; for example, Moderna has the first right to prosecute, enforce or defend certain patent rights under its agreement with us, and although we may have the right to assume the prosecution, enforcement or defense of such patent rights if Moderna does not, our ability to do so may be compromised by Moderna's actions;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; for example, Moderna has the right to terminate its agreement with us for convenience in its entirety or with respect to a specific product or target on ninetydays' prior notice, in connection with a material breach of the agreement by us that remains uncured for a specified period of time or in the event of specified insolvency events involving us; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future of our collaborators were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

**If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators**

terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. All of the risks relating to product development, marketing approval and commercialization described herein also apply to the activities of our collaborators.

We may in the future decide to collaborate with biopharmaceutical companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment

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of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

*We may seek to establish additional collaborations. If we are not able to establish or maintain additional collaborations, on commercially reasonable terms, we may have to alter our development and commercialization plans and our business could be adversely affected.*

To realize the full potential of our macrophage engineering platform and accelerate the development of additional macrophage engineering programs, we plan to continue to selectively pursue collaborations with leading biopharmaceutical companies with particular experience, including development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These



established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration we may enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate revenue from product sales, which could have an adverse effect on our business, prospects, financial condition and results of operations.

*We have a number of academic collaborations to supplement our internal discovery and product development program. If any such collaborator decides to discontinue*

*or devote less resources to such research, our discovery programs could be diminished.*

Our discovery engine is supplemented by academic collaborations to expand our platform, which we rely upon to advance our development and commercialization plans for our product candidates. In August 2020, we entered into a scientific research and licensing agreement with Nathaniel R. Landau, Ph.D. and NYU Langone Health through which we obtained exclusive rights to develop their Vpx lentiviral vector globally for all indications. We also have an ongoing discovery program in neurodegeneration being pursued through a sponsored research agreement with Dr. Saar Gill, Associate Professor of Medicine at the University of Pennsylvania and co-founder of our company, to develop CAR macrophages and microglia targeted against protein aggregates associated with neurodegenerative disease pathology. In addition, we, from time to time, may enter into academic research collaborations to explore the development of new technologies and indications.

While these academic institutions have contractual obligations to us, they are independent entities and are not under our control or the control of our officers or directors. Our research and licensing agreements with academic collaborators generally provide academic collaborators with license maintenance fees, development and regulatory milestone payments, royalties on net sales of products and a portion of sublicense income that we receive. Upon the scheduled expiration of any academic collaboration, we may not be able to renew the related agreement, or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or the academic institution generally may terminate the sponsored research agreement for convenience following

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a specified notice period. If any of these academic institutions decides to not renew or to terminate the related agreement or decides to devote fewer resources to such activities, our discovery efforts would be diminished, while our royalty obligations, if any, would continue unmodified.

*Any acquisitions or in-license transactions that we complete could disrupt our business, cause dilution to our stockholders or reduce our financial resources.*

We have licensed three patent families from the University of Pennsylvania and one patent family from New York University and may enter into transactions to in-license or acquire other businesses, intellectual property, technologies, product candidates or products. If we determine to pursue a particular transaction, we may not be able to complete the Merger transaction on favorable terms, or at all. Any in-licenses or acquisitions we complete may result not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in negative publicity and/ connection with an in-license or a negative impression of us in the investment community, could significantly harm the market price of acquisition or issue our common stock or other equity securities to the stockholders of the target company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. In-license and acquisition transactions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of additional future in-licenses or acquisitions or the effect that any such transactions might have on our operating results.

*The FDA, European Medicines Agency, or EMA, or other comparable foreign regulatory authorities could require the clearance or approval of a companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our product development strategy and we may not realize the commercial potential of any such product candidate.*

If safe and effective use of any of our other product candidates depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of obtaining or creating such diagnostic is time consuming and costly. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA, EMA and other comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review

during which the sponsor must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.

Given our limited experience in developing and commercializing diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these companion diagnostics. We may not be able to enter into arrangements with a provider to develop a companion diagnostic for use in connection with a registrational trial for our product candidates or for commercialization of our product candidates, or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics by physicians.

Any companion diagnostic collaborator or third party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with employees such collaborator or third party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative diagnostic test for use in connection with the development and

commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

#### Risks Related to Our Intellectual Property

*If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected and we may not be able to compete effectively in our market.*

Our commercial success depends in part on our ability to obtain, maintain and enforce protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other **partners** countries with respect to any proprietary technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our **business community**.

and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain, maintain or enforce patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the **Merger** patent applications we own, co-own or license may fail to result in issued patents in the United States or in other foreign countries.

The patent prosecution process is expensive, time-consuming and complex, and we may not **completed**, be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our **board of directors may decide that** research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our **stockholders** business.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to

dissolve the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our company licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and liquidate patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our assets. In licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that event, either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, our owned or in-licensed pending and future patent applications may not result in patents being issued which protects our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our owned or licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of cash available time required for distribution the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

*Patent terms may be inadequate to protect our competitive position with respect to our stockholders would depend heavily on current or future product candidates for an adequate amount of time.*

Patents have a limited lifespan. In the timing United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there is no assurance that any such decision extensions will be obtained, and ultimately, such liquidation since the life of a patent, and the protection it affords, is limited. Even if patents covering our current or future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of cash available time required for distribution continues the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to decrease exclude others from commercializing products similar or identical to us.



In the United States, patent term can also be adjusted due to delays that occur during examination of patent applications, which may extend the term of a patent beyond 20 years. There is a risk that we may take action that detracts from any accrued patent term adjustment.

It is necessary to pay certain maintenance fees, also referred to as annuities or renewal fees in some countries, throughout the lifetime of a patent at regular intervals. Failure to pay these fees can cause a granted patent to prematurely expire, without an opportunity for revival. There is a risk that we fund may be unable to maintain patent protection for certain patents in all markets due to finite availability of resources.

*If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our operations and incurs fees and expenses related obligations under such agreements, our business could be harmed.*

It may be necessary for us to use the Merger. In addition, if patented or proprietary technology of third parties to commercialize our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidate(s), which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, we may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties



under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement.

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Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in us having to negotiate new or restated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

*If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.*

In the United States, the term of a patent that covers an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Delaware General Corporation Law Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as compensation for the loss of a patent term during the FDA regulatory review process for a drug product subject to pay the provisions of the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years, but patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our outstanding obligations, product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. There is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions could be for a shorter period than we anticipate. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due

diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to make reasonable provision obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

*Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.*

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the maintenance, enforcement or defense of our owned or in-licensed issued patents.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and wakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

The federal government retains certain rights in inventions created using its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for contingent its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the

government may grant the license itself. We collaborate with a number of universities with respect to certain of our research and unknown obligations, prior development. We cannot be sure that any co-developed intellectual property will be free from government rights pursuant to making any distributions the Bayh-Dole Act. If, in liquidation the future, we co-own or in-license technology which is critical to our stockholders. As a result business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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*Although we or our licensors are not currently involved in any litigation, we may become involved in lawsuits to protect or enforce our patent, the patents of our assets licensors or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.*

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensor's issued patents, the patents of our licensors or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's product. To counter infringement or misappropriation, we or our licensors may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation file infringement, misappropriation or other intellectual property related claims, related to a liquidation which can be expensive and dissolution of time-consuming and can distract our company. If a liquidation management and dissolution were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, our stockholders could lose all or a significant portion of their investment in the event of a liquidation and dissolution of our company.

***Our stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.***

The right of our stockholders to receive any future payment on or derive any value from the CVRs will be contingent solely upon the occurrence of a certain triggering event. In particular, CVR holders will be entitled to a pro rata portion of the \$30.0 million milestone payment to be made by Roche to us upon Roche's initiation of a Phase 3 clinical trial with legacy IL-6 antagonist antibody technology previously owned by us for a certain indication if initiated prior to December 31, 2026, pursuant to the

Roche Asset Purchase Agreement, less certain permitted deductions. We may not receive any future payment pursuant to the Roche Asset Purchase Agreement after the closing of the Merger. If this milestone is not achieved for any reason within the time period specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be retained or deducted by us, no payments will be made under the CVRs, and the CVRs will expire valueless.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company.

*The US federal income tax treatment of the CVRs is unclear and there is no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us, alleging that we infringe, misappropriate or otherwise violate their intellectual property.*

*In addition, in a patent infringement proceeding, such parties could counterclaim that the Internal Revenue Service would not patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness, enablement, or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Similarly, if we or our licensors assert trademark infringement claims, a court may determine that the marks we or our licensors have asserted are invalid or unenforceable, or that the party against whom we or our licensors have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.*

*An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent, and could limit our or our licensor's ability to assert those patents against those parties, or other competitors, and curtail or preclude our ability to exclude third parties from developing and commercializing similar or competitive products. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed*

**patents do not cover such technology. Even if we establish infringement, a court would may not sustain, a position that could result in adverse US federal income tax consequences order the third party to holders stop using the technology at issue and instead award only monetary damages to us, which may not be an adequate remedy. Furthermore, because of the CVRs.**

The US federal income tax treatment substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. There could also be public announcements of the CVRs is unclear. There is no legal authority directly addressing results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the US federal income tax treatment price of our common stock. Any of the receipt foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and payments on, prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the CVRs, and there can USPTO may be no assurance that necessary to determine the Internal Revenue Service (the "IRS"), would not assert, or that a court would not sustain, a position that could result in adverse US federal income tax consequences to holders priority of the CVRs.

We intend to treat the issuance of the CVRs as a distribution of property inventions with respect to our stock. However, there patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is no authority directly addressing whether contingent value rights with characteristics similar offered and our competitors gain access to the CVRs should be treated as a distribution same technology. Our defense of property with respect to the corporation's stock, a distribution of equity, a "debt instrument" litigation or an "open transaction" for US federal income tax purposes. Although we will estimate the value of the CVRs for purposes of reporting on Form 1099 to our stockholders, the value of the CVRs is uncertain interference or derivation proceedings may fail and, the IRS or a court could determine that the value of the CVRs at the time of issuance was higher. In such case, our stockholders could be treated as having additional income or gain upon receipt of the CVRs. Further, notwithstanding our position that the receipt of CVRs, the receipt of any cash distributed pursuant to a special cash dividend and the proposed reverse stock split are appropriately treated as separate transactions, it is possible that the IRS or a court could determine that our stockholders' receipt of the CVRs, the receipt of any cash distributed pursuant to a special cash dividend and the proposed reverse stock split constitute a single "recapitalization" for US federal income tax purposes. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to our position, which could even if successful, may result in adverse US federal income tax consequences to holders of the CVRs.

**We have never paid substantial costs and distract our management, technical personnel and other than in connection employees. In addition, the uncertainties associated with the Merger with Carisma, do not intend to pay any cash dividends in the foreseeable future.**

We litigation could have never paid cash dividends on any of our capital stock. Pursuant to the terms of the Merger Agreement, we may, in addition to the CVRs, declare and pay a special cash dividend to our stockholders of record prior to the Merger consisting of cash in an amount not to exceed \$25.0 million, subject to us having net cash as of the closing of the Merger greater than or equal to \$100.0 million. The amount of such special cash dividend is currently uncertain, pending the determination of our outstanding obligations and net cash position as of the closing of the Merger. Other than such potential special cash dividend in connection with the closing of the Merger, we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future.

***We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.***

As of September 20, 2022, we had 17 full-time employees. Our ability to successfully complete the Merger depends in large part material adverse effect on our ability to retain certain remaining personnel. Despite raise the funds necessary to continue our efforts clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to retain these employees, market.

Any such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources

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in one or more may terminate their employment with us on short notice. The loss aspects, or for other reasons. Uncertainties resulting from the initiation and continuation of the services of certain employees patent litigation or other proceedings could potentially harm compromise our ability to consummate compete in the Merger, marketplace.

***We may need to run license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

**A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.**

## Risks Related to Ownership of Our Common Stock

If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock products. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from the Nasdaq Capital Market such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than us, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the biopharmaceutical industry. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as opposition proceedings before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings



may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents our products or product candidates may infringe. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing our proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringe upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

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Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense



and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, we could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right, we could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

*If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.*

While we seek to protect the trademarks and trade names we use in the United States and in other countries, we may be unsuccessful in obtaining registrations or otherwise protecting these trademarks and trade names, which we need to build name recognition in our markets of interest and among potential partners or customers. We rely on both registration and common law protection for our trademarks. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. At times, competitors may adopt trademarks and trade names similar to ours, or our collaborators may fail to use our trade names or trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of

other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. If we are unable to protect our rights to trademarks and trade names, we may be prevented from using such marks and names unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, more difficult or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for you confusion with other product names. If the FDA objects to sell your shares any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

We may license our trademarks and trade names to third parties, such as distributors and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of or failure to use our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

***Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

**Our common stock is listed** Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the **Nasdaq Capital Market, USPTO** and foreign patent agencies in several stages or annually over the lifetime of our patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we **are therefore subject** rely on our licensing partners to **Nasdaq's continued listing requirements, including requirements** pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market **value** with similar or identical products or technology. If we or our licensors fail

to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of publicly-held shares, market value of listed shares, minimum bid price per share, operations and minimum stockholders' equity, among others, and requirements relating to board and committee independence. prospects.

***If we fail to comply with our obligations in our current and future intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.***

We are party to a number license and research agreements. Some of these agreements provide us with the intellectual property rights required for the development of our product candidates, including the license agreement with the University of Pennsylvania. These licenses and research agreements and similar agreements in the future may impose diligence, development and commercialization timelines, and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with such obligations, the parties to these agreements may decide to terminate the agreements or require us to grant them certain rights, in which we may not be able to develop, manufacture, or market any products without the rights granted to us by these agreements and may face other penalties. Any such occurrences could adversely affect the value of any product candidate being developed, including CT-0508.

For a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose similar obligations on us. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or restated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to such agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

In addition to the above risks, intellectual property rights that our licenses in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our

licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

- Disputes may arise regarding intellectual property subject to a licensing agreement, including:
- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the payment obligations with respect to licensed technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. 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, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Further, licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on our licensors to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even when we do have such rights, we may require the cooperation of our licensors and upstream licensors, which may not be forthcoming. Licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Our business could be adversely affected if we or our licensors are unable to prosecute, maintain and enforce our licensed and sublicensed intellectual property effectively.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the

sole and exclusive owners of the patents and patent applications of our in-licenses. If other third parties have ownership rights to patents or patent applications of our in-licenses, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

*We may not be able to protect our intellectual property and proprietary rights throughout the world.*

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. 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 products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, 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 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

*We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.*

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our



agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

*We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, including of their current or former employers or claims asserting we have misappropriated their intellectual property, or is claiming ownership of what we regard as our own intellectual property.*

Many of our employees, consultants and contractors have been previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.



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*If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.*

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We may have also entered into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. To the extent we become involved in litigation that may require discovery of our trade secrets, know-how and other proprietary technology, we will seek to secure protective orders from the court that bind the parties with access to the discovered information. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. In addition, we cannot be certain that proprietary technical information and related confidential documents that we have shared with our collaborators and/or submitted to governmental agencies, including regulatory agencies for evaluation and supervision of pharmaceutical products, will be kept confidential. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

*Intellectual property rights do not necessarily address all potential threats to us.*

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not

**adequately protect our business or permit us to maintain our competitive advantage. For example:**

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or license;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- claims of issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research, development, testing or commercialization activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- the U.S. Supreme Court, other federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

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- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### Risks Related to Regulatory Approval and Other Legal Compliance Matters

*The regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.*

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future will ever obtain marketing approval.

Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for our proposed indication;
- results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, to the FDA or other submission or to obtain marketing approval in the United States;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain marketing approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA has substantial discretion in the approval process and determining when or whether marketing approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Finally, our ability to develop and market new products may be threatened by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a Risk Evaluation and Mitigation Strategy, or REMS. In reaching that decision, the district court made a number of findings that numerous representatives of the pharmaceutical and biotechnology industry believe will chill the development, approval and distribution of new drug and biologic products in the United States. Among other determinations, the district court substituted its scientific judgement for that of the FDA and it held that FDA must provide a special justification for any differences between an approved drug's labeling and the conditions that existed in the drug's clinical trials. Further, the district court read the jurisdictional requirements governing litigation in federal court so as to potentially allow virtually any party to bring a lawsuit against the FDA in connection with its decision to approve an NDA or biologics license application, or BLA, or establish requirements under a REMS. On

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April 13, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the US Supreme Court entered a stay pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit or the Supreme Court. Depending on the outcome of this litigation and the regulatory uncertainty it has engendered, our abilities to develop new product candidates, maintain approval of existing products and measures adopted under a REMS, if any, are at risk and could be delayed, undermined or subject to protracted litigation.

*Even if we complete the necessary pre-clinical 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 some or all 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.*

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, export and import are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by the EMA and other regulatory authorities outside of the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. 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 us from obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities 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 pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical 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 our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

*Failure to obtain marketing approval in foreign jurisdictions would prevent 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 our products in the European Union and many other foreign jurisdictions, we and 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 marketing approval process outside the United States generally includes all of the 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 approved for sale in that country. We or these third parties 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. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue.

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Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and European

Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has been incorporated into the domestic law of the body of European Union law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union. The MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure until December 31, 2023. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

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.

*Inadequate funding for the FDA, the Securities and Exchange Commission, or the SEC, and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.*

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other 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.

For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The same is true of the COVID-19 pandemic or any similar event that may occur in the future. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. The FDA has now indicated that it can and will conduct timely reviews of applications for medical in line with its user fee performance goals, including conducting domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, in the event of a resurgence of the COVID-19 pandemic or a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended., Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may also experience delays in their regulatory activities.

Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

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***Regulatory requirements governing gene therapy products are periodically updated and may continue to change in the future.***



The FDA has established the Office of Tissues and Advanced Therapies, or the OTAT, within the Center for Biologics Evaluation and Research, or the CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. In September 2022, the FDA announced retitling of the OTAT to the Office of Therapeutic Products, or the OTP, and elevation of the OTP to a “Super Office” to meet its growing cell and gene therapy workload and new commitments under the Prescription Drug User Fee Act agreement for fiscal years 2023-2027. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, also are potentially subject to review by the Office of Biotechnology Activities’ Recombinant DNA Advisory Committee, or the RDAC; however, the NIH announced that the RDAC will only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks. Although the FDA decides whether individual gene therapy protocols may proceed, the RDAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an IND on a clinical hold even if the RDAC has provided a favorable review or an exemption from in-depth, public review. If we were to engage an NIH-funded institution to conduct a clinical trial, that institution’s Institutional Biosafety Committee, or IBC, as well as our IRB would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of our product candidates.

The FDA has issued various guidance documents regarding gene therapies, including final guidance documents released in January 2020 relating to chemistry, manufacturing and controls information for gene therapy INDs, gene therapies for rare diseases and gene therapies for retinal disorders. Although the FDA has indicated that these and other guidance documents it previously issued are not legally binding, we believe that our compliance with them is likely necessary to gain approval for any gene therapy product candidate that we may develop. The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper pre-clinical assessment of gene therapies; the chemistry, manufacturing, and control information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. Further, the FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years

of annual examinations followed by 10 years of annual queries, either in person or by questionnaire.

Further, for a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with good tissue practices, or GTP. These standards are found in FDA regulations and guidance that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Finally, ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations or prohibiting the processes that we may use. Federal and state agencies, congressional committees and foreign governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that our product candidates are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

As we advance our product candidates through clinical development, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue.

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

Once marketing approval has been granted, an approved product and our manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any of our collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any of our collaborators will not be able to promote any products developed for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third-party manufacturers, any of our collaborators and their third-party manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any of our collaborators, receive marketing approval for one or more of the their product candidates, we, and any of our collaborators, and our and any of our collaborators' respective third-party manufacturers will continue 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 their products withdrawn by regulatory authorities and we or such collaborators' ability to market any future products could be limited, which could adversely affect our ability to 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.

*We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United*

*States, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.*

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious 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. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be **delisted** available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA, including the Fast Track designation we received for CT-0508. In addition, even if one or more of our product

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**candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.**

***We, or our collaborators, may seek approval from the Nasdaq Capital Market.***

On January 24, 2022, FDA or comparable foreign regulatory authorities to use accelerated development pathways for our product candidates. If we, received notice (the "Notice") or our collaborators, are not able to use such pathways, we, or they, 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, or they, receive them at all. In addition, even if an accelerated approval pathway is available to us, or our collaborators, it may not lead to expedited approval of our product candidates, or approval at all.

Under the Federal Food, Drug, and Cosmetic Act 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, or our collaborators, will continue to seek feedback from the Nasdaq Stock Market LLC ("Nasdaq") that FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

With passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical

trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months (until the study is completed); and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, the FDORA requires the FDA to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval. More recently, in March 2023, FDA issued draft guidance outlining its current thinking on accelerated approval for oncology products. While such guidance has not been finalized and, even when final, will not be legally binding, we were not currently in will likely need to assure compliance with the \$1.00 minimum bid price requirement for continued listing on terms of this guidance.

There can be no assurance that the Nasdaq Global Market, as set forth FDA or foreign regulatory agencies will agree with our, or our collaborators', surrogate endpoints or intermediate clinical endpoints in Nasdaq Listing Rule 5450(a)(1). The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until July 25, 2022, to regain compliance with the minimum bid price requirement by having the closing bid price any of our, common stock meet or exceed \$1.00 per share their, clinical trials, or that we, or our collaborators, will decide to pursue or submit any additional application for at least ten consecutive business days. On July 26, 2022, we received accelerated approval to transfer the listing or any other form of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market. As a result, we were granted a second 180-day grace period, expedited development, review or until January 23, 2023, to regain compliance with the minimum bid price requirement.

If we do not regain compliance by January 23, 2023, we will receive notification from Nasdaq that our common stock is subject to delisting. At that time, we may then appeal the delisting determination to a Nasdaq hearings panel. Such notification will have no immediate effect on our listing on the Nasdaq Capital Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. However, approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we, or our collaborators, will be able continue to regain compliance with Nasdaq's minimum bid price requirement. If we regain compliance with Nasdaq's minimum bid price requirement, 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 we such submission or application will be able to maintain compliance with the continued listing requirements accepted for the Nasdaq Capital Market filing or that our common stock any expedited development, review or approval will not be delisted from the Nasdaq Capital Market in the future. In addition, we may be unable granted on a timely basis, or at all.

A failure to meet obtain accelerated approval or any other applicable listing requirements form of the Nasdaq Capital Market, including maintaining minimum levels of stockholders' equity expedited development, review or market values of our

common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

Delisting from the Nasdaq Capital Market would adversely affect our ability to consummate the Merger and may adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our common stock, or negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

If we are delisted from Nasdaq and we are not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the “pink sheets.” As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations approval for our common stock;
- product candidates, or withdrawal of a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly product candidate, would result in a reduced level longer time period until commercialization of trading activity such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the secondary trading market for our securities;

#### marketplace.

- a limited amount of news and little or no analyst coverage for us;
- we would no longer qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and
- a decreased ability to issue additional securities (including pursuant to short-form Registration Statements on Form S-3) or obtain additional financing in the future.

### Risks Related to our Business and Operations

***Our restructuring plans and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.***

On August 30, 2021, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following receipt of the CRL from the FDA regarding our BLA for Vicineum for the treatment of BCG-unresponsive NMIBC (the “2021 Restructuring Plan”). On July 15, 2022, we approved a restructuring plan to reduce operating expenses and better align our workforce with the needs of our business following our decision to voluntarily pause further development of Vicineum in the US (the “2022 Restructuring Plan”). Execution of the 2021 Restructuring Plan was substantially completed by the end of 2021. Execution of the 2022 Restructuring Plan is expected to be substantially completed in connection with the closing of the proposed Merger with Carisma, which is expected to occur approximately two to three months from the date of this form 10-Q filing, November 7, 2022. The 2022 Restructuring Plan includes an incremental reduction in our workforce as well as additional cost-saving initiatives intended to preserve capital during the pendency of the proposed Merger with Carisma and while we seek a potential partner for the further development of Vicineum.



We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. For example, we may incur unanticipated charges not currently contemplated as a result of the restructuring plans. If we are unable to realize the expected operational cost savings from the restructuring, our operating results and financial condition would be adversely affected.

*We may not be able to enter into obtain orphan drug exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.*

*Under the Orphan Drug Act, the FDA may designate a transaction 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 approval of orphan products by the EMA 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 EMA 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. The exclusivity period in the European Union can be reduced to*

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*six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.*

*In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a suitable acquiror patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or licensee disease for Vicineum 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 and comparable foreign regulatory authorities such as the EMA can subsequently approve the same product for the same condition if the FDA or such other authorities conclude 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 or EMA*



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 2017, the Congress passed the FDA Reauthorization Act of 2017, or the FDARA. The FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under omnibus legislation signed by former President Trump in December 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by the FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any transaction entered into changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

*If we are unable to successfully develop companion diagnostics for our product candidates and secure clearance or approval of such devices by the FDA and other regulatory authorities, or we experience significant delays in doing so, we may not realize the full commercial potential of our therapeutics.*

We believe that our success will depend, in part, on our ability to develop companion diagnostics, which are assays or tests to identify an appropriate patient population for these product candidates. We have little experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to

commercialization. Given our limited experience in developing diagnostics, we rely and expect to continue to rely in part or in whole on third parties for their design and manufacture. We also may in the future depend on other third parties for the development of other companion diagnostics for our therapeutic product candidates. If we or our collaborators are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so:

- the development of our therapeutic product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our therapeutic product candidates may not receive marketing approval if safe and effective use of a therapeutic product candidate depends on an *in vitro* diagnostic; and
- we may not realize the full commercial potential of any therapeutics that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

As a result of any of these events, our business would be harmed materially.

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*Any product candidate for which we, or any of our collaborators, obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we, or any of our collaborators, may be subject to substantial penalties if we, or any of our collaborators, fail to comply with regulatory requirements or if we, or any of our collaborators, experience unanticipated problems with our products when and if any of them are approved.*

Any product candidate for which we, or any of our collaborators, obtain marketing approval, as well as 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, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, 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, including

the requirement to implement a risk evaluation and mitigation strategy. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA and other regulatory agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, DOJ and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown side effects or other problems with our products or our manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- receipt of warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements,

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requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

*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 civil, criminal and administrative sanctions, contractual damages, reputational harm and diminished future profits and earnings.*

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any drugs for which we obtain marketing approval. Our future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable state and federal 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 any drugs for which we obtain marketing approval. These include the following:

- *Anti-Kickback Statute*, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, ordering, leasing, arranging for, or recommending the purchasing, ordering, or leasing of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid;

- *False Claims Act*- the federal civil and criminal false claims laws, including the civil False Claims Act, and Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, false or fraudulent claims for payment or knowingly making, using or causing to made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;
- *HIPAA*- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and apply regardless of the payor (e.g., public or private);
- *HIPAA and HITECH*- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose obligations on HIPAA covered entities and their business associates, including mandatory contractual terms and required implementation of administrative, physical and technical safeguards to maintain the privacy and security of individually identifiable health information;
- *Transparency Requirements*- the federal physician transparency requirements known as the Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires manufacturers of drugs, medical devices, biological and medical supplies covered by Medicare, Medicaid, or State Children's Health Insurance Program to report annually to the Centers for Medicare& Medicaid Services, or CMS, within the United States Department of Health and Human Services, or 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, Local and Foreign Laws*- analogous state, local and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader than similar federal laws, can apply to claims involving healthcare items or services regardless of payor, and are enforced by many different federal and state agencies as well as through private actions.

**Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare 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 pre-empted by HIPAA, thus complicating compliance efforts.**

**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

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subject to significant civil, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is 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.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States.

*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.*

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. 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 collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is

subject to the E.U. General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or the EEA, in May 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 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 or 20.0 million Euros, 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.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws are also being considered at both the state and federal levels. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though CCPA does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects or the Common Rule.

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, other states, including Virginia, Colorado, Utah, and Connecticut, already have passed state privacy laws. Virginia's privacy law also went into effect on January 1, 2023, and the laws in the other three states will go into effect later in the year. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. 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.

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Given the breadth and depth of changes in data protection obligations, preparing for and complying with such 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. 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, which may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could 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 business.

*Current and future legislation may increase the difficulty and cost for us and any of our collaborators to obtain marketing approval of and commercialize product*



*candidates and affect the prices we, or any of our collaborators, may obtain.*

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, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability, or the ability of any of our collaborators, to profitably sell or commercialize any product candidates for which we, or any of our collaborators, obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. 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, or any of our collaborators, may receive for any FDA approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for prescription drugs purchased through a pharmacy by the elderly and disabled and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this statute provides authority for limiting the number of drugs that will be covered in any therapeutic class, subject to certain exceptions. Cost reduction initiatives and other provisions of this statute could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, then-President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes 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 2031 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. 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. Under current legislation, the actual reductions in Medicare payments may vary up to 4%.

Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, or the Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Appropriation Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Further, with passage of the Inflation Reduction Act, or the IRA, in August 2022, Congress extended the expansion of the Patient Protection and Affordable Care Act premium tax credits through 2025. Those subsidies were originally extended through 2022 under the American Rescue Plan Act of 2021. These laws may result in additional reductions in Medicare and other healthcare funding and

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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.

Since enactment of the ACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts for Jobs Act, or the TCJA, in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the

remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden rescinded those orders and issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the health insurance marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This executive order also directs the HHS to create a special enrollment period for the health insurance marketplace in response to the COVID-19 pandemic.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

*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 drug products, if and when approved.*

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent 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 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the 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. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary

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point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with passage of the IRA has been delayed by Congress to January 1, 2032.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at 2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the

catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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, 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.

In other countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

*We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.*

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA, the Bribery Act, and other anticorruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, United Kingdom, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which is collectively referred to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by the United States, the United Kingdom or other authorities could also have an adverse impact on our reputation, business, results of operations and financial condition.

*We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, 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 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, including comprehensive regulatory systems in the United States, the European Union and the United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in an enforcement action against us, including fines, imprisonment of company officials and public censure, 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 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



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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 General Data Protection Regulation, or 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 will significantly expand 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. Most CPRA provisions took effect on January 1, 2023, though the obligations apply to any personal information collected after January 1, 2022. These provisions may apply to some of our business activities. In addition, other states, including Virginia and Colorado, already have passed state privacy laws. Other states will be considering these laws in the future. 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.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our

or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20.0 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU invalidated the European Union-United States Privacy Shield, or Privacy Shield, 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. While we are not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States, generally, and increase 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.

Following the withdrawal of the United Kingdom from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. As with other issues related to Brexit, there are open questions about how personal data will be protected in the United Kingdom and whether personal information can transfer from the European Union to the United Kingdom. Following the withdrawal of the United Kingdom from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the GDPR, has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. The U.K. government has already determined that it considers all European Union and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union/EEA remain unaffected. In addition, a recent decision from the EC appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the European Union to the United Kingdom, although this decision may be re-evaluated in the future.

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

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activities, including both our clinical trials and any eventual 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 United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such 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. 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 business, financial condition, results of operations or prospects.

*If our employees, independent contractors, consultants, collaborators and vendors engage in misconduct or other improper activities, including non-compliance with regulatory standards and/or requirements and insider trading, we could sustain significant liability and harm to our reputation.*

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, collaborators and vendors. Misconduct by these partners could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of foreign jurisdictions, including the GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee or third-party misconduct, and the precautions that we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. 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 and results of operations, including the imposition of significant fines or other sanctions.

*If we or any third-party manufacturer we engage now or in the future fails to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could significantly harm our business.*

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Although we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our 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 for failure to comply with such laws and regulations.

We maintain general liability insurance as well as workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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**Risks Related to Employee Matters and Managing Growth**

*Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.*

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our discovery programs, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable

terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Failure to succeed in clinical trials may make it even more challenging to recruit and retain qualified scientific personnel. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

*We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, clinical, regulatory affairs, manufacturing and quality control and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Future growth will impose significant added responsibilities on members of our management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for CT-0508 and other product candidates we are developing or may develop in the future, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize CT-0508 and any other product candidate we are developing or may develop in the future will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational

mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Many of the biopharmaceutical companies, and in particular cell therapy companies, that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and operate our business will be limited.

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*Our internal computer systems, or those of our collaborators, vendors, suppliers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.*

Our internal computer systems and those of any of our collaborators, vendors, suppliers, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or email fraud to cause payments or information to be transmitted to an unintended recipient.

If we experience any material system failure, accident, cyber-attack or security that causes interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether



due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. 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, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

*Our employees, independent contractors, including principal investigators, consultants and vendors and any third parties we may engage in connection with discovery programs, research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.*

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, including principal investigators, consultants and vendors and any other third parties we engage. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state data privacy, security, fraud and other healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report complete financial information or data accurately or disclose unauthorized activities to us. Misconduct by employees and other third parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter misconduct by employees and other third parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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**Risks Related to the Ownership of Our Common Stock**

*The market price of our common stock may be volatile, and the market price of our common stock may drop in the future.*

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and pre-clinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of qualified scientific and management personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the biopharmaceutical sector;
- sales of securities by us or our stockholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;

- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

*We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.*

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of the company prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

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*Once we are no longer a “smaller reporting company” or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.*

We will be subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as a “smaller reporting company,” as defined in Item 10(f)(1) of Regulation S-K, we may take advantage of certain exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer qualified as a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, then we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

*Our executive officers, directors and principal stockholders may have the ability to control or significantly influence all matters submitted to our stockholders for approval.*

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 53.95% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of the company on terms that are favorable other stockholders may desire.

***We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.***

***We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to us.***

apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You do not have the opportunity to influence our decisions on how to use our cash resources.

***We may be responsible for unwinding contractual relationships related to a strategic transaction with respect to Vicineum, which may adversely impact our business, financial condition and results of operations.***

On July 15, 2022, we Sesen Bio made the strategic decision to voluntarily pause further development of Vicineum in the United States. As a result of such decision, the primary paths available U.S. and we do not expect to derive value from the Vicineum asset are to find a suitable acquiror or licensee for the asset. Supporting diligence activities conducted by potential acquirors or licensees and negotiating the financial and other terms of an agreement or license are typically long and complex processes, and the results of such processes cannot be predicted. There can be no assurance that we will enter into any transaction as a result of this effort or that any transaction entered into will be on terms that are favorable to us. Furthermore, if we enter into and complete a transaction relating to Vicineum, we cannot predict the impact that such transaction might have on our stock price. We also cannot predict the impact on our stock price if we fail to enter into and complete a transaction relating to Vicineum.

***In connection with our strategic decision to voluntarily pause pursue further development of Vicineum in for the United States, we may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization treatment of Vicineum, which may be time consuming, costly and could divert our efforts and attention from consummating the proposed Merger with Carisma and harm our efforts to seek a partner to continue development of Vicineum.***

We have non-muscle invasive bladder cancer. Sesen Bio previously entered into various agreements and licenses with licensees, licensors and other counterparties related to the development and/or commercialization of Vicineum. These agreements Prior to the consummation of the Merger of the company and licenses impose a variety of obligations on us and the counterparties to such agreements and licenses. On July 15, 2022, we made the strategic decision to voluntarily pause further development of Vicineum in the United States. As a result of such decision and our subsequent decision to enter into the proposed Merger with Carisma, we have begun Sesen Bio, Sesen Bio began the process of winding-down our winding down its operations relating to Vicineum. In connection with a strategic transaction with respect to Vicineum, and are seeking a partner we may be responsible for the further development of Vicineum. Disagreements and disputes between us and certain counterparties have arisen unwinding contractual relationships related to such wind-down efforts and additional disagreements or disputes may arise in the future between us and our

counterparties regarding each parties' obligations under the respective agreement or license relating to Vicineum.

Any such disagreement or dispute could become time consuming, costly and Vicineum, which could divert the attention of our efforts management teams and attention employees from consummating the Merger with Carisma and harm our efforts to seek a partner to continue development of Vicineum. Any disagreements or disputes with such parties that lead to litigation, arbitration or similar proceedings will day-to-day business, result in us incurring significant legal expenses, as well as potential significant legal liability.

Further, any disagreements or disputes over our obligations or intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms. If we fail to meet our obligations under these agreements or licenses in a material respect, the respective counterparty may have the right to terminate the respective agreement or license and to re-obtain the related technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement or license was in force that relates to the applicable technology. While we would expect to exercise our rights and remedies available to us in the event we fail to meet our obligations under such agreement or license in any material respect liability, impose additional costs and otherwise seek to preserve adversely affect our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under any agreement or license relating to Vicineum could result in our loss of rights business and may lead to a complete termination of the respective agreement or license. Termination of one of these agreements or licenses for any reason could prevent us from completing a transaction to sell or license Vicineum.

#### **financial condition.**

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

We

#### ***Recent Sales of Unregistered Securities***

During the period covered by this Quarterly Report on Form 10-Q, we did not issue any unregistered equity securities other than pursuant to transactions previously disclosed in our Current Reports on Form 8-K.

#### ***Purchase of Equity Securities***

We did not purchase any of our registered equity securities during the nine months ended September 30, 2022. period covered by this Quarterly Report on Form 10-Q.

### **Item 3. Defaults Upon Senior Securities.**

80

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

---

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**Item 6. Exhibits.****Exhibit Index**

**Exhibit**  
**No.**

**Number****Description**

**2.1**

[Agreement and Plan of Merger, dated as of September 20, 2022, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc. and CARISMA Therapeutics Inc. \(incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K \(File No. 001-36296\) filed on September 21, 2022\).](#)

**2.2**

[First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 20, 2022 December 29, 2022, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc., and CARISMA Therapeutics Inc. \(incorporated by reference to Exhibit 2.1 to our the registrant's Current Report on Form 8-K filed on September 21, 2022 \(File No. 001-36296\), filed on December 29, 2022\).](#)

2.3<sup>3.1</sup>Ü

Second Amendment to Agreement and Plan of Merger and Reorganization, dated as of February 13, 2023, by and among Sesen Bio, Inc., Seahawk Merger Sub, Inc., and CARISMA Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on February 14, 2023).

3.1

Restated Certificate of Incorporation of Eleven Biotherapeutics, Carisma Therapeutics Inc. Incorporated, dated March 7, 2023 (incorporated by reference to Exhibit 3.1 to our the registrant's Current Report on Form 8-K filed on February 18, 2014 (File No. 001-36296), filed on March 8, 2023).

3.2

3.3

Certificate of  
Amendment  
of Certificate  
of  
Incorporation.  
Incorporated  
by reference  
to Exhibit 3.3  
to our  
Quarterly  
Report on  
Form 10-Q  
filed on May  
10, 2021 (File  
No. 001-  
36296).

3.4

Amended and  
Restated By-Laws.  
Incorporated By-Laws  
of Carisma  
Therapeutics Inc.,  
dated March 7, 2023  
(incorporated by  
reference to Exhibit 3.2  
to our the registrant's  
Current Report on  
Form 8-K filed on May  
17, 2018 (File No. 001-  
36296), filed on March  
8, 2023).



4.1  
10.1†

Specimen Stock Certificate  
evidencing the shares of  
common stock.  
Incorporated Collaboration  
and License Agreement, dated  
January 7, 2022, by and  
between Carisma and  
ModernaTX, Inc. (incorporated  
by reference to Exhibit  
4.1 10.32 to our the Registrant's  
Registration Statement on  
Form S-1/S-4/A (File No. 333-  
267891), filed on January 23,  
2014 (File No. 333-  
193131), January 18, 2023).

4.2  
10.2†

Form License Agreement,  
dated as of Warrant issued to  
Silicon Valley Bank November  
10, 2017, by and Life Science  
Loans, LLC dated November  
25, 2014.  
Incorporated between Carisma  
and the Trustees of the  
University of Pennsylvania, as  
amended (incorporated by  
reference to Exhibit 10.23 10.33  
to our the Registrant's  
Registration Statement on  
Form S-1 S-4 (File No. 333-  
267891), filed on December 19,  
2014 (File No. 333-  
201176), October 14, 2022).

4.3  
10.3†

Form License Agreement,  
dated as of Common Warrant.  
Incorporated July 24, 2020, by  
and between Carisma and New  
York University (incorporated  
by reference to Exhibit  
4.1 10.34 to our the Registrant's  
Registration Statement on  
Form S-4 (File No. 333-267891),  
filed on October 14, 2022).

10.4	Registration Rights Agreement, dated March 7, 2023 (incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on November 3, 2017 (File No. 001-36296), March 8, 2023).
4.4	<b>Form of Warrant.</b>
10.5	<b>Incorporated</b> Contingent Value Rights Agreement, dated March 7, 2023 (incorporated by reference to Exhibit 4.1 10.5 to our the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 23, 2018 (File No. 001-36296), March 8, 2023).
4.5	Form of 2017 Warrant Amendment Agreement.
10.6	<b>Incorporated</b> Indemnification Agreement for Directors and Officers of Carisma Therapeutics Inc. (incorporated by reference to Exhibit 4.2 10.6 to our the registrant's Current Report on Form 8-K filed on October 29, 2019 (File No. 001-36296), filed on March 8, 2023).
4.6	<b>Form of 2018 Warrant Amendment Agreement.</b>
10.7#	<b>Incorporated</b> Employment Agreement, dated March 7, 2023, by and between Carisma Therapeutics Inc. and Steven Kelly (incorporated by reference to Exhibit 4.4 10.7 to our the registrant's Current Report on Form 8-K filed on October 29, 2019 (File No. 001-36296), filed on March 8, 2023).

<b>10.8#</b>	<a href="#"><u>Employment Agreement, dated March 7, 2023, by and between Carisma Therapeutics Inc. and Richard Morris (incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).</u></a>
<b>10.9#</b>	<a href="#"><u>Employment Agreement, dated March 7, 2023, by and between Carisma Therapeutics Inc. and Michael Klichinsky (incorporated by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).</u></a>
<b>10.10#</b>	<a href="#"><u>CARISMA Therapeutics Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).</u></a>
<b>10.11#</b>	<a href="#"><u>Form of Nonstatutory Stock Option Agreement under the CARISMA Therapeutics Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).</u></a>
<b>10.12#</b>	<a href="#"><u>Form of Incentive Stock Option Agreement under the CARISMA Therapeutics Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.12 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).</u></a>

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10.13#

[Carisma Therapeutics Inc. Amended and Restated 2014 Stock Incentive Plan](#) (incorporated by reference to Exhibit 10.13 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).

10.1†

10.14#

[Asset](#) [Form of Stock Option Agreement under the Carisma Therapeutics Inc. 2014 Amended and Restated Stock Incentive Plan](#) (incorporated by reference to Exhibit 10.14 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).

10.15#

[Form of Restricted Stock Unit Agreement under the Carisma Therapeutics Inc. 2014 Amended and Restated Stock Incentive Plan](#) (incorporated by reference to Exhibit 10.15 to the registrant's Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).

10.16#

[Carisma Therapeutics Inc.](#)  
[2014 Employee Stock](#)  
[Purchase Plan](#)  
[\(incorporated by reference](#)  
[to Exhibit 10.16 to the](#)  
[registrant's Current Report](#)  
[on Form 8-K \(File No. 001-](#)  
[36296\) filed on March 8,](#)  
[2023\).](#)

10.17<sup>U</sup>

[Voting and Support](#)  
[Agreement, dated as of July](#)  
[15, 2022](#) [February 13, 2023,](#)  
[by and among the Radoff](#)  
[Family Foundation,](#)  
[Bradley L. Radoff, JEC II](#)  
[Associates, LLC, the K.](#)  
[Peter Heiland 2008](#)  
[Irrevocable Trust, Michael](#)  
[Torok, CARISMA](#)  
[Therapeutics Inc. and](#)  
[Sesen Bio, Inc., F.](#)  
[Hoffmann-La Roche Ltd](#)  
[and Hoffmann-La Roche](#)  
[Inc. Incorporated](#)  
[\(incorporated by reference](#)  
[to Exhibit 10.1 to our](#)  
[registrant's Current Report](#)  
[on Form 8-K filed on July](#)  
[18, 2022 \(File No. 001-](#)  
[36296\), filed on February](#)  
[14, 2023\).](#)

10.2

10.18\*

[Form of Contingent](#)  
[Value Rights Agreement.](#)  
[Incorporated](#) [Lease, dated](#)  
[April 22, 2019, by reference](#)  
[to Exhibit 10.1 to our](#)  
[Current Report on Form 8-](#)  
[K filed on September 21,](#)  
[2022 \(File No. 001-](#)  
[36296\), and between](#)  
[Wexford-SCEC 3675 Market](#)  
[Street, LLC and CARISMA](#)  
[Therapeutics Inc.](#)

10.3

31.1\*

10.4

[Form of  
Sesen Bio  
Support  
Agreement.  
Incorporated  
by reference  
to Exhibit  
10.3 to our  
Current  
Report on  
Form 8-K  
filed on  
September  
21, 2022 \(File  
No. 001-  
36296\).](#)

10.5

[Form of Lock-Up Agreement.  
Incorporated by reference to  
Exhibit 10.4 to our Current  
Report on Form 8-K filed on  
September 21, 2022 \(File No.  
001-36296\).](#)

31.1\*

Certification of the  
Chief Principal Executive  
Officer Pursuant to Rules 13a-  
14(a) and 15d-14(a) under the  
Securities Exchange Act of  
1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-  
Oxley Act of 2002 2002

31.2\*

Certification of the  
Chief Principal Financial  
Officer Pursuant to Rules  
13a-14(a) and 15d-  
14(a) under the Securities  
Exchange Act of 1934, as  
Adopted Pursuant to  
Section 302 of the  
Sarbanes-Oxley Act of  
2002 2002

32.1\*\*

32.1+

Certification Certifications  
of the Chief Principal  
Executive Officer Pursuant  
to 18 U.S.C. Section 1350,  
as Adopted Pursuant to  
Section 906 of the  
Sarbanes-Oxley Act of  
2002 2002

32.2\*\*

32.2+

Certification Certifications  
of the Chief Principal  
Financial Officer Pursuant  
to 18 U.S.C. Section 1350,  
as Adopted Pursuant to  
Section 906 of the  
Sarbanes-Oxley Act of  
2002 2002

101*	XBRL Instance
101.INS*	Document – the Quarterly Period ended September 30, 2022 filed in XBRL). The financial information contained in the XBRL-related documents is "unaudited" and "unreviewed." The instance document does not appear in the interactive file Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. document
104*	Inline XBRL Taxonomy
101.SCH*	Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and with applicable taxonomy extension information contained in Exhibit Exhibits 101).
<hr/>	
*	Filed herewith.



- + **Furnished herewith.**
- # **Indicates a management contract or any compensatory plan, contract or arrangement.**
- †

*	Filed herewith.
**	This certification is being furnished solely to accompany Portions of this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as

amended,  
whether  
made before  
or after the  
date hereof,  
regardless of  
any general  
incorporation  
language in  
such filing.

†

In  
accordance  
with Item  
601(b)(10)(iv)  
of Regulation  
S-K, certain  
provisions of  
the Asset  
Purchase  
Agreement  
have been  
redacted. We  
will provide  
an  
unredacted  
copy of the  
exhibit on a  
supplemental  
basis to the  
SEC or its  
staff upon  
request.

+

Exhibits  
and/or  
schedules  
have been  
omitted  
pursuant to  
Item 601(a)  
(5) 601(b)(10)  
(iv) of  
Regulation S-  
K. The  
Company  
hereby  
undertakes

ü Certain schedules and exhibits have been omitted pursuant to furnish supplementally copies Item 601 of Regulation S-K. A copy of any of omitted schedule and/or exhibit will be furnished to the omitted exhibits and schedules SEC upon request by the SEC; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act, for any exhibits or schedules so furnished, request.

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**SIGNATURES**

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**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.

**SESEN BIO,  
CARISMA  
THERAPEUTICS  
INC.**

**Date:**

**May**

**11,**

**2023 By:**

**/s/**

**Steven**

**Kelly**

**/s/**

**Thomas**

**R.**

**Cannell,**

**D.V.M.**

**Steven**

**By: Kelly**

\_\_\_\_\_  
Thomas

R.

Cannell,

Name: D.V.M.

Title:

President, and Chief  
Executive Officer  
(Principal Executive  
Officer and Duly  
Authorized Director

(Principal  
Executive  
Officer)

Date:

May

11,

2023 By:

/s/ Richard

Morris

Richard

Morris

Chief

Financial

Officer

(Principal

Financial

and

Accounting

Officer)

## LEASE

by and between

WEXFORD-SCEC 3675 MARKET STREET, LLC,  
a Delaware limited liability company,  
Landlord

and

CARISMA THERAPEUTICS INC.,  
a Delaware corporation,  
Tenant

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## ii

### LEASE

THIS LEASE (this "Lease") is entered into as of this 22 day of April, 2019 (the "Effective Date"), by and between WEXFORD-SCEC 3675 MARKET STREET, LLC, a Delaware limited liability company ("Landlord"), and CARISMA THERAPEUTICS INC., a Delaware corporation ("Tenant").

### RECITALS

A. WHEREAS, Landlord owns or leases certain real property described on Exhibit A-1 attached hereto (the "Land") and the improvements now or hereafter to be constructed on the Land including the building located or to be located at 3675 Market Street, Philadelphia, Pennsylvania (the "Building") and the appurtenances related thereto (collectively, the "Property").

B. WHEREAS, Landlord wishes to lease to Tenant, and Tenant desires to lease from Landlord, certain premises (the "Premises") known as Suite 401 located on the fourth (4<sup>th</sup>) floor of the Building, pursuant to the terms and conditions of this Lease, as detailed below.

### AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby

acknowledged, and intending to be legally bound, agree as follows:

1. **Lease of Premises.**

1.1. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Premises, as shown on Exhibit A-2 attached hereto, for use by Tenant in accordance with the Permitted Use and no other uses.

All portions of the Building that are for the non-exclusive use of the tenants of the Building, such as service corridors, stairways, elevators, public restrooms and public lobbies, are hereinafter referred to as "Common Area."

2. **Definitions and Basic Lease Provisions.** Definitions of capitalized terms appear throughout the Lease. A table referencing the location of the definitions appears as Schedule 1. For convenience of the parties, certain basic provisions of this Lease are set forth herein. The provisions set forth herein are subject to the remaining terms and conditions of this Lease and are to be interpreted in light of such remaining terms and conditions. A Property Specific Rider and Special Provision Rider, which may alter the provisions of this Lease, are attached hereto and made a part hereof. In the event of a conflict between the provisions of the Property Specific Rider or Special Provisions Rider and any provision of this Lease, the terms of the Property Specific Rider or Special Provisions Rider shall prevail.

2.1. This Lease shall take effect upon the Effective Date and, except as specifically otherwise provided within this Lease, each of the provisions hereof shall be binding upon and inure to the benefit of Landlord and Tenant from the date of execution and delivery hereof by all parties hereto.



2.2. In the definitions below, each current Rentable Area is expressed in square feet. Rentable Area and “Tenant’s Pro Rata Share” are subject to adjustment as provided in this Lease.

<u>Definition or Provision</u>	<u>Means the Following (As of the Effective Date)</u>
Rentable Area of Premises	4,369 square feet
Rentable Area of Building	344,052 square feet
Tenant’s Pro Rata Share of Building	1.27%

2.3. Initial monthly and initial annual installments of Base Rent for the Premises (“Base Rent”) as of the Rent Commencement Date, subject to adjustment under this Lease:

<u>Dates</u>	<u>Square Feet of Rentable Area</u>	<u>Initial Base Rent per Square Foot of Rentable Area</u>	<u>Initial Monthly Base Rent</u>	<u>Initial Annual Base Rent</u>	
Rent Commencement Date - day immediately preceding the first (1st) anniversary of the Rent Commencement Date	4,369	\$43.00 annually	\$15,655.58	\$187,867.00	

Base Rent shall be subject to an annual upward adjustment of three percent (3%) of the then-current Base Rent. The first such adjustment shall become effective commencing on the first (1st) annual

anniversary of the Rent Commencement Date, and subsequent adjustments shall become effective on every successive annual anniversary of the Rent Commencement Date for so long as this Lease continues in effect.

2.4. **Length of Term:** One hundred and twenty (120) months from the Rent Commencement Date plus, if the Rent Commencement Date is not the first day of the month, the partial month containing the Rent Commencement Date.

2.5. **Estimated Term Commencement Date:** Nine (9) months from the Effective Date. The Term Commencement Date is set forth in Section 4.2.

2.6. **Rent Commencement Date:** The Rent Commencement Date shall be the Term Commencement Date.

## 2

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2.7. **Security Deposit:** \$62,622.32.

2.8. **TI Allowance:** not to exceed Five Hundred Twenty Four Thousand Two Hundred Eighty Dollars (\$524,280) based upon One Hundred and Twenty Dollars (\$120) per square foot of Rentable Area of the Premises and subject to revision to reflect the actual Rentable Area of the Premises as of the Term Commencement Date.

2.9. **Intentionally Omitted.**

2.10. **Intentionally Omitted.**

2.11. **Permitted Use:** Solely for Office use in conformity with all federal, state, municipal and local zoning and other laws, codes, ordinances, rules and regulations of Governmental Authorities, the CC&Rs, committees, associations, or other regulatory

committees, agencies or governing bodies having jurisdiction over the Premises, the Building, the Property, Landlord or Tenant, including both statutory and common law and hazardous waste rules and regulations ("Applicable Laws").

2.12. **Guarantor: None.**

2.13. **Landlord's Project Management Fee for management, supervision and/or review of the Tenant Improvements: 3% of the Total Construction Costs, including the TI Allowance.**

2.14. **Address for Rent Payment: SCEC 3675 Market Street JV LLC**

**Attn: Entity 6779  
P.O. Box 511467  
Los Angeles, CA 90051-8002**

2.15. **Address for Notices to**

**Landlord: WEXFORD-SCEC 3675 MARKET STREET, LLC  
c/o Ventas, Inc.  
353 North Clark Street, Suite 3300  
Chicago, Illinois 60654  
Attn: Asset Management (Life Sciences)  
Phone: (312) 660-3800  
Email: dliu@lillibridge.com;  
james.mendelson@lillibridge.com**

**With a copy to: WEXFORD-SCEC 3675 MARKET STREET, LLC  
c/o Wexford Asset Management, LLC  
801 West Baltimore Street, Suite 505  
Baltimore, Maryland 21201  
Attn: Senior Vice President, Asset Management  
E-mail:  
mark.korczakowski@wexfordscitech.com**

**and**

Attn: General  
Counsel  
Email:  
danielle.howarth@wexfordscitech.com

And with a copy to: WEXFORD-SCEC 3675  
MARKET STREET, LLC  
c/o Ventas, Inc.  
353 North Clark Street,  
Suite 3300  
Chicago, Illinois 60654  
Attn: Legal Department  
Phone: (312) 660-3800  
Email:  
bberman@ventasreit.com;

2.16. Address for Invoices to Tenant: CARISMA  
THERAPEUTICS  
INC.  
3675 Market  
Street  
Philadelphia,  
PA 19104  
Attention:  
Chief Financial  
Officer

2.17. Landlord's Broker: Cushman and Wakefield  
of Pennsylvania, LLC

2.18. Tenant's Broker: Paul Garvey, Cushman and  
Wakefield of Pennsylvania, LLC

2.19. The following Schedules, Riders and Exhibits  
are attached hereto and incorporated herein by  
reference:

Schedule 1 Index of Defined Terms  
Property Specific Rider  
Special Provisions Rider

Exhibit A-1The Land  
Exhibit A-2Drawing Depicting the Premises  
Exhibit BWork Letter  
Exhibit B-1Tenant Work Insurance Schedule  
Exhibit B-2Construction Rules  
Exhibit CAcknowledgement of Term  
Commencement Date, Rent Commencement  
Date and Term Expiration Date  
Exhibit DIntentionally Omitted  
Exhibit EList of Additional Insureds and  
Indemnitees  
Exhibit FRules and Regulations  
Exhibit GForm of Estoppel Certificate  
Exhibit HTenant's Required Insurance  
Coverages  
Exhibit IOperating Expenses Defined  
Exhibit JJanitorial Schedule

3. **Term.**

3.1. The actual term of this Lease (as the same may be earlier terminated in accordance with this Lease, the "**Term**") shall commence on the actual Term Commencement Date, continue for the time period specified in Section 2.4, and expire at the end of such time period (such date, the "**Term Expiration Date**"), subject to extension or earlier termination of this Lease as provided herein.

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3.2. "**Lease Year**" as used herein shall mean (a) each and every consecutive twelve (12) month period during the Term of this Lease, or (b) in the event of Lease expiration or termination, the period between the last complete Lease Year and said expiration or termination. The first such twelve (12) month period shall commence on the Rent Commencement Date. If the Rent Commencement Date is any day other than the first day

of the month, then the first Lease Year shall include the partial month in which the Rent Commencement Date occurs and the next consecutive twelve (12) months.

**4. Possession and Term Commencement Date.**

**4.1. Landlord shall use commercially reasonable efforts to tender possession of the Premises to Tenant on the Estimated Term Commencement Date, with the work (the “Tenant Improvements”) required of Landlord described in the Work Letter attached hereto as Exhibit B (the “Work Letter”) Substantially Complete. Landlord and Tenant agree that in the event the Term Commencement Date has not occurred by the Estimated Term Commencement Date for any reason, then (a) this Lease shall not be void or voidable, (b) Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, (c) the Term Expiration Date shall be extended accordingly, (d) Tenant shall not be responsible for the payment of any Base Rent or Tenant’s Share of Operating Expenses until the actual Term Commencement Date occurs, and (e) if the Term Commencement Date has not occurred by the date that is sixty (60) days following the Estimated Term Commencement Date, then for each day thereafter until the actual Term Commencement Date occurs, Tenant shall receive a rent credit applicable against the first Base Rent due equal to one (1) days’ Base Rent. The terms “Substantially Completed” or “Substantial Completion” shall be deemed to have occurred for all purposes under the Lease when Landlord obtains a temporary or permanent certificate of occupancy for the Premises or other local equivalent provided by local government agencies or a certificate of substantial completion issued by Landlord’s architect. Notwithstanding anything in this Lease (including the Work Letter) to the contrary, Landlord’s obligation to timely achieve Substantial Completion shall be subject to extension on a day-for-day basis as a result of Force Majeure and Tenant Delay.**

**4.2. The “Term Commencement Date” shall be the day the Tenant Improvements are Substantially Complete and the Premises are made available to Tenant**

broom-clean and free of all occupants. If possession is delayed by a Tenant Delay, then the Term Commencement Date shall be the date that the Term Commencement Date would have occurred but for such Tenant Delay. Upon request by Landlord and delivery to Tenant of an unexecuted, but completed, copy of the form attached hereto as Exhibit C, Tenant shall execute and deliver to Landlord written acknowledgment of the actual Term Commencement Date, the Rent Commencement Date and the Term Expiration Date within ten (10) days of such request. Failure to execute and deliver such acknowledgment, however, shall not affect the Term Commencement Date, the Rent Commencement Date, the Term Expiration Date or Landlord's or Tenant's liability hereunder. Failure by Tenant to obtain validation by the Food and Drug Administration, any medical review board, health department, liquor control board or other similar governmental licensing of the Premises required for the Permitted Use by Tenant shall not serve to extend the Term Commencement Date.

4.3. In the event that Landlord permits (in Landlord's sole and absolute discretion) Tenant to enter upon the Premises prior to the Term Commencement Date for the purpose of the

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placement of personal property, Tenant shall furnish to Landlord in advance evidence satisfactory to Landlord that insurance coverages required of Tenant under the provisions of Article 22 are in effect, and such entry shall be subject to all the terms and conditions of this Lease other than the payment of Base Rent and Tenant's Share of Operating Expenses; and provided, further, that if the Term Commencement Date is delayed due to such early access, then the Term Commencement Date shall be the date that the Term Commencement Date would have

occurred but for such delay. Tenant shall not perform any construction or installation of improvements, relocate any employees to the Premises or commence any business operations from the Premises during any period of early access. Tenant's early access under the terms of this Section 4.3 shall be subject to and coordinated with Landlord's construction of the Tenant Improvements and shall only be permitted to the extent that such access does not interfere with Landlord's construction of the Tenant Improvements. Landlord shall coordinate with Tenant for the installation of furniture and data cabling prior to the Term Commencement Date. Tenant shall be responsible for any damage caused by Tenant, its agents, employees or contractors to the Building, the Premises, the Tenant Improvements or the property of any contractors engaged by Landlord. Any personal property brought into the Premises and any improvements made by Tenant, its agents, employees or contractors during any period of early access shall be at the sole risk of Tenant, and Tenant acknowledges that the Premises may be an active construction site during the course of construction of the Tenant Improvements and that such property may be damaged or destroyed.

4.4. Landlord shall cause the Tenant Improvements to be constructed in the Premises pursuant to the Work Letter, subject to the Tenant's obligation to timely fund any Excess TI Costs as required by this Lease. Landlord's obligation to fund the cost of the Tenant Improvements shall not exceed the TI Allowance. The TI Allowance may be applied to the costs of (m) construction, (n) Landlord's Project Management Fee, (o) commissioning of mechanical, electrical and plumbing systems by a licensed, qualified commissioning agent hired by Landlord, (p) space planning, architect, engineering and other related services performed by third parties unaffiliated with Tenant, (q) building permits, connection charges, impact fees and other taxes, fees, charges and levies by Governmental Authorities for permits or for inspections of the Tenant Improvements, (r) costs of builders risk and other insurance and bonds, and (s) costs and



expenses for labor and material (collectively, the “Tenant Improvement Costs”). In no event shall the TI Allowance be used for (v) payments to Tenant or any affiliates of Tenant, (w) payment of moving expenses, (x) the purchase of any furniture, information technology equipment and/or audio-visual equipment, personal property or other non-building system equipment, (y) costs resulting from any default by Tenant of its obligations under this Lease or (z) costs that are recoverable by Tenant from a third party (e.g., insurers, warrantors, or tortfeasors).

4.5. Tenant shall have until that date which is one hundred eighty (180) days after the Term Commencement Date (the “TI Deadline”), to expend the unused portion of the TI Allowance, after which date Landlord’s obligation to fund such costs shall expire.

4.6. To the extent that the total projected Tenant Improvements Costs (as reasonably projected by Landlord, based upon contractor bids) exceeds the TI Allowance (such excess, the “Excess TI Costs”), Tenant shall advance to Landlord any Excess TI Costs within ten (10) days after receipt of an invoice therefor, but in any case before Landlord commences construction of the Tenant Improvements. Landlord shall use diligent efforts to run a fair bid process that will result in competitive pricing for the hard costs related to the construction Tenant Improvements

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and Landlord shall review such bid packages with Tenant. If the cost of the Tenant Improvements (as projected by Landlord) increases over Landlord’s initial projection, then Landlord may notify Tenant and Tenant shall deposit any additional Excess TI Costs with Landlord in the same way that Tenant deposited the initial Excess TI Costs. If the actual Excess TI Costs are less than the Excess TI Costs paid by Tenant to Landlord,

Landlord shall credit Tenant with the overage paid by Tenant against Tenant's Rent obligations, beginning after Landlord has completed the final accounting for the Tenant Improvements. If Landlord is delayed in commencing the Tenant Improvements due to Tenant's failure to timely pay all or any portion of the Excess TI Costs to Landlord, Landlord shall not be required to proceed with the Tenant Improvements until payment is made, and such delay by Tenant shall constitute a Tenant Delay. In the event that the TI Allowance exceeds the total cost of the Tenant Improvements, Tenant shall have the option to apply a portion of such excess TI Allowance, up to seven percent (7%) of the total TI Allowance, to the documented costs of furniture, movable equipment and moving expenses for the Premises. In no event shall any unused TI Allowance entitle Tenant to a credit against Rent payable under this Lease.

5. **Condition of Premises.** Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Premises, the Building or the Property, or with respect to the suitability of the Premises, the Building or the Property for the conduct of Tenant's business. Tenant acknowledges that (a) it is fully familiar with the condition of the Premises and agrees to take the same in its condition "as is" as of the Term Commencement Date, and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Premises for Tenant's occupancy or to pay for or construct any improvements to the Premises, except with respect to any obligations of Landlord specifically set forth in Article IV and the Work Letter and payment of the TI Allowance. Tenant's taking of possession of the Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the Premises, the Building and the Property were at such time in good, sanitary and satisfactory condition and repair.

6. **Rentable Area.**

6.1. The term "**Rentable Area**" shall mean the rentable square footage as calculated using the BOMA

2010 Office Standard (ANSI/BOMA Z65.1-2010 Method A (legacy method)), as calculated by Landlord's architect, and as reduced to exclude any below grade space not used for normal office or laboratory use, all as the same may be reasonably adjusted from time to time by Landlord in consultation with Landlord's architect to reflect changes to the Premises, the Building or the Property, as applicable.

6.2. Review of allocations of Rentable Areas as between tenants of the Building shall be made as frequently as Landlord deems appropriate, including in order to facilitate an equitable apportionment of Operating Expenses. If such review is by a licensed architect and allocations are certified by such licensed architect as being correct, then Tenant shall be bound by such certifications, but the Base Rent shall not be increased as a result of any remeasurement.

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### 7. Rent.

7.1. Tenant shall pay to Landlord as Base Rent for the Premises, commencing on the Rent Commencement Date, the sums set forth in Section 2.3, subject to the rental adjustments and increases provided therein and, if applicable, the rental increases provided in Article IV. Base Rent shall be paid in equal monthly installments as set forth in Section 2.3, subject to the rental adjustments and increases provided therein, each in advance on the first day of each and every calendar month during the Term.

7.2. In addition to Base Rent, Tenant shall pay to Landlord as additional rent ("Additional Rent") at times hereinafter specified in this Lease (a) from and after the Rent Commencement Date, Tenant's Share of Operating Expenses, and (b) any other amounts that Tenant assumes or agrees to pay under the provisions of this

Lease that are owed to Landlord, including indemnification payments, Excess TI Costs, and any and all other sums that may become due by reason of any default of Tenant or failure on Tenant's part to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after notice and the lapse of any applicable cure periods.

7.3. Base Rent and Additional Rent shall together be denominated "Rent." Rent shall be paid to Landlord, without abatement, deduction or offset, in lawful money of the United States of America to the address set forth in Section 2.14 or to such other person or at such other place as Landlord may from time designate in writing. In the event the Rent Commencement Date occurs on a day other than the first day of a calendar month or the Term ends on a day other than the last day of a calendar month, then the Rent for such fraction of a month shall be prorated for such period on the basis of the number of days in the month and shall be paid at the then-current rate for such fractional month. Additional Rent shall be paid by Tenant within the time periods set forth in this Lease, or, if no time period is established, then within thirty (30) days after written demand from Landlord.

7.4. Tenant's obligation to pay Rent shall not be discharged or otherwise affected by (a) any Applicable Laws now or hereafter applicable to the Premises, (b) any other restriction on Tenant's use, (c) except as expressly provided herein, any casualty or taking or (d) any other occurrence; and Tenant waives all rights now or hereafter existing to terminate or cancel this Lease or quit or surrender the Premises or any part thereof, or to assert any defense in the nature of constructive eviction to any action seeking to recover rent. Tenant's obligation to pay Rent with respect to any period or obligations arising, existing or pertaining to the period prior to the date of the expiration or earlier termination of the Term or this Lease shall survive any such expiration or earlier termination; provided, however, that nothing in this sentence shall in any way affect Tenant's obligations with respect to any other period.

8. **Operating Expenses.**

8.1. (a) Operating Expenses are defined in Exhibit I attached hereto.

(b) Notwithstanding anything herein to the contrary, if Landlord is not furnishing any particular work or service (the cost of which if performed by Landlord would constitute an Operating Expense) to any tenant or tenants who have undertaken to perform such

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work or service in lieu of the performance thereof by Landlord, then Tenant's Pro Rata Share of such item of Operating Expenses shall be determined by dividing (i) the Rentable Area of the Premises, by (ii) the Rentable Area of the Building reduced by the Rentable Area of those tenants for whom Landlord does not provide such work or service.

8.2. From and after the Rent Commencement Date, Tenant shall pay to Landlord commencing on the Rent Commencement Date and on the first day of each calendar month thereafter of the Term, as Additional Rent, Landlord's estimate of Tenant's Pro Rata Share of Operating Expenses with respect to the Building and the Property, as applicable, for such month, and:

(a) Within one hundred twenty (120) days after the conclusion of each calendar year (or such longer period as may be reasonably required by Landlord), Landlord shall furnish to Tenant a statement showing in reasonable detail the actual Operating Expenses, Tenant's Pro Rata Share of Operating Expenses, and the cost of providing utilities to the Premises for the previous calendar year ("Landlord's Statement"). Any additional sum due from Tenant to Landlord shall be due and payable within thirty (30) days after receipt of an invoice therefor. If the amounts paid

by Tenant pursuant to this Section exceed Tenant's Pro Rata Share of Operating Expenses and the cost of providing utilities to the Premises for the previous calendar year, then Landlord shall credit the difference against the Rent next due and owing from Tenant; provided that, if the Term has expired, Landlord shall accompany Landlord's Statement with payment for the amount of such difference.

(b) Any amount due under this Section for any period that is less than a full month shall be prorated for such fractional month on the basis of the number of days in the month.

8.3. Landlord may, from time to time, modify Landlord's calculation and allocation procedures for Operating Expenses, so long as such modifications produce results substantially consistent with Landlord's then-current practice at the Property. For example, as the Building may contain both retail and office components, certain Operating Expenses (including, but not limited to, systems that may serve such components disproportionately) may be allocated by Landlord disproportionately between such components. Landlord or an affiliate(s) of Landlord may own or lease other property(ies) adjacent to or near the Property (collectively, "Neighboring Properties"). In connection with Landlord performing services for the Property pursuant to this Lease, similar services may be performed by the same vendor(s) for the Neighboring Properties or aggregate costs may be incurred for the Property and the Neighboring Properties. In such a case, Landlord may reasonably allocate to the Property such costs based upon the ratio that the rentable square footage of the Building (as applicable) bears to the total rentable square footage of all buildings within the Neighboring Properties and the Property for which the services are performed or the costs incurred, unless the scope of the services performed for any building or property (including the Building) is disproportionately more or less than for others, in which case Landlord shall equitably allocate the costs based on the scope of the services being performed for each building or property (including the Building).

8.4. Landlord may annualize certain Operating Expenses incurred prior to the Rent Commencement Date over the course of the budgeted year during which the Rent Commencement Date occurs, and Tenant shall be responsible for the annualized portion of such Operating

Expenses corresponding to the number of days during such year, commencing with the Rent Commencement Date, for which Tenant is otherwise liable for Operating Expenses pursuant to this Lease. Tenant's responsibility for Tenant's Pro Rata Share of Operating Expenses shall continue to the latest of (a) the date of termination of the Lease, (b) the date Tenant has fully vacated the Premises and (c) if termination of the Lease is due to a default by Tenant, the date of rental commencement of a replacement tenant.

8.5. Operating Expenses for the calendar year in which Tenant's obligation to share therein commences and for the calendar year in which such obligation ceases shall be prorated on a basis reasonably determined by Landlord. Expenses such as taxes, assessments and insurance premiums that are incurred for an extended time period shall be prorated based upon the time periods to which they apply so that the amounts attributed to the Premises relate in a reasonable manner to the time period wherein Tenant has an obligation to share in Operating Expenses.

8.6. In the event that the Building is less than fully occupied during a calendar year, Tenant acknowledges that Landlord may extrapolate Operating Expenses that vary depending on the occupancy of the Building to equal Landlord's reasonable estimate of what such Operating Expenses would have been had the Building been fully occupied during such calendar year;

provided, however, that Landlord shall not recover more than one hundred percent (100%) of Operating Expenses.

9. Taxes on Tenant's Property.

9.1. Tenant shall be solely responsible for the payment of any and all taxes levied upon (a) personal property and trade fixtures located at the Premises and (b) any gross or net receipts of or sales by Tenant, and shall pay the same at least twenty (20) days prior to delinquency.

9.2. If any such taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property or, if the assessed valuation of the Building or the Property is increased by inclusion therein of a value attributable to Tenant's personal property or trade fixtures, and if Landlord, after written notice to Tenant, pays the taxes based upon any such increase in the assessed value of the Building or the Property, then Tenant shall, upon demand, repay to Landlord the taxes so paid by Landlord.

9.3. Tenant shall also pay to the appropriate federal, state, regional, local or municipal governmental authority, agency or subdivision ("Governmental Authority"), before any penalties or fines are assessed, any use and occupancy tax in connection with the Premises. In the event Landlord is required by law to collect such tax, Tenant shall pay such use and occupancy tax to Landlord as Additional Rent within ten (10) days of demand and Landlord shall remit any amounts so paid to Landlord to the appropriate Governmental Authority in a timely fashion. Tenant shall also pay to Landlord the applicable state sales, rent or similar tax, if any, on all Rent simultaneously with the payment by Tenant of the Rent as otherwise required by Applicable Law. If Tenant is entitled to an exemption from any such use and occupancy tax or sales, rent or similar tax, Tenant shall deliver to Landlord prior to the Rent Commencement Date a copy of the certification, permit or other written evidence from the appropriate governmental authority



confirming that Tenant is exempt therefrom and all annual updates thereto such that Landlord

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can at all times during the Term of this Lease confirm that Tenant is entitled to such exemption and upon any failure to do so, Tenant shall pay before any penalties or fines are assessed to the appropriate governmental authority any use and occupancy or sales, rent or similar tax in connection with the Premises, or in the event Landlord is required by law to collect such tax, Tenant shall pay such tax to Landlord as Additional Rent within twenty (20) days of demand.

### 10. Security Deposit.

10.1. Tenant shall deposit in cash with Landlord on or before the Effective Date the sum set forth in Section 2.7 (the "Security Deposit"), which sum shall be held by Landlord as security for the faithful performance by Tenant of all of the terms, covenants and conditions of this Lease to be kept and performed by Tenant during the Term. If Tenant Defaults with respect to any provision of this Lease, including any provision relating to the payment of Rent, then Landlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any Rent or any other sum in default, or to compensate Landlord for any other loss or damage that Landlord may suffer by reason of Tenant's default. If any portion of the Security Deposit is so used or applied, then Tenant shall, within ten (10) days following demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount, and Tenant's failure to do so shall be a material breach of this Lease. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

10.2. In the event of bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for all periods prior to the filing of such proceedings.

10.3. Landlord may deliver to any purchaser of Landlord's interest in the Premises the funds deposited hereunder by Tenant, and thereupon Landlord shall be discharged from any further liability with respect to such deposit. This provision shall also apply to any subsequent transfers.

10.4. If Tenant shall fully and faithfully perform every provision of this Lease to be performed by it, then the Security Deposit, or any balance thereof, shall be returned to Tenant (or, at Landlord's option, to the last assignee of Tenant's interest hereunder) within thirty (30) days after the expiration or earlier termination of this Lease; provided, however, that Landlord may retain an amount of the Security Deposit, as it shall reasonably determine, to secure the payment of any Rent, the amount of which Landlord is then unable to determine finally (and Landlord shall return any such retained amount to Tenant promptly following the final determination of such Rent amount and the full payment to Landlord of such Rent).

10.5. The Security Deposit shall not be deemed an advance payment of Rent or a measure of Landlord's damages for any default under this Lease by Tenant, nor shall it be a bar or defense to any action that Landlord may at any time commence against Tenant. The Security Deposit shall be the property of Landlord and Landlord may commingle the Security Deposit with other assets of Landlord or its affiliates and Tenant shall not be entitled to any interest on the Security Deposit.

**11. Use.**

**11.1. Tenant shall use the Premises for the Permitted Use, and shall not use the Premises, or permit or suffer the Premises to be used, for any other purpose without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.**

**11.2. Tenant shall not use or occupy the Premises in violation of Applicable Laws; the CC&Rs; zoning ordinances; or the certificate of occupancy issued for the Building or the Property, and shall, upon five (5) days' written notice from Landlord, discontinue any use of the Premises that is declared or claimed by any Governmental Authority having jurisdiction to be a violation of any of the above, or that in Landlord's reasonable opinion violates any of the above. Tenant shall comply with any direction of any Governmental Authority having jurisdiction that shall, by reason of the nature of Tenant's use or occupancy of the Premises, impose any duty upon Tenant or Landlord with respect to the Premises or with respect to the use or occupation thereof.**

**11.3. Tenant shall not allow the Premises or any part thereof to be used for any trade or business consisting of the operation of: (a) a shooting gallery; (b) an adult bookstore or facility selling or displaying pornographic books, literature, or videotapes (materials shall be considered "adult" or "pornographic" for such purpose if the same are not available for sale or rental to children under 18 years old because they explicitly deal with or depict human sexuality); (c) an establishment offering bingo or similar games of chance, but lottery tickets and other items commonly sold in retail establishments may be sold as an incidental part of business; (d) a video game or amusement arcade, except as an incidental part of another primary business; (e) drug or addiction treatment centers or clinics or parole or probation offices, whether as the principal or accessory use, (f) lodging, sleeping or any residential use, or (g) for the sale, distribution or use of marijuana or products using marijuana or similar drugs that are**

currently illegal to manufacture or distribute or sell under any Applicable Laws.

11.4. Tenant shall not do or permit to be done anything that will invalidate or increase the cost of any fire, environmental, extended coverage or any other insurance policy covering the Building or the Property, and shall comply with all rules, orders, regulations and requirements of the insurers of the Building and the Property, and Tenant shall promptly, upon demand, reimburse Landlord for any additional premium charged for such policy by reason of Tenant's failure to comply with the provisions of this Article.

11.5. Tenant shall keep all doors opening onto public corridors or the exterior of the Building closed, except when in use for ingress and egress.

11.6. No additional locks or bolts of any kind shall be placed upon any of the doors or windows by Tenant, nor shall any changes be made to existing locks or the mechanisms thereof without Landlord's prior written consent. Tenant shall, upon termination of this Lease, return to Landlord all keys to offices and restrooms either furnished to or otherwise procured by Tenant. In the event any key so furnished to Tenant is lost, Tenant shall pay to Landlord the cost of replacing the same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such change.

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11.7. No awnings or other projections shall be attached to any outside wall of the Building. No curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises other than Landlord's standard window coverings. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without Landlord's prior written consent, nor shall any

bottles, parcels or other articles be placed on the windowsills or items attached to windows that are visible from outside the Premises. No equipment, furniture or other items of personal property shall be placed on any exterior balcony without Landlord's prior written consent.

11.8. No sign, advertisement or notice ("Signage") shall be exhibited, painted or affixed by Tenant on any part of the Premises or the Building without Landlord's prior written consent. Signage shall conform to any design criteria adopted by Landlord from time to time. For any Signage, Tenant shall, at Tenant's own cost and expense, (a) acquire all permits for such Signage in compliance with Applicable Laws and (b) design, fabricate, install and maintain such Signage in a first-class condition. Notwithstanding the foregoing, building-standard interior signs on certain entry doors to the Premises (including directional signage in the elevator lobby area on the floor of the Premises and suite entry signage) and the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at Tenant's sole cost and expense, which may be paid for out of the TI Allowance if one is provided for in this Lease, and shall be of a size, color and type and be located in a place acceptable to Landlord. The directory tablet shall be provided exclusively for the display of the name and location of tenants only. Tenant shall not place anything on the exterior of the corridor walls or corridor doors other than Landlord's standard lettering. At Landlord's option, Landlord may install any Tenant Signage, and Tenant shall pay all costs associated with such installation within thirty (30) days after demand therefor.

11.9. Tenant may only place equipment within the Premises with floor loading consistent with the Building's structural design unless Tenant obtains Landlord's prior written approval. Tenant may place such equipment only in a location designed to carry the weight of such equipment.

11.10. Tenant shall cause any equipment or machinery to be installed in the Premises so as to

reasonably prevent sounds or vibrations therefrom from extending into the Common Area or other offices in the Property.

11.11. Tenant shall not (a) do or permit anything to be done in or about the Premises that shall in any way obstruct or interfere with the rights of other tenants or occupants of the Property, or injure or annoy them, (b) use or allow the Premises to be used for immoral, unlawful or objectionable purposes, (c) cause, maintain or permit any nuisance or waste in, on or about the Property or (d) take any other action that would in Landlord's reasonable determination in any manner adversely affect other tenants' quiet use and enjoyment of their space or adversely impact their ability to conduct business in a professional and suitable work environment. Notwithstanding anything in this Lease to the contrary, Tenant may not install any security systems (including cameras) outside the Premises or that record sounds or images outside the Premises without Landlord's prior written consent, which Landlord may withhold in its sole and absolute discretion.

11.12. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for all liabilities, costs and expenses arising out of or in connection with the compliance

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of the Premises with the Americans with Disabilities Act, 42 U.S.C. § 12101, et seq., and any state and local accessibility laws, codes, ordinances and rules (collectively, and together with regulations promulgated pursuant thereto, the "ADA"). Landlord may perform at Tenant's expense, or require that Tenant perform, and Tenant shall be responsible for the cost of, ADA Title III "path of travel" requirements triggered by alterations within the Premises made subsequent to the Term

Commencement Date by, or at the request of, Tenant.

Notwithstanding the foregoing, Landlord shall be responsible for assuring that any Tenant Improvements installed by Landlord pursuant to Exhibit B comply with the ADA at the time of their installation. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

**12. Rules and Regulations, CC&Rs, Parking Facilities and Common Area.**

12.1. Tenant shall have the non-exclusive right, in common with others, to use the Common Area in conjunction with Tenant's use of the Premises for the Permitted Use, and such use of the Common Area and Tenant's use of the Premises shall be subject to the rules and regulations adopted by Landlord and attached hereto as Exhibit F, together with such other different and/or additional reasonable and nondiscriminatory rules and regulations as are hereafter promulgated by Landlord in its sole and absolute discretion (collectively, the "Rules and Regulations"). Tenant shall and shall ensure that its contractors, subcontractors, employees, subtenants and invitees faithfully observe and comply with the Rules and Regulations. Landlord shall not be responsible to Tenant for the nonobservance by any other tenant or person of any Rules and Regulations.

12.2. This Lease is subject to (a) any ground or master lease, and any and all amendments thereto, and (b) any recorded covenants, conditions or restrictions on the Property (collectively, the "CC&Rs"), as the same may be amended, amended and restated, supplemented or otherwise modified from time to time. Tenant shall comply with the CC&Rs.

12.3. Landlord shall have no obligation to provide parking facilities to Tenant in connection with this Lease or Tenant's use of the Premises.

12.4. Subject to the terms of this Lease including the Rules and Regulations and the rights of other tenants of the Building, Tenant shall have the non-exclusive right to access the freight loading dock and freight elevator, if any, at no additional cost.

**13. Property Control by Landlord.**

**13.1. Landlord reserves full control over the Building and the Property to the extent not inconsistent with Tenant's enjoyment of the Premises as provided by this Lease. This reservation includes Landlord's right to subdivide the Property; convert the Building and other buildings within the Property to condominium units; remove Common Areas and/or portions of the Land from the Property; change the size of the Property by selling all or a portion of the Property or adding real property and any improvements thereon to the Property; grant easements and licenses to third parties; maintain or establish ownership of the Building separate from fee title to the Property; make additions to or reconstruct portions of the Building and the Property; install, use, maintain, repair, replace and relocate for service to the Premises and other parts of the Building or the Property pipes, ducts, conduits, wires and appurtenant fixtures, wherever located in the**

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**Premises, the Building or elsewhere at the Property; and alter, modify or relocate any other Common Area or facility, including any private drives, parking areas, lobbies, entrances and landscaping; provided, however, that such rights shall be exercised in a way that does not materially adversely affect Tenant's beneficial use and occupancy of the Premises, including the Permitted Use and Tenant's access to the Premises. Tenant acknowledges that Landlord specifically reserves the right to allow the exclusive use of corridors and restroom facilities located on specific floors to one or more tenants occupying such floors; provided, however, that Tenant shall not be deprived of the use of the corridors reasonably required to serve the Premises or of restroom facilities serving the floor upon which the Premises are located.**



13.2. Possession of areas of the Premises necessary for utilities, services, safety and operation of the Building is reserved to Landlord.

13.3. Tenant agrees not to oppose any initiatives by Landlord or its affiliates (a) that involve land use, zoning or other regulatory changes as to the Building, the Property or Neighboring Properties, or (b) that involve financing, incentives or subsidies of any kind for the Building, the Property or the Neighboring Properties, so long as Tenant's use of the Premises for the Permitted Use is not materially, adversely affected. Tenant shall, at Landlord's request, promptly execute such further documents as may be reasonably appropriate to assist Landlord in the performance of its obligations hereunder.

13.4. Landlord may, at any and all reasonable times, and upon twenty-four (24) hours' prior notice (which may be oral or by email to the office manager or other Tenant-designated individual at the Premises; but provided that no time restrictions shall apply or advance notice be required if an emergency necessitates immediate entry), enter the Premises to (u) inspect the same and to determine whether Tenant is in compliance with its obligations hereunder, (v) supply any service Landlord is required to provide hereunder, (w) alter, improve or repair any portion of the Building other than the Premises for which access to the Premises is reasonably necessary, (x) post notices of nonresponsibility, (y) access the telephone equipment, electrical substation and fire risers and (z) show the Premises to prospective tenants during the final year of the Term and current and prospective purchasers and lenders at any time. In connection with any such alteration, improvement or repair as described in Subsection 13.4(w), Landlord may erect in the Premises or elsewhere in the Property scaffolding and other structures reasonably required for the alteration, improvement or repair work to be performed. In no event shall Tenant's Rent abate as a result of Landlord's activities pursuant to this Section; provided, however, that all such activities shall be conducted in such a manner so as to cause as little interference to Tenant as

is reasonably possible. Landlord shall at all times retain a key with which to unlock all of the doors in the Premises. If an emergency necessitates immediate access to the Premises, Landlord may use whatever force is necessary to enter the Premises, and any such entry to the Premises shall not constitute a forcible or unlawful entry to the Premises, a detainer of the Premises, or an eviction of Tenant from the Premises or any portion thereof.

14. Quiet Enjoyment. Landlord covenants that Tenant, upon paying the Rent and performing its obligations contained in this Lease, may peacefully and quietly have, hold and enjoy the Premises, free from any claim by Landlord or persons claiming under Landlord, but subject to all of the terms and provisions hereof, provisions of Applicable Laws and rights of record to which

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this Lease is or may become subordinate. This covenant is in lieu of any other quiet enjoyment covenant, either express or implied.

15. Utilities, Utility Charges and Services.

15.1. (a) Tenant shall pay for all water, sewer, gas, heat, light, power, air, telephone, internet service, cable television, other telecommunications and other utilities supplied to the Premises, together with any fees, deposits, surcharges and taxes thereon. If any such utility is not separately metered to Tenant, Tenant shall pay Tenant's Pro Rata Share of all charges of such utility jointly metered with other premises as part of Tenant's Pro Rata Share of Operating Expenses or, in the alternative, Landlord may, at its option, monitor the usage of such utilities by Tenant and charge Tenant with the cost of purchasing, installing and monitoring such metering equipment, which cost shall be paid by Tenant

as part of the Tenant Improvements if installed at that time or as Additional Rent if installed later. Landlord may base its bills for utilities on reasonable estimates; and reconcile annually based on the actual cost of providing utilities in the same manner as Operating Expenses under Section 8.2. Electrical service for any air handling units exclusively serving the Premises and for any rooftop equipment installed by Tenant with Landlord's express written consent or installed as part of the Tenant Improvements, will be submetered to the Premises and such submetering shall be paid for by Tenant as part of the Tenant Improvements. Tenant shall not be liable for the cost of utilities supplied to the Premises attributable to the time period prior to the Term Commencement Date; provided, however, that, if Landlord shall permit Tenant possession of the Premises prior to the Term Commencement Date and Tenant uses the Premises for any purpose other than placement of personal property as set forth in Section 4.3 or construction of the Tenant Improvements if the Tenant is responsible for their construction, then Tenant shall be responsible for the cost of utilities supplied to the Premises from such earlier date of possession.

(b) If Tenant uses more than Tenant's Pro Rata Share of HVAC, Landlord may elect to allocate and charge Tenant and not charge other tenants in the Building, as Additional Rent, separately for electricity used in the Common Areas, with such allocation to be based on the consumption of electricity in the Premises relative to consumption of electricity by all other Building tenants, as reasonably determined by Landlord. If Landlord so elects, the (x) the Common Area electric charge payable with respect to the Premises shall be payable monthly on an estimated basis and reconciled annually in the same manner as Operating Expenses under Sections 8.2, and (y) Tenant's Pro Rata Share of Operating Expenses for the Premises shall be calculated in the same manner as herein provided except that all costs of electricity for the Common Areas shall be deducted from Operating Expenses.

(c) In general water service will either not be provided to the Premises or, if provided, will be

provided only for limited lavatory purposes and will not be separately metered or monitored. However, that if Landlord determines that Tenant requires, uses or consumes water for any purpose other than ordinary lavatory purposes (including, without limitation, for a restaurant use), Landlord may install a water meter or submeter ("Tenant Water Meter") and thereby measure Tenant's water consumption for all purposes. Tenant shall pay Landlord for the costs of any Tenant Water Meter and the installation and maintenance thereof during the Term. If Landlord installs a Tenant Water Meter, Tenant shall pay for water consumed, as shown on such meter, as and when bills are rendered. If Tenant fails to timely make such payments, Landlord

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may pay such charges and collect the same from Tenant. Any such costs or expenses incurred or payments made by Landlord for any of the reasons or purposes stated in this Section shall be deemed to be Additional Rent payable by Tenant and collectible by Landlord as such.

(d) If Tenant shall require utilities or services in excess of those usually furnished or supplied for tenants in similar spaces in the Building or the Property by reason of Tenant's equipment or extended hours of business operations, then Tenant shall first procure Landlord's consent for the use thereof, which consent Landlord may condition upon the availability of such excess utilities or services, and Tenant shall pay as Additional Rent an amount equal to the cost of providing such excess utilities and services.

15.2. For the Premises, Landlord shall (a) maintain and operate the central heating, ventilating and air conditioning systems located outside the Premises and serving other tenants in the Building ("HVAC") and (b) subject to the other provisions of this Section, furnish HVAC as reasonably required (except as this Lease

otherwise provides or as to any special requirements that arise from Tenant's particular use of the Premises) for reasonably comfortable occupancy of the Premises twenty-four (24) hours a day, every day during the Term, subject to casualty, eminent domain or as otherwise specified in this Article. If Tenant will require HVAC outside normal business hours of business days (as reasonably designated by Landlord) in the Premises ("Overtime HVAC"), then Landlord shall be obligated to provide Overtime HVAC only if Tenant requests it by 4 p.m. on the immediately preceding business day. To the extent that Tenant occupies the Premises for laboratory purposes, Tenant directs Landlord to provide Overtime HVAC at all times outside normal business hours of business days (as reasonably designated by Landlord), pending further written notice from Tenant. Tenant shall pay Landlord, as Additional Rent, Landlord's standard charge for Overtime HVAC for the Premises. As of the Effective Date, Landlord's hourly rate per floor for Overtime HVAC is \$50.00 per hour, but such charge may be adjusted from time to time by Landlord consistent with rates charged for similar buildings in the metropolitan area in which the Building is located.

15.3. Tenant shall pay for, prior to delinquency of payment therefor, any utilities and services that may be furnished to the Premises during or, if Tenant occupies the Premises after the expiration or earlier termination of the Term, after the Term, beyond those utilities provided by Landlord, including telephone, internet service, cable television and other telecommunications, together with any fees, surcharges and taxes thereon. Upon Landlord's demand, utilities and services provided to the Premises that are separately metered shall be paid by Tenant directly to the supplier of such utilities or services.

15.4. Tenant shall not, without Landlord's prior written consent, use any device in the Premises (including data processing machines) that will in any way (a) increase the amount of ventilation, air exchange, gas, steam, electricity or water required or consumed in the Premises based upon Tenant's Pro Rata Share of the Building (as applicable) beyond the existing capacity of

the Building or the Property usually furnished or supplied for the Permitted Use or (b) exceed Tenant's Pro Rata Share of the Building's or Property's (as applicable) capacity to provide such utilities or services; provided, however, the installation in the Premises of the improvements and equipment contemplated by the Approved Plans for the Tenant Improvements shall not be deemed to violate the foregoing.

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15.5. Tenant may install equipment to provide emergency power, in a location in the Premises, subject to Landlord's prior written approval of the equipment and location. The installation of such equipment shall constitute Alterations.

15.6. For any utilities serving the Premises for which Tenant is billed directly by the utility provider, Tenant agrees to furnish to Landlord (a) any invoices or statements for such utilities within thirty (30) days after Tenant's receipt thereof, (b) within thirty (30) days after Landlord's request, any other utility usage information reasonably requested by Landlord, and (c) within thirty (30) days after each calendar year during the Term, authorization to allow Landlord to access Tenant's usage information necessary for Landlord to complete an ENERGY STAR® Statement of Performance (or similar comprehensive utility usage report (e.g., related to Labs 21), if requested by Landlord) and any other information reasonably requested by Landlord for the immediately preceding year; and Tenant shall comply with any other energy usage or consumption requirements required by Applicable Laws. Tenant shall retain records of utility usage at the Premises, including invoices and statements from the utility provider, for at least sixty (60) months, or such other period of time as may be requested by Landlord. Tenant acknowledges that any utility information for the Premises, the Building and

the Property may be shared with third parties, including Landlord's consultants and Governmental Authorities.

In the event that Tenant fails to comply with this Section, Tenant hereby authorizes Landlord to collect utility usage information directly from the applicable utility providers. In addition to the foregoing, Tenant shall comply with all applicable Laws related to the disclosure and tracking of energy consumption at the Premises. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

15.7. Tenant's use of electric energy in the Premises shall not at any time exceed the capacity of any of the electrical conductors and equipment in or otherwise serving the Premises. In order to ensure that such capacity is not exceeded, and to avert a possible adverse effect upon the Property's distribution of electricity via the Property's electric system, Tenant shall not, without Landlord's prior written consent in each instance (which consent Landlord may condition upon the availability of electric energy in the Property as allocated by Landlord to various areas of the Property) connect any fixtures, appliances or equipment (other than normal business machines) to the Building's or Property's electric system or make any alterations or additions to the electric system of the Premises existing on the date hereof. Should Landlord grant such consent, all additional risers, distribution cables or other equipment required therefor shall be provided by Landlord and the cost thereof shall be paid by Tenant to Landlord on demand (or, at Tenant's option, shall be provided by Tenant pursuant to plans and contractors approved by Landlord, and otherwise in accordance with the provisions of this Lease). Landlord shall have the right to require Tenant to pay sums on account of such cost prior to the installation of any such risers or equipment. The installation in the Premises of the improvements and equipment contemplated by the Approved Plans for the Tenant Improvements shall not be deemed to violate the foregoing.

15.8. If required by Applicable Law, Landlord may, upon sixty (60) days' prior written notice to Tenant, discontinue Landlord's provision of electric energy

hereunder. If Landlord discontinues provision of electric energy pursuant to this Section, Tenant shall not be released from any liability under this Lease, except that as of the date of such discontinuance, Tenant's obligation to pay Landlord additional charges for electric energy thereafter supplied to the Premises shall cease. As of such date, Landlord shall permit Tenant to receive electric energy

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directly from the public utility company supplying electric energy to the Property, and Tenant shall pay all costs and expenses of obtaining such direct electrical service. Such electric energy may be furnished to Tenant by means of the Building's then-existing system feeders, risers and wiring to the extent that the same are available, suitable and safe for such purpose. All meters and additional panel boards, feeders, risers, wiring and other conductors and equipment that may be required to obtain electric energy directly from such public utility company shall be furnished and installed by Landlord, and reimbursed by Tenant as an Operating Expense.

15.9. The parties hereto agree to comply with all mandatory energy, water or other conservation controls or requirements applicable to the Building issued by the Federal, State, county, municipal or other applicable governments, the U.S. Green Building Council or Green Building initiative or its successors or peer organizations, or any public utility or insurance carrier including, without limitation, controls on the permitted range of temperature settings in buildings or requirements necessitating curtailment of the volume of energy consumption or the hours of operation of the Building. Any terms or conditions of this Lease that conflict or interfere with compliance by Landlord with such controls or requirements shall be suspended for the duration of such controls or requirements. It is further agreed that compliance with such controls or



requirements shall not be considered an eviction, actual or constructive, of Tenant from the Premises and shall not entitle Tenant to terminate this Lease or to an abatement or reduction of any rent payable hereunder.

15.10. Tenant acknowledges that security devices and services, if any, while intended to deter crime, may not in given instances prevent theft or other criminal acts. Landlord has no duty to provide security for any portion of the Premises, and Tenant assumes sole responsibility and liability for the security of itself, its employees, customers and invitees and their respective property, in the Premises. Landlord shall not be liable for injuries or losses caused by criminal acts of third parties on or near the Property, and Tenant assumes the risk that any security device or service may malfunction or otherwise be circumvented by a criminal. If Tenant desires protection against such criminal acts, then Tenant shall, at Tenant's sole cost and expense, obtain appropriate insurance coverage. Tenant's security programs and equipment for the Premises shall be coordinated with Landlord and subject to Landlord's reasonable approval.

15.11. Landlord shall not be liable for, nor shall any eviction of Tenant result from, the failure to furnish any utility or service, whether or not such failure is caused by accidents; breakage; casualties (to the extent not caused by Landlord); Severe Weather Conditions; physical natural disasters (but excluding weather conditions that are not Severe Weather Conditions); strikes, lockouts or other labor disturbances or labor disputes (other than labor disturbances and labor disputes resulting solely from the acts or omissions of Landlord); acts of terrorism; riots or civil disturbances; wars or insurrections; shortages of materials (which shortages are not unique to Landlord); government regulations, moratoria or other governmental actions, inactions or delays; failures by third parties to deliver gas, oil or another suitable fuel supply, or inability of Landlord, by exercise of reasonable diligence, to obtain gas, oil or another suitable fuel; or other causes beyond the reasonable control of Landlord (collectively, "Force Majeure"); or, to the extent permitted by Applicable

Laws, Landlord's negligence. Landlord reserves the right to stop service of the elevator, plumbing, HVAC and utility systems, when Landlord deems necessary or desirable, due to accident, emergency or the need to make repairs, alterations or improvements, until such repairs, alterations or improvements shall have been completed, and Landlord shall

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further have no responsibility or liability for failure to supply elevator facilities, plumbing, HVAC or utility service when prevented from doing so by Force Majeure or, to the extent permitted by Applicable Laws, Landlord's negligence; a failure by a third party to deliver gas, oil or another suitable fuel supply; or Landlord's inability by exercise of reasonable diligence to obtain gas, oil or another suitable fuel. Without limiting the foregoing, it is expressly understood and agreed that any covenants on Landlord's part to furnish any service pursuant to any of the terms, covenants, conditions, provisions or agreements of this Lease, or to perform any act or thing for the benefit of Tenant, shall not be deemed breached if Landlord is unable to furnish or perform the same by virtue of Force Majeure or, to the extent permitted by Applicable Laws, Landlord's negligence. In the event of such failure, Tenant shall not be entitled to termination of this Lease or any abatement or reduction of Rent, nor shall Tenant be relieved from the operation of any covenant or agreement of this Lease. "Severe Weather Conditions" means weather conditions that are materially worse than those that reasonably would be anticipated for the Property at the applicable time based on historic meteorological records. In no event shall Landlord be liable to Tenant for any failure or defect in the supply or character of electric energy furnished to the Premises by reason of any requirement, act or omission of the public utility serving the Property with electric energy.

16. **Alterations.**

16.1. Other than as may be specifically permitted by the Work Letter, if applicable, Tenant shall make no alterations, additions or improvements, other than the Tenant Improvements, in or to the Premises or engage in any construction, demolition, reconstruction, renovation or other work (whether major or minor) of any kind in, at or serving the Premises ("Alterations") without Landlord's prior written approval, which approval Landlord shall not unreasonably withhold; provided, however, that, in the event any proposed Alteration affects (a) any structural portions of the Building, including exterior walls, the roof, the foundation or slab, foundation or slab systems (including barriers and subslab systems), or the core of the Building, (b) the exterior of the Building or (c) any Building systems, including elevator, plumbing, HVAC, electrical, security, life safety and power, then Landlord may withhold its approval in its sole and absolute discretion. Tenant shall, in making any Alterations, use only those architects, contractors, suppliers and mechanics of which Landlord has given prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed. In seeking Landlord's approval, Tenant shall provide Landlord, at least thirty (30) days in advance of any proposed construction, with plans, specifications, bid proposals, certified stamped engineering drawings and calculations by Tenant's engineer of record or architect of record, (including connections to the Building's structural system, modifications to the Building's envelope, non-structural penetrations in slabs or walls, and modifications or tie-ins to life safety systems), work contracts, requests for laydown areas and such other information concerning the nature and cost of the Alterations as Landlord may reasonably request. In no event shall Tenant use or Landlord be required to approve any architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in a Class "A" building and, if applicable, in lab areas or are

not financially credit-worthy given the cost of the Alterations. Notwithstanding the foregoing, Tenant may make strictly cosmetic changes to the Premises that do not require any permits or more than three (3) total contractors and subcontractors ("Cosmetic Alterations") without Landlord's consent; provided that (y) the cost of any Cosmetic Alterations does not exceed Twenty Five Thousand Dollars (\$25,000.00) annually, (z) such Cosmetic Alterations do not (i) require any structural or other

substantial modification to the Premises, (ii) require any changes to or adversely affect the Building systems, (iii) affect the exterior of the Building or (iv) trigger any requirement under Applicable Laws that would require Landlord to make any alteration or improvement to the Premises, the Building or the Project.

16.2. Tenant shall not construct or permit to be constructed partitions or other obstructions that might interfere with free access to mechanical installation or service facilities of the Building or with other tenants' components located within the Building, or interfere with the moving of Landlord's equipment to or from the enclosures containing such installations or facilities. Tenant shall take, and shall cause its contractors to take, commercially reasonable steps to protect the Premises during the performance of any Alterations, including covering or temporarily removing any window coverings so as to guard against dust, debris or damage. Tenant may not, as part of the Tenant Improvements, Alterations or otherwise install any work of art in the Premises or elsewhere in the Building that is incorporated into the Building, is a part of the Building or may not be removed from the Building without causing the destruction, distortion, mutilation or other modification of the work of art, without first obtaining

the prior written approval of Landlord of the installation of the specific work of art, which approval may be withheld in Landlord's sole and absolute discretion.

Approval of plans and specifications for the Tenant Improvements or Alterations shall not, by itself, constitute approval of the installation of a work of art.

16.3. Tenant shall accomplish any work performed on the Premises or the Building in such a manner as to permit any life safety systems to remain fully operable at all times.

16.4. Any work performed on the Premises, the Building or the Property by Tenant or Tenant's contractors shall be done at such times and in such manner as Landlord may from time to time designate. Tenant covenants and agrees that all work done by Tenant or Tenant's contractors shall be performed in full compliance with Applicable Laws, CC&Rs and the construction rules set forth in Exhibit B-2 hereto (the "Construction Rules"). At all times while Alterations are being performed, Tenant shall cause its contractors and subcontractors to maintain in effect all insurance required under and fully comply with the provisions of Exhibit B-1.

16.5. Before commencing any Alterations, Tenant shall (a) give Landlord at least thirty (30) days' prior written notice of the proposed commencement of such work and the names and addresses of the persons who are to supply labor or materials therefor so that Landlord may enter the Premises to post and keep posted thereon and therein notices or to take any further action that Landlord may reasonably deem proper for the protection of Landlord's interest in the Property and (b) shall, if required by Landlord, secure, at Tenant's own cost and expense, a completion and lien indemnity bond satisfactory to Landlord for such work.

16.6. Within thirty (30) days after completion of any Alterations, including, without limitation, Cosmetic Alterations, Tenant shall provide Landlord with complete "as built" drawing print sets and electronic CADD files on disc (or files in such other current format

in common use as Landlord reasonably approves or requires) showing any changes in the Premises, as well as a commissioning report prepared by a licensed, qualified commissioning agent hired by Tenant and approved by Landlord for all new or affected mechanical, electrical and plumbing systems. Any such “as built” plans shall show the applicable Alterations as an overlay on the Building as-built

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plans; provided that Landlord provides the Building “as built” plans to Tenant. Within sixty (60) days after final completion of any Alterations performed by Tenant with respect to the Premises, Tenant shall submit to Landlord documentation showing the amounts expended by Tenant with respect thereto, together with supporting documentation reasonably acceptable to Landlord.

16.7. Tenant shall repair any damage to the Premises caused by Tenant’s removal of any property from the Premises. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if such space were otherwise occupied by Tenant. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

16.8. The Premises plus any Alterations, Tenant Improvements, attached equipment, decorations, fixtures, movable laboratory casework and related appliances, and other additions and improvements attached to or built into the Premises, made by either of the parties (including all floor and wall coverings, paneling, sinks and related plumbing fixtures, laboratory benches, exterior venting fume hoods, walk-in freezers and refrigerators, ductwork, conduits, electrical panels and circuits, attached machinery and equipment, and built-in furniture and cabinets, in each case, together with all additions and accessories

thereto), shall (unless, prior to such construction or installation, Landlord elects otherwise in writing) at all times remain the property of Landlord, shall remain in the Premises and shall (unless, prior to construction or installation thereof, Landlord elects otherwise in writing) be surrendered to Landlord upon the expiration or earlier termination of this Lease. Notwithstanding the foregoing, all wiring and cabling installed by or on behalf of Tenant in the Premises or in the utility closets or chases of the Building, all of Tenant's Signage, all of Tenant's personal property (except as otherwise provided in Section 16.9 below), all works of art and all window coatings or sunscreens installed by Tenant on windows of the Building shall be removed by Tenant upon the expiration or earlier termination of the Lease, and Tenant shall restore the Property to its condition prior to such installation upon the expiration or earlier termination of the Lease. If Tenant shall fail to remove any of the foregoing, and restore the Property as required, Tenant shall be responsible for reimbursing Landlord for costs incurred by Landlord in removing any of such property and restoring the Property to its condition prior to such installation.

16.9. Notwithstanding any other provision of this Article to the contrary, in no event shall Tenant remove any improvement, fixture, personal property or equipment from the Premises as to which Landlord contributed payment, including the Tenant Improvements, without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.

16.10. Upon the expiration or earlier termination of this Lease, Tenant shall peaceably leave and surrender the Premises to Landlord broom clean and otherwise in the condition in which the Premises are required to be maintained and surrendered by the terms of this Lease, reasonable wear and tear excepted. Tenant shall surrender all keys for the Premises to Landlord and shall inform Landlord of the combinations to all locks, safes and vaults in the Premises. Tenant shall, at its expenses, remove from the Premises on or prior to expiration or earlier termination of this Lease all furnishings, fixtures

and equipment situated thereon as well as those Alterations that are required to be removed pursuant to Section 16.8.

16.11. If Tenant shall fail to remove any of the property which Tenant is required to remove pursuant to Section 16.8 above from the Premises or the Building (including, without

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limitation, any wiring or cabling in the utility closets or chases of the Building and any Tenant's Signage) prior to the expiration or earlier termination of this Lease, then Landlord may, at its option, remove the same in any manner that Landlord shall choose and store such effects without liability to Tenant for loss thereof or damage thereto, and Tenant shall pay Landlord, upon demand, any costs and expenses incurred due to such removal and storage or Landlord may, at its sole option and without notice to Tenant, sell such property or any portion thereof at private sale and without legal process for such price as Landlord may obtain and apply the proceeds of such sale against any (a) amounts due by Tenant to Landlord under this Lease and (b) any expenses incident to the removal, storage and sale of such property.

16.12. Tenant shall pay to Landlord an amount equal to three percent (3%) of the cost to Tenant of all Alterations to cover Landlord's overhead and expenses for plan review, engineering review, coordination, scheduling and supervision thereof. For purposes of payment of such sum, Tenant shall submit to Landlord copies of all bills, invoices and statements covering the costs of such charges, accompanied by payment to Landlord of the fee set forth in this Section. Tenant shall reimburse Landlord for any extra expenses incurred by Landlord by reason of faulty work done by Tenant or its



contractors, or by reason of delays caused by such work, or by reason of inadequate clean-up.

16.13. Tenant's obligation under Sections 16.7, 16.8, 16.9, 16.10, 16.11, and 16.12 shall survive the expiration or earlier termination of this Lease.

**17. Repairs and Maintenance.**

17.1. Landlord shall repair and maintain the structural and exterior portions and Common Area of the Building and the Property, including roofing and covering materials; foundations (excluding any architectural slabs, but including any structural slabs); exterior walls; plumbing; common fire sprinkler systems (but excluding sprinkler heads which must be maintained by Tenant); base building HVAC systems (but excluding air handlers exclusively serving the Premises which must be maintained by Tenant); common elevators; and common electrical systems installed or furnished by Landlord.

17.2. Except for services of Landlord, if any, required by Section 17.1 hereof, Tenant will take good care of the Premises and the fixtures and improvements therein (including, without limitation, all walls, doors, ceilings and lighting fixtures) and all electrical, plumbing, mechanical and HVAC equipment exclusively serving the Premises (but excluding all common utilities and common HVAC systems and all electrical, plumbing, mechanical and HVAC equipment serving portions of the Building other than the Premises) and all sprinkler heads located in the Premises, will make all repairs and replacements thereto (excluding structural repairs and replacements, unless caused by Tenant's acts or omissions), whether foreseen or unforeseen, ordinary or extraordinary, so as to keep the Premises in a first class condition and state of repair, reasonable wear and tear excepted, and will neither commit nor suffer any active or permissive waste or injury thereof, and shall, within fifteen (15) days after receipt of written notice from Landlord, provide to Landlord any maintenance records that Landlord reasonably requests. Tenant's responsibilities shall include the maintenance, repair

and replacement of all of Tenant's signage (both interior and exterior) and all other facilities and equipment of Tenant located outside of the Premises and all improvements, systems, equipment, and other installations, including, without limitation, all

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related lines, conduits, pipes, cabling, connections and the like, located outside of the Premises that were installed by Tenant or installed by Landlord for Tenant as part of the Tenant Improvements or otherwise pursuant to this Lease. Landlord will maintain any Building standard air handler or Building standard condenser that exclusively serves the Premises (but any specialty equipment, such as Liebert type units and HEPA filtration units, shall remain Tenant's responsibility) and sprinkler heads located in the Premises, but Tenant shall be solely responsible for the cost thereof as Additional Rent. Tenant's responsibilities in conjunction therewith shall also include, but not be limited to, the cleaning of window coverings, mini-blinds and shades, the shampooing and re-stretching of carpet, and the regular painting and decorating of the Premises so as to maintain the Premises in a first-class condition and state of repair. All bulbs, tubes and lighting fixtures for the Premises shall be provided and installed by Tenant at Tenant's cost and expense and must comply with Landlord's sustainability practices, including any third-party rating system concerning the environmental compliance of the Building or the Premises, as the same may change from time to time. All such repair work and maintenance and any alterations permitted by Landlord shall be done at Tenant's sole cost and expense by persons or contractors selected by Tenant and consented to in writing by Landlord. Tenant shall, at Tenant's expense, but under the direction of Landlord, by contractors selected by Tenant and consented to in writing by Landlord, promptly repair any injury or

damage to the Premises or Building caused by the misuse or neglect thereof by Tenant, by Tenant's contractors, subcontractors, customers, employees, licensees, agents, or invitees permitted or invited (whether by express or implied invitation) on the Premises by Tenant, or by Tenant moving in or out of the Premises. Tenant shall be responsible for all janitorial service, trash removal and biological and hazardous waste removal (if applicable) from the Premises. Tenant covenants and agrees, at its sole cost and expense: (a) to comply with all present and future laws, orders and regulations of the Federal, State, county, municipal or other governing authorities regarding the collection, sorting, separation, and recycling of garbage, trash, rubbish and other refuse (collectively, "trash"); (b) to comply with Landlord's recycling policy as part of Landlord's sustainability practices where it may be more stringent than applicable law; (c) to sort and separate its trash and recycling into such categories as are provided by law or Landlord's sustainability practices; (d) that Landlord reserves the right to refuse to collect or accept from Tenant any waste that is not separate and sorted as required by Applicable Laws or Landlord's sustainability practices, and to require Tenant to arrange for such collection at Tenant's sole cost and expense, utilizing a contractor satisfactory to Landlord; and (e) that Tenant shall pay all costs, expenses, fines, penalties or damages that may be imposed on Landlord or Tenant by reason of Tenant's failure to comply with the provisions of this Section.

17.3. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance that is Landlord's obligation pursuant to this Lease unless such failure shall persist for an unreasonable time after Tenant provides Landlord with written notice of the need of such repairs or maintenance. Tenant waives its rights under Applicable Laws now or hereafter in effect to make repairs at Landlord's expense.

17.4. If any excavation shall be made upon land adjacent to or under the Building, or shall be authorized to be made, Tenant shall afford to the person causing or authorized to cause such excavation, license to enter the

Premises for the purpose of performing such work as such person shall deem necessary or desirable to preserve and protect the Building from injury or

damage and to support the same by proper foundations, without any claim for damages or liability against Landlord and without reducing or otherwise affecting Tenant's obligations under this Lease.

17.5. Landlord shall clean the exterior of the exterior windows of the Building no more than two (2) times per year. Tenant, at Tenant's sole cost and expense, shall be responsible for the regular cleaning of the interior of the exterior windows and any interior windows consistent with Tenant's obligations under Section 17.2.

17.6. This Article relates to repairs and maintenance arising in the ordinary course of operation of the Building and the Property. In the event of a casualty described in Article 23, Article 23 shall apply in lieu of this Article. In the event of eminent domain, Article 24 shall apply in lieu of this Article.

17.7. Costs incurred by Landlord pursuant to this Article shall constitute Operating Expenses. Notwithstanding the foregoing, to the extent that the cost of such repairs and maintenance caused by Tenant's acts, neglect, fault or omissions exceeds the limits of any insurance maintained or required to be maintained by Tenant pursuant to this Lease but are covered by insurance maintained or required to be maintained by Landlord under this Lease, then Landlord shall file a claim for such excess pursuant to Landlord's insurance and Tenant shall reimburse Landlord for the deductible therefor any increase in premium resulting from such claim within thirty (30) days after receipt of an invoice therefor.

**18. Liens.**

18.1. Subject to the immediately succeeding sentence, Tenant shall keep the Premises, the Building and the Property free from any liens arising out of work or services performed, materials furnished to or obligations incurred by Tenant. Tenant further covenants and agrees that any mechanic's or materialman's lien filed against the Premises, the Building or the Property for work or services claimed to have been done for, or materials claimed to have been furnished to, or obligations incurred by Tenant shall be discharged or bonded by Tenant within ten (10) days after the filing thereof, at Tenant's sole cost and expense.

18.2. Should Tenant fail to discharge or bond against any lien of the nature described in Section 18.1, Landlord may, at Landlord's election, pay such claim or post a statutory lien bond or otherwise provide security to eliminate the lien as a claim against title, and Tenant shall immediately reimburse Landlord for the costs thereof as Additional Rent.

18.3. In the event that Tenant leases or finances the acquisition of office equipment, furnishings or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code financing statement shall, upon its face or by exhibit thereto, indicate that such financing statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Premises, the Building or the Property be furnished on a financing statement without qualifying language as to applicability of the lien only to removable personal property located in an identified suite leased by Tenant. Should any holder of a financing statement record or place of record a financing statement that appears to constitute a lien against any interest of Landlord or

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against equipment that may be located other than within an identified suite leased by Tenant, Tenant shall, within ten (10) days after filing such financing statement, cause (a) a copy of the lender security agreement or other documents to which the financing statement pertains to be furnished to Landlord to facilitate Landlord's ability to demonstrate that the lien of such financing statement is not applicable to Landlord's interest and (b) Tenant's lender to amend such financing statement and any other documents of record to clarify that any liens imposed thereby are not applicable to any interest of Landlord in the Premises, the Building or the Property.

19. **Estoppel Certificate.** Tenant shall, within ten (10) days after receipt of written notice from Landlord, execute, acknowledge and deliver a statement in writing substantially in the form attached to this Lease as **Exhibit G**, or on any other form reasonably requested by a current or proposed Lender or encumbrancer or proposed purchaser, (a) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which rental and other charges are paid in advance, if any, (b) acknowledging that there are not, to Tenant's knowledge, any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (c) setting forth such further information with respect to this Lease or the Premises as may be requested thereon. Upon Landlord's request, Tenant shall cause the Guarantor to also execute and deliver such statement within such time period. Any such statements may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the Property. Tenant's failure to deliver any such statement within such the prescribed time shall, at Landlord's option, constitute a Default under this Lease, and, in any event, shall be binding upon Tenant and constitute Tenant's irrevocable acknowledgement and agreement that all of the matters stated in such statement are true, correct and complete.

**20. Hazardous Materials.**

20.1. Tenant shall not cause or permit any Hazardous Materials to be brought upon, kept or used in or about the Premises, the Building or the Property by Tenant or any of its employees, agents, contractors or invitees (collectively with Tenant, each a "Tenant Party"). Notwithstanding the foregoing, Tenant may keep, store and use upon the Premises de minimus amounts of typical cleaning and office supplies that constitute Hazardous Materials, provided that such cleaning and office supplies are kept, stored, used, maintained and disposed of in accordance with all Applicable Laws and manufacturer's instructions and further provided that Tenant may not discharge or dispose of any such Hazardous Materials in any drains in the Building. If (a) Tenant breaches such obligation, (b) the presence of Hazardous Materials as a result of such a breach results in contamination of the Property, any portion thereof, or any adjacent property, (c) contamination of the Premises otherwise occurs during the Term or any extension or renewal hereof or holding over hereunder or (d) contamination of the Property occurs as a result of Hazardous Materials that are placed on or under or are released into the Property by a Tenant Party, then Tenant shall indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord) and hold the Landlord Indemnitees harmless from and against any and all Claims of any kind or nature, including (w) diminution in value of the Property or any portion thereof, (x) damages for the loss or restriction on use of rentable or usable space or of any amenity of the Property, (y) damages arising from any adverse impact on marketing of space in the Property or any portion thereof and (z) sums paid in settlement of Claims that arise before, during or after the Term as a result of such breach or contamination. This indemnification by Tenant includes costs incurred in connection

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with any investigation of site conditions or any clean-up, remedial, removal or restoration work required by any Governmental Authority because of Hazardous Materials present in the air, soil or groundwater above, on, under or about the Property. Without limiting the foregoing, if the presence of any Hazardous Materials in, on, under or about the Property, any portion thereof or any adjacent property caused or permitted by any Tenant Party results in any contamination of the Property, any portion thereof or any adjacent property, then Tenant shall promptly take all actions at its sole cost and expense as are necessary to return the Property, any portion thereof or any adjacent property to its respective condition existing prior to the time of such contamination; provided that Landlord's written approval of such action shall first be obtained, which approval Landlord shall not unreasonably withhold; and provided, further, that it shall be reasonable for Landlord to withhold its consent if such actions could have a material adverse long-term or short-term effect on the Property, any portion thereof or any adjacent property. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation.

20.2. At any time, and from time to time, prior to the expiration of the Term, Landlord shall have the right to conduct appropriate tests of the Property or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the

acts or omissions of a Tenant Party. Tenant shall pay all reasonable costs of such tests if such tests reveal that Hazardous Materials exist at the Property in violation of this Lease.

20.3. Tenant shall promptly report to Landlord any actual or suspected presence of mold or water intrusion at the Premises.



20.4. Tenant's obligations under this Article shall survive the expiration or earlier termination of the Lease. During any period of time needed by Tenant or Landlord after the termination of this Lease to complete the removal from the Premises of any such Hazardous Materials, Tenant shall be deemed a holdover tenant and subject to the provisions of Article 26.

20.5. As used herein, the term "Hazardous Material" means (a) any toxic, explosive, corrosive, flammable, infectious, radioactive, carcinogenic, mutagenic or otherwise hazardous substance, material or waste that is or becomes regulated by Applicable Laws or any Governmental Authority, and (b) (i) "chemotherapeutic waste", "infectious waste" or "medical waste" as may now or hereafter be defined by any future law, statute, order, ordinance or regulation, (ii) "radioactive waste" as may now or hereafter be defined by any future law, statute, order, ordinance or regulation, (iii) human corpses, remains and anatomical parts that are donated and used for scientific or medical education, research or treatment, (iv) body fluids or biologicals which are being stored at a laboratory prior to laboratory testing, and/or (v) similar laboratory wastes and materials.

21. Odors and Exhaust. Tenant acknowledges that Landlord would not enter into this Lease with Tenant unless Tenant assured Landlord that under no circumstances will any other occupants of the Building or the Property (including persons legally present in any outdoor areas of the Property) be subjected to odors or fumes (whether or not noxious), and that the Building and the

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Property will not be damaged by any exhaust, in each case from Tenant's operations. Landlord and Tenant

therefore agree as follows:

21.1. Tenant shall not cause or permit (or conduct any activities that would cause) any release of any odors or fumes of any kind from the Premises.

21.2. If the Building has a ventilation system that, in Landlord's judgment, is adequate, suitable, and appropriate to vent the Premises in a manner that does not release odors affecting any indoor or outdoor part of the Property, Tenant shall vent the Premises through such system. If Landlord at any time determines that any existing ventilation system is inadequate, or if no ventilation system exists, Tenant shall in compliance with Applicable Laws vent all fumes and odors from the Premises (and remove odors from Tenant's exhaust stream) as Landlord requires. The placement and configuration of all ventilation exhaust pipes, louvers and other equipment shall be subject to Landlord's approval. Tenant acknowledges Landlord's legitimate desire to maintain the Property (indoor and outdoor areas) in an odor-free manner, and Landlord may require Tenant to abate and remove all odors in a manner that goes beyond the requirements of Applicable Laws.

21.3. Tenant shall, at Tenant's sole cost and expense, provide odor eliminators and other devices (such as filters, air cleaners, scrubbers and whatever other equipment may in Landlord's judgment be necessary or appropriate from time to time) to completely remove, eliminate and abate any odors, fumes or other substances in Tenant's exhaust stream that, in Landlord's judgment, emanate from Tenant's Premises. Any work Tenant performs under this Section shall constitute Alterations.

21.4. Tenant's responsibility to remove, eliminate and abate odors, fumes and exhaust shall continue throughout the Term. Landlord's approval or construction of the Tenant Improvements shall not preclude Landlord from requiring additional measures to eliminate odors, fumes and other adverse impacts of Tenant's exhaust stream (as Landlord may designate in Landlord's discretion). Tenant shall install additional

equipment as Landlord requires from time to time under the preceding sentence. Such installations shall constitute Alterations.

21.5. If Tenant fails to install satisfactory odor control equipment within ten (10) business days after Landlord's demand made at any time, then Landlord may, without limiting Landlord's other rights and remedies, require Tenant to cease and suspend any operations in the Premises that, in Landlord's determination, cause odors, fumes or exhaust. For example, if Landlord determines that Tenant's production of a certain type of product causes odors, fumes or exhaust, and Tenant does not install satisfactory odor control equipment within ten (10) business days after Landlord's request, then Landlord may require Tenant to stop producing such type of product in the Premises unless and until Tenant has installed odor control equipment satisfactory to Landlord.

22. Insurance; Waiver of Subrogation.

22.1. Landlord shall maintain Commercial Property insurance for the Building and the Property in amounts equal to full replacement cost (exclusive of the costs of excavation, foundations and footings, engineering costs or such other costs to the extent the same are not incurred in the event of a rebuild and without reference to depreciation taken by Landlord upon its

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books or tax returns) or such lesser coverage as Landlord may elect, provided that such coverage shall not be less than the amount of such insurance Landlord's Lender, if any, requires Landlord to maintain, providing protection against any peril generally included within the classification "All-Risk" or "Special Form" subject to

standard terms, conditions, limitations and exclusions. Landlord, subject to availability thereof, shall further insure, if Landlord deems it appropriate, coverage against flood, environmental hazard, earthquake, loss or failure of building equipment, rental loss during the period of repairs or rebuilding. Landlord's insurance shall also cover the Tenant Improvements to the extent constructed by Landlord or paid for by Landlord, but shall not cover any other improvements installed by Tenant, any Alterations or Tenant's business or personal property.

22.2. In addition, Landlord shall carry Commercial General Liability insurance with limits of not less than One Million Dollars (\$1,000,000) per occurrence and One Million Dollars (\$1,000,000) general annual aggregate for bodily injury (including death), or property damage with respect to third-party liability occurring in, on or about the Property, but only to the extent caused by Landlord's negligence.

22.3. Tenant shall, at its own cost and expense, including any policy deductible or self-insured retentions, procure and maintain beginning on the Term Commencement Date or the date of occupancy (including, without limitation, occupancy for the purpose of Tenant constructing any Tenant Improvements), whichever occurs first, and continuing throughout the Term, or such other period as specified herein, insurance for the benefit of Tenant and Landlord (as their interests may appear) as specified in Exhibit H attached hereto.

22.4. The Commercial General Liability, Auto Liability, Liquor Liability (if required), Umbrella/Excess Liability and Pollution Legal Liability insurance required to be purchased and maintained by Tenant pursuant to this Lease and as specified in Exhibit B-1 attached hereto shall name the Landlord Parties (as defined below) and any other entity from time to time designated by Landlord as additional insureds for both ongoing and completed operations as respects liability arising from work or operations performed by or on behalf of Tenant and Tenant's use or occupancy of the Premises, and

ownership, maintenance or use of vehicles by or on behalf of Tenant.. The insurance required of Tenant by this Article shall be with companies authorized to do business in the state in which the Property is located and at all times having a current rating of not less than A- and financial category rating of at least Class VII in "A.M. Best's Insurance Guide" current edition. Tenant shall obtain for Landlord from the insurance companies/broker or cause the insurance companies/broker to furnish certificates of insurance attaching key endorsements including but not limited to additional insured, waiver of subrogation and notice of cancellation evidencing all coverages required herein to Landlord prior to the Term Commencement Date or any earlier entry upon the Premises by Tenant. Landlord reserves the right to require complete, certified copies of all required insurance policies including any endorsements. No such policy shall be cancelable, non-renewed or subject to reduction of coverage or other modification or cancellation except after thirty (30) days' prior written notice to Landlord from the insurer (except in the event of non-payment of premium, in which case ten (10) days' written notice shall be given). Should the carrier be unwilling or unable to provide such notice, Tenant shall provide notice to Landlord in accordance with this Section. All such policies, whether in the form of primary or umbrella/excess insurance, shall be written as primary policies, not contributing with and not in excess of the coverage that Landlord may carry. Tenant's required

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policies shall contain severability of interests clauses stating that, except with respect to limits of insurance, coverage shall apply separately to each insured or additional insured. All of Tenant's required policies shall provide waiver of subrogation and all rights of recovery in favor of the Landlord Parties. Tenant shall, at least

ten (10) days prior to the expiration of such policies, furnish Landlord with renewal certificates of insurance or binders. Tenant agrees that if Tenant does not take out and maintain such insurance, Landlord may (but shall not be required to) procure such insurance on Tenant's behalf and at its cost to be paid by Tenant as Additional Rent. If any Tenant policies are written on a claims-made policy form, those coverages shall have a retroactive date not later than the Term Commencement Date and Tenant shall, at Tenant's sole cost and expense, including any policy deductibles or self-insured retentions, either maintain these coverages satisfying the foregoing requirements, or secure "tail" or extended reporting coverage if any claims-made insurance is cancelled or not renewed.

22.5. In each instance where insurance is to name Landlord Indemnitees and other entities designated by Landlord as additional insureds (collectively, the "Landlord Parties"), Tenant shall, upon Landlord's written request, also designate and furnish certificates of insurance evidencing such Landlord Parties as additional insureds to (a) any Lender of Landlord holding a security interest in the Building or the Property, (b) the landlord under any lease whereunder Landlord is a tenant of the Property if the interest of Landlord is or shall become that of a tenant under a ground lease rather than that of a fee owner and (c) any management company retained by Landlord to manage the Property.

22.6. Tenant assumes the risk of damage to any fixtures, goods, inventory, merchandise, equipment, leasehold improvements and personal property, and Landlord shall not be liable for injury to Tenant's business or any loss of income therefrom, relative to such damage, all as more particularly set forth within this Lease. Tenant shall, at Tenant's sole cost and expense, carry such insurance as Tenant desires for Tenant's protection with respect to business or personal property of Tenant or business interruption. Landlord shall have no obligation to insure Tenant's business interruption exposure.

22.7. Anything in this Lease to the contrary notwithstanding, to the full extent permitted by law,

Tenant hereby waives, and shall cause its insurers to waive, any and all rights of recovery, claim, action or cause of action, against Landlord and the Landlord Parties for any loss or damage that may occur to the Premises, any improvements thereto, or any personal property of Tenant, by reason of fire, the elements, or any other cause to the extent such loss or damage is covered, or, under the terms of this Lease, required to be covered, by the terms of a commercial property insurance policy with "all risk" or special causes of loss coverage in effect at the time of such loss regardless of cause or origin, including negligence of Landlord or any of the Landlord Parties, and covenants that no insurer shall hold any right of subrogation against Landlord or any of the Landlord Parties. Tenant will cause its insurers to issue appropriate waiver of subrogation rights endorsements to all policies of commercial property insurance carried in connection with the Premises. Anything in this Lease to the contrary notwithstanding, to the full extent permitted by law, Landlord hereby waives, and shall cause its insurers to waive, any and all rights of recovery, claim, action or cause of action, against Tenant, its agents or employees, for any loss or damage that may occur to the Building, any improvements thereto, or any personal property of Landlord, by reason of fire, the elements or any other cause to the extent such loss or damage is covered or, under the terms of this Lease, required to be covered, by the terms of a valid and collectible

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commercial property insurance policy with "all risk" or special causes of loss coverage in effect at the time of such loss regardless of cause or origin, including negligence of Tenant, its agents or employees, and covenants that no insurer shall hold any right of subrogation against Tenant, its agents or employees. Landlord will cause its insurers to issue appropriate

waiver of subrogation rights endorsements to all policies of commercial property insurance policy with special causes of loss coverage carried in connection with the Property.

22.8. Landlord, from time to time, may require insurance policy limits required under this Lease to be raised to conform with requirements of Landlord's Lender or to bring coverage limits to levels then being required of new tenants within the Property.

22.9. Any costs incurred by Landlord pursuant to this Article shall constitute a portion of Operating Expenses, including the insurance premiums and costs of any policies required to be carried under this Article or that Landlord elects or is otherwise required to carry in connection with its ownership, operation and management of the Property.

22.10. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

23. **Damage or Destruction.**

23.1. In the event of a partial destruction of (a) the Premises or (b) Common Area of the Building or the Property ((a) and (b) together, the "Affected Areas") by fire or other perils covered by extended coverage insurance not exceeding twenty-five percent (25%) of the full insurable value of the Premises or the Building, and provided that (x) the damage thereto is such that the Affected Areas may be repaired, reconstructed or restored within a period of six (6) months from the date of the happening of such casualty, (y) Landlord shall receive insurance proceeds sufficient to cover the cost of such repairs, reconstruction and restoration (except for any deductible amount provided by Landlord's policy, which deductible amount, if paid by Landlord, shall constitute an Operating Expense) and (z) such casualty was not intentionally caused by a Tenant Party, then Landlord shall commence and proceed diligently with the work of repair, reconstruction and restoration of the Affected Areas and this Lease shall continue in full force and effect.



23.2. In the event of any damage to or destruction of the Building or the Property other than as described in Section 23.1, Landlord may elect to repair, reconstruct and restore the Building or the Property, as applicable, in which case this Lease shall continue in full force and effect. If Landlord elects not to repair, reconstruct and restore the Building or the Property, as applicable, then, at Landlord's election by written notice to Tenant, this Lease shall terminate as of the date of such notice from Landlord.

23.3. Upon any termination of this Lease under any of the provisions of this Article, the parties shall be released thereby without further obligation to the other from the date possession of the Premises is surrendered to Landlord, except with regard to (a) items occurring and obligations accruing prior to the damage or destruction, and (b) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

23.4. In the event of repair, reconstruction and restoration as provided in this Article, all Rent to be paid by Tenant under this Lease shall be abated proportionately based on the extent to

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which Tenant's use of the Premises is impaired during the period of such repair, reconstruction or restoration, unless Landlord provides Tenant with other space during the period of repair, reconstruction and restoration that, in Tenant's reasonable opinion, is suitable for the temporary conduct of Tenant's business; provided, however, that the amount of such abatement shall be reduced by the amount of Rent that is received by Tenant as part of the business interruption or loss of rental income with respect to the Premises from the

proceeds of business interruption or loss of rental income insurance.

23.5. If Landlord is obligated to or elects to repair, reconstruct or restore as herein provided, then Landlord shall be obligated to make such repairs, reconstruction or restoration only with regard to (a) those portions of the Premises that were originally provided at Landlord's expense and (b) the Common Area portion of the Affected Areas. The repairs, reconstruction or restoration of improvements not originally provided by Landlord or at Landlord's expense, including, but not limited to, any Alterations, shall be the obligation of Tenant. Landlord's obligation, should it elect or be obligated to repair, reconstruct or restore, shall be conditioned upon Landlord receiving any permits or authorizations required by Applicable Laws.

23.6. Notwithstanding anything to the contrary contained in this Article, Landlord shall not have any obligation whatsoever to repair, reconstruct or restore the Premises if the damage resulting from any casualty covered under this Article occurs during the last twenty-four (24) months of the Term or any extension thereof, or to the extent that insurance proceeds are not available therefor.

23.7. Tenant shall, at its expense, replace or fully repair all of Tenant's personal property, all improvements not originally provided by Landlord or at Landlord's expense, and any Alterations installed by Tenant existing at the time of such damage or destruction. If Affected Areas are to be repaired, reconstructed or restored in accordance with the foregoing, Landlord shall make available to Tenant any portion of insurance proceeds it receives that are allocable to the improvements not originally provided by Landlord or at Landlord's expense and Alterations constructed by Tenant pursuant to this Lease; provided Tenant is not then in default under this Lease, and subject to the requirements of any Lender or mortgagee of Landlord. If any casualty event results in a hazardous condition at the Affected Areas due to Tenant's activities at or use of the Premises, including radioactive or

biological contamination, then Tenant shall be responsible for addressing such hazardous condition at its sole expense and making the Affected Areas safe for Landlord and its employees, agents and contractors, and Landlord's restoration obligations or any abatement of Rent resulting from such casualty shall be tolled until the Affected Areas are safe for Landlord and its employees, agents and contractors to commence restoration work in the Affected Areas.

23.8. This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any damage or destruction.

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24. **Eminent Domain.**

24.1. In the event (a) the whole of the Premises or (b) such part thereof as shall substantially interfere with Tenant's use and occupancy of the Premises for the Permitted Use shall be taken for any public or quasi-public purpose by any lawful power or authority by exercise of the right of appropriation, condemnation or eminent domain, or sold or conveyed to prevent such taking, Tenant or Landlord may terminate this Lease effective as of the date possession is required to be surrendered to such authority, except with regard to (y) items occurring or obligations accruing prior to the taking and (z) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

24.2. In the event of a partial taking of (a) the Building or the Property or (b) drives, walkways or parking areas serving the Building or the Property for

any public or quasi-public purpose by any lawful power or authority by exercise of right of appropriation, condemnation, or eminent domain, or sold or conveyed to prevent such taking, then, without regard to whether any portion of the Premises occupied by Tenant was so taken, Landlord may elect to terminate this Lease (except with regard to (y) items occurring or obligations accruing prior to the taking and (z) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof) as of such taking if such taking is, in Landlord's sole opinion, of a material nature such as to make it uneconomical to continue use of the unappropriated portion for their intended purposes.

24.3. Tenant shall be entitled to any award that is specifically awarded as compensation for (a) the taking of Tenant's personal property that was installed at Tenant's expense and (b) the costs of Tenant moving to a new location. Except as set forth in the previous sentence, any award for such taking shall be the property of Landlord.

24.4. If, upon any taking of the nature described in this Article, this Lease continues in effect, then Landlord, to the extent of the award received by Landlord, shall promptly proceed to restore any damage to the remainder of the improvements resulting from the taking to substantially their same condition prior to such partial taking. To the extent such restoration is infeasible, as determined by Landlord in its sole and absolute discretion, the Rent shall be decreased proportionately to reflect the loss of any portion of the Premises no longer available to Tenant.

24.5. This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any damage or destruction.

25. Surrender.

25.1. At least ten (10) days prior to Tenant's surrender of any part of the Premises, Landlord may conduct a site inspection with Tenant.

25.2. No surrender of possession of any part of the Premises shall release Tenant from any of its obligations hereunder, unless such surrender is accepted in writing by Landlord.

25.3. The voluntary or other surrender of this Lease by Tenant shall not effect a merger with Landlord's fee title or leasehold interest in the Premises, the Building, the Property or the

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Property, unless Landlord consents in writing, and shall, at Landlord's option, operate as an assignment to Landlord of any or all subleases.

25.4. The voluntary or other surrender of any ground lease, master lease, or other underlying lease that now exists or may hereafter be executed affecting the Building or the Property, or a mutual cancellation thereof or of Landlord's interest therein by Landlord and its lessor shall not effect a merger with Landlord's fee title or leasehold interest in the Premises, the Building or the Property and shall, at the option of the successor to Landlord's interest in the Building or the Property, as applicable, operate as an assignment of this Lease.

26. **Holding Over.**

26.1. If, with Landlord's prior written consent, Tenant holds possession of all or any part of the Premises after the Term, Tenant shall become a tenant from month to month after the expiration or earlier termination of the Term, and in such case Tenant shall continue to pay (a) Base Rent in accordance with Article Z, as adjusted in accordance with the provisions of this

Lease, and (b) any amounts for which Tenant would otherwise be liable under this Lease if the Lease were still in effect, including payments for Tenant's Pro Rata Share of Operating Expenses and electricity and other utility costs. Any such month-to-month tenancy shall be subject to every other term, covenant and agreement contained herein.

26.2. Notwithstanding the foregoing, if Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without Landlord's prior written consent,

(a) Tenant shall become a tenant at sufferance subject to the terms and conditions of this Lease, except that the monthly Base Rent shall be equal to one hundred fifty percent (150%) of the Base Rent in effect during the last thirty (30) days of the Term, and (b) Tenant shall be liable to Landlord for any and all damages suffered by Landlord as a result of such holdover, including any lost rent or consequential, special and indirect damages (in each case, regardless of whether such damages are foreseeable).

26.3. Acceptance by Landlord of Rent after the expiration or earlier termination of the Term shall not result in an extension, renewal or reinstatement of this Lease.

26.4. The foregoing provisions of this Article are in addition to and do not affect Landlord's right of reentry or any other rights of Landlord hereunder or as otherwise provided by Applicable Laws.

26.5. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

**27. Indemnification and Exculpation.**

27.1. Tenant agrees to indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord) and hold Landlord, the entities listed on Exhibit E hereto, the Property Manager, and their respective officers, directors, employees, agents, general partners, members, subsidiaries, affiliates; and

any lender, mortgagee, ground lessor, master landlord, beneficiary, historic tax credit investor, and New Markets tax credit investors (each, a "Lender")

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and, collectively with all of the foregoing, collectively, the "Landlord Indemnitees") harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages, suits or judgments, real or alleged, and all reasonable expenses (including reasonable attorneys' fees, charges and disbursements, regardless of whether the applicable demand, claim, action, cause of action or suit is voluntarily withdrawn or dismissed) incurred in investigating or resisting the same of any kind or nature that arise before, during or after the Term (collectively, "Claims") arising from (a) injury to or death of any person or damage to any property occurring within or about the Premises, the Building or the Property, arising directly or indirectly out of (i) the presence at or use or occupancy of the Premises or Property by a Tenant Party, or (ii) an act or omission on the part of any Tenant Party; (b) a breach or default by Tenant in the performance of any of its obligations hereunder, including, without limitation, any breach by Tenant of its obligations under Section 11.2 or Section 11.12; (c) injury to or death of persons or damage to or loss of any property, real or alleged, arising from the serving of alcoholic beverages at the Premises or the Property, including liability under any dram shop law, host liquor law or similar Applicable Law; (d) any liens referenced in Section 18.1 and any Claims arising from such liens, including administrative, court or other legal proceedings relate to such liens; (e) any failure to obtain waiver of subrogation endorsements to Tenant's insurance as required under Article 22, or (f) any Claim for compensation by any broker or agent, other than the Brokers, employed or engaged by Tenant or claiming to have been employed or engaged by Tenant in connection

with this Lease or the leasing of the Premises to Tenant, all except to the extent directly caused by Landlord's gross negligence or willful misconduct. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation or the amount of insurance maintained or required to be obtained by Tenant hereunder or in connection with this Lease or the Premises. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease.

27.2. Notwithstanding anything in this Lease to the contrary, Landlord shall not be liable to Tenant for and Tenant assumes all risk of (a) damage or losses caused by fire, electrical malfunction, gas explosion or water damage of any type (including broken water lines, malfunctioning fire sprinkler systems, roof leaks or stoppages of lines), unless any such loss is due to Landlord's willful disregard of written notice by Tenant of need for a repair that Landlord is responsible to make for an unreasonable period of time, and (b) damage to personal property or scientific research, including loss of records kept by Tenant within the Premises (in each case, regardless of whether such damages are foreseeable). To the extent Landlord provides security to the Common Areas, Landlord does not warrant the efficacy of any such security personnel, services, procedures or equipment. Landlord shall not be responsible for or liable in any manner for failure of any such security personnel, services, procedures or equipment to prevent or control, or apprehend anyone suspected of, personal injury or property damage in, on or around the Project. Tenant further waives any claim for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property as described in this Section. Landlord may elect to install a wifi or similar system that is intended to provide access to the internet for infrequent use by occupants and invitees of the Common Area. Such a system will not be intended for use on a regular basis by



anyone, whether in the Common Areas or other portions of the Building, and should not be relied on by Tenant or its employees or invitees for access to the internet.  
Landlord

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makes no representations or warranties as to the availability of any such system, its fitness for any purpose or any other representations or warranties as to such system.

27.3. Notwithstanding anything in the foregoing or this Lease to the contrary, except (x) as otherwise provided in this Article 27, (y) as may be provided by Applicable Laws, or (z) in the event of Tenant's breach of Article 20 or Article 26, in no event shall Landlord or Tenant be liable to the other for any consequential, special or indirect damages arising out of this Lease, including lost profits (provided that this sentence shall not limit Tenant's liability for Base Rent or Additional Rent pursuant to this Lease).

27.4. Landlord shall not be liable for any damages arising from any act, omission or neglect of any other tenant in the Building or the Property, or of any other third party.

27.5. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

28. Assignment or Subletting.

28.1. Except to the extent, if any, expressly permitted by this Article, none of the following (each, a "Transfer"), either voluntarily or by operation of Applicable Laws, shall be directly or indirectly performed, without Landlord's prior written consent, not to be unreasonably withheld, conditioned or delayed: (a) Tenant selling, hypothecating, assigning, pledging, encumbering or otherwise transferring this Lease or

subletting the Premises or any portion thereof or (b) a controlling interest in Tenant being sold, assigned or otherwise transferred (other than as a result of shares in Tenant being sold on a public stock exchange). For purposes of the preceding sentence, "control" means (a) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person or (b) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. In no event shall Tenant perform a Transfer to or with an entity that is a tenant at the Property or that is in discussions or negotiations with Landlord or an affiliate of Landlord to lease premises comparable to the space being offered by Tenant at the Property or a property in the vicinity of the Property owned by Landlord or an affiliate of Landlord.

28.2. In the event Tenant desires to effect a Transfer, then, at least fifteen (15) but not more than ninety (90) days prior to the date when Tenant desires the Transfer to be effective (the "Transfer Date"), Tenant shall provide written notice to Landlord (the "Transfer Notice") containing information (including references) concerning the character and business experience of the proposed transferee, assignee or sublessee; the Transfer Date; the most recent unconsolidated financial statements of Tenant and of the proposed transferee, assignee or sublessee satisfying the requirements of Section 39 ("Required Financials"); any ownership or commercial relationship between Tenant and the proposed transferee, assignee or sublessee; any intended change in the use or operation of the Premises; and the consideration and all other material terms and conditions of the proposed Transfer, all in such detail as Landlord shall reasonably require. In addition, upon request from Landlord, Tenant shall provide such additional information regarding the Transfer and the proposed transferee as Landlord may reasonably require.

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28.3. Landlord, in determining whether consent should be given to a proposed Transfer, may give consideration to (a) the financial strength of Tenant and of such transferee, assignee or sublessee (taking into account Tenant remaining liable for Tenant's performance), (b) any change in use that such transferee, assignee or sublessee proposes to make in the use of the Premises, (c) the relevant business experience of the proposed assignee, transferee or sublessee, (d) any incident of Hazardous Materials contamination with which the proposed transferee was involved, and (e) Landlord's desire to exercise its rights under Section 28.8 to cancel this Lease. In no event shall Landlord be deemed to be unreasonable for declining to consent to a Transfer to a transferee, assignee or sublessee of poor reputation, lacking financial qualifications, having been involved in a previous incident of Hazardous Materials contamination, or seeking a change in the Permitted Use, or jeopardizing directly or indirectly the status of Landlord or any of Landlord's affiliates as a Real Estate Investment Trust under the Internal Revenue Code of 1986 (as the same may be amended from time to time, the "Revenue Code"). Notwithstanding anything contained in this Lease to the contrary, (w) no Transfer shall be consummated on any basis such that the rental or other amounts to be paid by the occupant, assignee, manager or other transferee thereunder would be based, in whole or in part, on the income or profits derived by the business activities of such occupant, assignee, manager or other transferee; (x) Tenant shall not furnish or render any services to any other occupant of the Property, any assignee of Tenant's interest in this lease, any manager for the Property, or any other transferee of Tenant's interest in this lease; (y) Tenant shall not consummate a Transfer with any person in which Landlord owns an interest, directly or indirectly (by applying constructive ownership rules set forth in Section 856(d)(5) of the Revenue Code); and (z) Tenant shall not consummate a Transfer with any person or in any manner that could cause any portion of the amounts received by Landlord

pursuant to this Lease or any sublease, license or other arrangement for the right to use, occupy or possess any portion of the Premises to fail to qualify as "rents from real property" within the meaning of Section 856(d) of the Revenue Code, or any similar or successor provision thereto or which could cause any other income of Landlord to fail to qualify as income described in Section 856(c)(2) of the Revenue Code.

28.4. The following are conditions precedent to a Transfer or to Landlord considering a request by Tenant to a Transfer:

(a) Tenant shall reimburse Landlord for Landlord's actual but reasonable costs and expenses, including reasonable attorneys' fees, charges and disbursements incurred in connection with the review, processing and documentation of such request;

(b) If Tenant's Transfer provides for the receipt by, on behalf of or on account of Tenant of any consideration of any kind whatsoever (including a premium rental for a sublease or lump sum payment for an assignment, but excluding Tenant's reasonable costs in marketing and subleasing the Premises) in excess of the rental and other charges due to Landlord under this Lease, Tenant shall pay fifty percent (50%) of all of such excess to Landlord, after making deductions for any reasonable marketing expenses, tenant improvement funds expended by Tenant, alterations, brokerage commissions, attorneys' fees and free rent actually paid by Tenant. If such consideration consists of cash paid to Tenant, payment to Landlord shall be made upon receipt by Tenant of such cash payment;

(c) The proposed transferee, assignee or sublessee shall agree that, in the event Landlord gives such proposed transferee, assignee or sublessee notice that Tenant is in default

under this Lease, such proposed transferee, assignee or sublessee shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments shall be received by Landlord without any liability being incurred by Landlord, except to credit such payment against those due by Tenant under this Lease, and any such proposed transferee, assignee or sublessee shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, that in no event shall Landlord or its Lenders, successors or assigns be obligated to accept such attornment;

(d) Landlord's consent to any such Transfer shall be effected on Landlord's forms with commercially reasonable edits;

(e) Tenant shall not then be in Default hereunder in any respect;

(f) Such proposed transferee, assignee or sublessee's use of the Premises and the Property shall be such as to comply with each of the terms and conditions of this Lease, including, but not limited to, the Permitted Use and the provisions limiting Transfers;

(g) Landlord shall not be bound by any provision of any agreement between the Tenant and the transferee pertaining to the Transfer, except for Landlord's written consent to the same;

(h) Tenant shall pay all transfer and other taxes (including interest and penalties) assessed or payable for any Transfer;

(i) Tenant shall deliver to Landlord one executed copy of any and all written instruments evidencing or relating to the Transfer; and

(j) Tenant shall deliver to Landlord a list of any Hazardous Materials, certified by the proposed transferee, assignee or sublessee to be true and correct, that the proposed transferee, assignee or sublessee intends to use or store in the Premises.

28.5. Any Transfer that is not in compliance with the provisions of this Article or with respect to which Tenant does not fulfill its obligations pursuant to this Article shall be void.

28.6. The consent by Landlord to (or the waiver of its rights as to) a Transfer shall not relieve Tenant or proposed transferee, assignee or sublessee from obtaining Landlord's consent to any further Transfer, nor shall it release Tenant or any proposed transferee, assignee or sublessee of Tenant from full and primary liability under this Lease.

28.7. Notwithstanding any Transfer, Tenant and any Guarantor shall remain fully and primarily liable for the payment of all Rent and other sums due or to become due hereunder and under any Guaranty, and for the full performance of all other terms, conditions and covenants to be kept and performed by Tenant and/or the Guarantor. The acceptance of Rent or any other sum due hereunder, or the acceptance of performance of any other term, covenant or condition thereof, from any person or entity other than Tenant shall not be deemed a waiver of any of the provisions of this Lease or a consent to any Transfer. Tenant agrees that it shall not be (and shall not be deemed to be) a guarantor or surety of this Lease, however, and waives its right to claim that is it

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is a guarantor or surety or to raise in any legal proceeding any guarantor or surety defenses permitted by this Lease or by Applicable Laws.

28.8. If Tenant delivers to Landlord a Transfer Notice indicating a desire to transfer this Lease to a proposed transferee, assignee or sublessee, then Landlord shall have the option, exercisable by giving notice to Tenant at any time within ten (10) days after

Landlord's receipt of such Transfer Notice, to terminate this Lease solely as to the portion of the Premises subject to the Transfer, as of the date specified in the Transfer Notice as the Transfer Date, except for those provisions that, by their express terms, survive the expiration or earlier termination hereof. If Landlord exercises such option, then Tenant shall have the right to withdraw such Transfer Notice by delivering to Landlord written notice of such election within five (5) days after Landlord's delivery of notice electing to exercise Landlord's option to terminate this Lease. In the event Tenant withdraws the Transfer Notice as provided in this Section, this Lease shall continue in full force and effect. No failure of Landlord to exercise its option to terminate this Lease shall be deemed to be Landlord's consent to a proposed Transfer.

28.9. If Tenant sublets the Premises or any portion thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and appoints Landlord as assignee and attorney-in-fact for Tenant, and Landlord (or a receiver for Tenant appointed on Landlord's application) may collect such rent and apply it toward Tenant's obligations under this Lease; provided that, until the occurrence of a Default by Tenant, Tenant shall have the right to collect such rent.

29. **Subordination and Attornment.**

29.1. This Lease shall be subject and subordinate to the lien of any mortgage, deed of trust, or ground or master lease in which Landlord is tenant now or hereafter in force against the Building or the Property and to all advances made or hereafter to be made upon the security thereof without the necessity of the execution and delivery of any further instruments on the part of Tenant to effectuate such subordination.

29.2. Notwithstanding the foregoing, Tenant shall execute and deliver upon demand such further instrument or instruments evidencing such subordination of this Lease to the lien of any such mortgage or mortgages or deeds of trust or lease in

which Landlord is tenant as may be required by Landlord. If any such mortgagee, beneficiary or landlord under a lease wherein Landlord is tenant (each, a "Mortgagee") so elects, however, this Lease shall be deemed prior in lien to any such lease, mortgage, or deed of trust upon or including the Premises regardless of date and Tenant shall execute a statement in writing to such effect at Landlord's request. If Tenant fails to execute any document required from Tenant under this Section within ten (10) days after written request therefor, Tenant hereby constitutes and appoints Landlord or its special attorney-in-fact to execute and deliver any such document or documents in the name of Tenant. Such power is coupled with an interest and is irrevocable.

29.3. Upon written request of Landlord, Tenant agrees to execute any Lease amendments not materially altering the terms of this Lease, if required by a Mortgagee incident to the financing of the real property of which the Premises constitute a part.

29.4. In the event any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by Landlord covering the Premises, Tenant shall at the election of the purchaser at such foreclosure or sale attorn to the purchaser upon any such foreclosure or sale and recognize such purchaser as Landlord under this Lease.

30. **Defaults and Remedies.**

30.1. Late payment by Tenant to Landlord of Rent and other sums due shall cause Landlord to incur costs not contemplated by this Lease, the exact amount of which shall be extremely difficult and impracticable to ascertain. Such costs include processing and accounting



charges and late charges that may be imposed on Landlord by the terms of any mortgage or trust deed covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within five (5) days after the date such payment is due, Tenant shall pay to Landlord (a) an additional sum of five percent (5%) of the overdue Rent as a late charge plus (b) interest at an annual rate (the “Default Rate”) equal to the lesser of (a) twelve percent (12%) and (b) the highest rate permitted by Applicable Laws. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Landlord shall incur by reason of late payment by Tenant and shall be payable as Additional Rent to Landlord due with the next installment of Rent or within five (5) business days after Landlord’s demand, whichever is earlier. Landlord’s acceptance of any Additional Rent (including a late charge or any other amount hereunder) shall not be deemed an extension of the date that Rent is due or prevent Landlord from pursuing any other rights or remedies under this Lease, at law or in equity.

30.2. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent payment herein stipulated shall be deemed to be other than on account of the Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord’s right to recover the balance of such Rent or pursue any other remedy provided in this Lease or in equity or at law. If a dispute shall arise as to any amount or sum of money to be paid by Tenant to Landlord hereunder, Tenant shall have the right to make payment “under protest,” such payment shall not be regarded as a voluntary payment, and there shall survive the right on the part of Tenant to institute suit for recovery of the payment paid under protest.

30.3. If Tenant fails to pay any sum of money required to be paid by it hereunder or perform any other act on its part to be performed hereunder, in each case within the applicable cure period (if any) described in Section 30.4, then Landlord may (but shall not be

obligated to), without waiving or releasing Tenant from any obligations of Tenant, make such payment or perform such act without being liable to prosecution of any claim for damages and Landlord not being liable for any damages resulting to Tenant from such action whether caused by the negligence of Landlord, its agents, employees or contractors or otherwise. Notwithstanding the foregoing, in the event of an emergency, Landlord shall have the right to enter the Premises and act in accordance with its rights as provided elsewhere in this Lease. In addition to the late charge described in Section 30.1, Tenant shall pay to Landlord as Additional Rent all sums so paid or incurred by Landlord, together with interest at the Default Rate, computed from the date such sums were paid or incurred.

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30.4. The occurrence of any one or more of the following events shall constitute a “Default” hereunder by Tenant:

- (a) Intentionally Omitted;
- (b) Tenant fails to make any payment of Rent, as and when due, or to satisfy its obligations under Article 18, where such failure shall continue for a period of five (5) days after written notice thereof from Landlord to Tenant;
- (c) Tenant or any Guarantor makes an assignment for the benefit of creditors;
- (d) A receiver, trustee or custodian is appointed to or does take title, possession or control of all or substantially all of Tenant’s or any Guarantor’s assets;

(e) Tenant or any Guarantor files a voluntary petition under the United States Bankruptcy Code or any successor statute (as the same may be amended from time to time, the "Bankruptcy Code") or an order for relief is entered against Tenant or any Guarantor (as applicable) pursuant to a voluntary or involuntary proceeding commenced under any chapter of the Bankruptcy Code;

(f) Any involuntary petition is filed against Tenant or any Guarantor under any chapter of the Bankruptcy Code and is not dismissed within one hundred twenty (120) days;

(g) A default exists under any other lease, license agreement, early occupancy agreement or right of entry by and between Tenant or any affiliate of Tenant and Landlord or any affiliate of Landlord which is not cured within any notice and cure period provided therein;

(h) A default exists under the Guaranty, if any, given by any Guarantor in favor of Landlord, after the expiration of any applicable notice and cure periods provided therein;

(i) Tenant fails to deliver an estoppel certificate in accordance with Article 19;

(j) Tenant's interest in this Lease is attached, executed upon or otherwise judicially seized and such action is not released within one hundred twenty (120) days of the action;

(k) Tenant fails to satisfy its obligations under Article 22, where such failure shall continue for a period of ten (10) days after written notice thereof from Landlord to Tenant; or

(l) Tenant fails to observe or perform any obligation or covenant contained herein (other than those described in (a) through (k) above) to be performed by Tenant, where such failure continues for a period of thirty (30) days after written notice thereof from Landlord to Tenant; provided that, if the nature of

Tenant's default is such that it reasonably requires more than thirty (30) days to cure, Tenant shall not be deemed to be in Default if Tenant commences such cure within such thirty (30) day period and thereafter diligently prosecutes the same to completion; and provided, further, that such cure is completed no later than sixty (60) days after Tenant's receipt of written notice from Landlord.

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No notice of default or notice to quit shall be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice.

30.5. In the event of a Default by Tenant, and at any time thereafter, with or without notice or demand and without limiting Landlord in the exercise of any right or remedy that Landlord may have, Landlord has the right to do any or all of the following:

(a) Halt any Tenant Improvements and Alterations and order Tenant's contractors, subcontractors, consultants, designers and material suppliers to stop work and cease funding any TI Allowance;

(b) Terminate Tenant's right to possession of the Premises with or without termination of this Lease by written notice to Tenant or by any lawful means, in which case Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby; and

(c) Terminate this Lease, in which event Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby. In the event that Landlord shall elect to so terminate this Lease, then Landlord shall be entitled to recover from Tenant all damages incurred by Landlord by reason of Tenant's Default, including:

(i)The sum of:

A.The worth at the time of award of any unpaid Rent that had accrued at the time of such termination; plus

B.The worth at the time of award of the amount by which the unpaid Rent that would have accrued during the period commencing with termination of the Lease and ending at the time of award exceeds that portion of the loss of Landlord's rental income from the Premises that Tenant proves to Landlord's reasonable satisfaction could have been reasonably avoided; plus

C.The worth at the time of award of the amount by which the unpaid Rent for the balance of the Term after the time of award exceeds that portion of the loss of Landlord's rental income from the Premises that Tenant proves to Landlord's reasonable satisfaction could have been reasonably avoided; plus

D.Any other amount necessary to compensate Landlord for all the detriment caused by Tenant's failure to perform its obligations under this Lease or that in the ordinary course of things would be likely to result therefrom, including the cost of restoring the

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Premises to the condition required under the terms of this Lease, including any rent payments not otherwise chargeable to Tenant (e.g., during any “free” rent period or rent holiday); plus

E. At Landlord’s election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Applicable Laws; or

(ii) At Landlord’s election, as minimum liquidated damages in addition to any (A) amounts paid or payable to Landlord pursuant to Section 30.5(c)(i)(A) prior to such election and (B) costs of restoring the Premises to the condition required under the terms of this Lease, an amount (the “Election Amount”) equal to the positive difference (if any, and measured at the time of such termination) between (1) the then-present value of the total Rent and other benefits that would have accrued to Landlord under this Lease for the remainder of the Term if Tenant had fully complied with the Lease minus (2) the then-present cash rental value of the Premises as determined by Landlord for what would be the then-unexpired Term if the Lease remained in effect, computed using the discount rate of the Federal Reserve Bank of Chicago at the time of the award plus one (1) percentage point (the “Discount Rate”). Landlord and Tenant agree that the Election Amount represents a reasonable forecast of the minimum damages expected to occur in the event of a breach, taking into account the uncertainty, time and cost of determining elements relevant to actual damages, such as fair market rent, time and costs that may be required to re-lease the Premises, and other factors; and that the Election Amount is not a penalty.

(iii) As used in Sections 30.5(c)(i)(A) and (B), “worth at the time of award” shall be computed by allowing interest at the Default Rate. As used in Section 30.5(c)(i)(C), the “worth at the time of the award” shall be

computed by taking the present value of such amount, using the Discount Rate.

30.6. In addition to any other remedies available to Landlord at law or in equity and under this Lease, Landlord may continue this Lease in effect after Tenant's Default or abandonment and recover Rent as it becomes due. In addition, Landlord shall not be liable in any way whatsoever for its failure or refusal to relet the Premises. For purposes of this Section, the following acts by Landlord will not constitute the termination of Tenant's right to possession of the Premises:

(a) Acts of maintenance or preservation or efforts to relet the Premises, including alterations, remodeling, redecorating, repairs, replacements or painting as Landlord shall consider advisable for the purpose of reletting the Premises or any part thereof; or

(b) The appointment of a receiver upon the initiative of Landlord to protect Landlord's interest under this Lease or in the Premises.

Notwithstanding the foregoing, in the event of a Default by Tenant, Landlord may elect at any time to terminate this Lease and to recover damages to which Landlord is entitled.

30.7. If Landlord does not elect to terminate this Lease as provided in Section 30.5, then Landlord may, from time to time, recover all Rent as it becomes due under this Lease. At any time thereafter, Landlord may elect to terminate this Lease and to recover damages to which Landlord is entitled.

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30.8. In the event Landlord elects to terminate this Lease and relet the Premises, Landlord may execute any new lease in its own name and Tenant shall pay to Landlord the cost of all storage charges or brokerage

commissions owing from Tenant to Landlord as the result of such reletting and the costs and expenses of reletting the Premises, including (i) alterations and repairs that Landlord deems reasonably necessary and advisable and (ii) reasonable attorneys' fees, charges and disbursements incurred by Landlord in connection with the retaking of the Premises and such reletting. Tenant hereunder shall have no right or authority whatsoever to collect any Rent from such tenant. The proceeds of any such reletting shall be applied as follows:

(a) First, to the payment of any indebtedness other than Rent due hereunder from Tenant to Landlord, including storage charges or brokerage commissions owing from Tenant to Landlord as the result of such reletting;

(b) Second, to the payment of the costs and expenses of reletting the Premises, including (i) alterations and repairs that Landlord deems reasonably necessary and advisable and (ii) brokerage commissions and reasonable attorneys' fees, charges and disbursements incurred by Landlord in connection with the retaking of the Premises and such reletting;

(c) Third, to the payment of Rent and other charges due and unpaid hereunder; and

(d) Fourth, to the payment of future Rent and other damages payable by Tenant under this Lease.

30.9. All of Landlord's rights, options and remedies hereunder shall be construed and held to be nonexclusive and cumulative. Landlord shall have the right to pursue any one or all of such remedies, or any other remedy or relief that may be provided by Applicable Laws, whether or not stated in this Lease. No waiver of any default of Tenant hereunder shall be implied from any acceptance by Landlord of any Rent or other payments due hereunder or any omission by Landlord to take any action on account of such default if such default persists or is repeated, and no express waiver shall affect defaults other than as specified in such waiver. Notwithstanding any provision of this Lease to the contrary, in no event shall Landlord be



required to mitigate its damages with respect to any default by Tenant, except as required by Applicable Laws. Any such obligation imposed by Applicable Laws upon Landlord to relet the Premises after any termination of this Lease shall be subject to the reasonable requirements of Landlord to (a) lease to high quality tenants on such terms as Landlord may from time to time deem appropriate in its discretion and (b) develop the Property in a harmonious manner with a mix of uses, tenants, floor areas, terms of tenancies, etc., as determined by Landlord. Landlord shall not be obligated to relet the Premises to (y) any Tenant's Affiliate or (z) any party (i) unacceptable to a Lender, (ii) that requires Landlord to make improvements to or re-demise the Premises, (iii) that desires to change the Permitted Use, (iv) that desires to lease the Premises for more or less than the remaining Term or (v) to whom Landlord or an affiliate of Landlord may desire to lease other available space in the Property or at another property owned by Landlord or an affiliate of Landlord, nor shall Landlord be obligated to provide any tenant improvements or other allowances.

30.10. Landlord's termination of (a) this Lease or (b) Tenant's right to possession of the Premises shall not relieve Tenant of any liability to Landlord that has previously accrued or that

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shall arise based upon events that occurred prior to the later to occur of (y) the date of Lease termination and (z) the date Tenant surrenders possession of the Premises.

30.11. To the extent permitted by Applicable Laws, Tenant waives any and all rights of redemption granted by or under any present or future Applicable Laws if Tenant is evicted or dispossessed for any cause, or if

Landlord obtains possession of the Premises due to Tenant's default hereunder or otherwise.

30.12. Landlord shall not be in default or liable for damages under this Lease unless Landlord fails to perform obligations required of Landlord within a reasonable time, but in no event shall such failure continue for more than thirty (30) days after written notice from Tenant specifying the nature of Landlord's failure; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for its performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion. In no event shall Tenant have the right to terminate or cancel this Lease, or to withhold or abate rent or to exercise any self-help to take any action on behalf of Landlord at law or in equity or to set off any Claims against Rent as a result of any default or breach by Landlord of any of its covenants, obligations, representations, warranties or promises hereunder, except as may otherwise be expressly set forth in this Lease.

30.13. In the event of any default by Landlord, Tenant shall give notice by registered or certified mail to any (a) beneficiary of a deed of trust or (b) mortgagee under a mortgage covering the Premises, the Building or the Property and to any landlord under a ground lease or master lease covering the Building or the Property, and shall offer such beneficiary, mortgagee or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Building or the Property by power of sale or a judicial action if such should prove necessary to effect a cure; provided that Landlord shall furnish to Tenant in writing, upon written request by Tenant, the names and addresses of all such persons who are to receive such notices.

31. **Bankruptcy.** In the event a debtor, trustee or debtor in possession under the Bankruptcy Code, or another person with similar rights, duties and powers under any other Applicable Laws, proposes to cure any

default under this Lease or to assume or assign this Lease and is obliged to provide adequate assurance to Landlord that (a) a default shall be cured, (b) Landlord shall be compensated for its damages arising from any breach of this Lease and (c) future performance of Tenant's obligations under this Lease shall occur, then such adequate assurances shall include any or all of the following, as designated by Landlord in its sole and absolute discretion:

31.1. Those acts specified in the Bankruptcy Code or other Applicable Laws as included within the meaning of "adequate assurance," even if this Lease does not concern a shopping center or other facility described in such Applicable Laws;

31.2. A prompt cash payment to compensate Landlord for any monetary defaults or actual damages arising directly from a breach of this Lease;

31.3. A cash deposit in an amount at least equal to the then-current amount of the Security Deposit; or

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31.4. The assumption or assignment of all of Tenant's interest and obligations under this Lease.

32. **Brokers.**

32.1. Tenant represents and warrants that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Lease other than Landlord's Broker and Tenant's Broker, if any (collectively, the "**Brokers**"), and that it knows of no other real estate broker or agent that is or might be entitled to a commission in connection with this Lease. Landlord shall compensate the Brokers in relation to this Lease pursuant to a separate written agreement between Landlord and Landlord's Broker.

32.2. Tenant represents and warrants that no broker or agent has made any representation or warranty relied upon by Tenant in Tenant's decision to enter into this Lease, other than as contained in this Lease.

32.3. Tenant acknowledges and agrees that the employment of brokers by Landlord is for the purpose of solicitation of offers of leases from prospective tenants and that no authority is granted to any broker to furnish any representation (written or oral) or warranty from Landlord unless expressly contained within this Lease. Landlord is executing this Lease in reliance upon Tenant's representations, warranties and agreements contained in this Article.

33. Definition of Landlord. With regard to obligations imposed upon Landlord pursuant to this Lease, the term "Landlord," as used in this Lease, shall refer only to Landlord or Landlord's then-current successor-in-interest. In the event of any transfer, assignment or conveyance of Landlord's interest in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, Landlord herein named (and in case of any subsequent transfers or conveyances, the subsequent Landlord) shall be automatically freed and relieved, from and after the date of such transfer, assignment or conveyance, from all liability for the performance of any covenants or obligations contained in this Lease thereafter to be performed by Landlord and, without further agreement, the transferee, assignee or conveyee of Landlord's interest in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, shall be deemed to have assumed and agreed to observe and perform any and all covenants and obligations of Landlord hereunder during the tenure of its interest in the Lease or the Property. Landlord or any subsequent Landlord may transfer its interest in the Premises or this Lease without Tenant's consent.

34. Limitation of Landlord's Liability.

34.1. If Landlord is in default under this Lease and, as a consequence, Tenant recovers a monetary judgment against Landlord, the judgment shall be satisfied only out of (a) the proceeds of sale received on execution of the judgment and levy against the right, title and interest of Landlord in the Building and the Property, (b) rent or other income from the Building and the Property receivable by Landlord or (c) the consideration received by Landlord from the sale, financing, refinancing or other disposition of all or any part of Landlord's right, title or interest in the Building or the Property.

34.2. Neither Landlord nor any of its affiliates, nor any of their respective partners, shareholders, directors, officers, employees, members or agents shall be personally liable for

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Landlord's obligations or any deficiency under this Lease, and service of process shall not be made against any shareholder, director, officer, employee or agent of Landlord or any of Landlord's affiliates. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be sued or named as a party in any suit or action, and service of process shall not be made against any partner or member of Landlord except as may be necessary to secure jurisdiction of the partnership, joint venture or limited liability company, as applicable. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be required to answer or otherwise plead to any service of process, and no judgment shall be taken or writ of execution levied against any partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates.

34.3. Each of the covenants and agreements of this Article shall be applicable to any covenant or agreement either expressly contained in this Lease or imposed by Applicable Laws and shall survive the expiration or earlier termination of this Lease.

35. **Joint and Several Obligations.** If more than one person or entity executes this Lease as Tenant, then:

35.1. Each of them is jointly and severally liable for the keeping, observing and performing of all of the terms, covenants, conditions, provisions and agreements of this Lease to be kept, observed or performed by Tenant, and such terms, covenants, conditions, provisions and agreements shall be binding with the same force and effect upon each and all of the persons executing this Agreement as Tenant; and

35.2. The term “Tenant,” as used in this Lease shall mean and include each of them, jointly and severally. The act of, notice from, notice to, refund to, or signature of any one or more of them with respect to the tenancy under this Lease, including any renewal, extension, expiration, termination or modification of this Lease, shall be binding upon each and all of the persons executing this Lease as Tenant with the same force and effect as if each and all of them had so acted, so given or received such notice or refund, or so signed.

36. **Representations.** Tenant warrants and represents that (a) Tenant is duly incorporated or otherwise established or formed and validly existing under the laws of its state of incorporation, establishment or formation, (b) Tenant has and is duly qualified to do business in the state in which the Property is located, (c) Tenant has full corporate, partnership, trust, association or other appropriate power and authority to enter into this Lease and to perform all Tenant’s obligations hereunder, (d) each person (and all of the persons if more than one signs) signing this Lease on behalf of Tenant is duly and validly authorized to do so and (e) neither (i) the execution, delivery or performance of this Lease nor (ii) the consummation of the transactions contemplated hereby will violate or conflict with any provision of

documents or instruments under which Tenant is constituted or to which Tenant is a party. In addition, Tenant warrants and represents that none of (x) it, (y) its affiliates or partners nor (z) to the best of its knowledge, its members, shareholders or other equity owners or any of their respective employees, officers, directors, representatives or agents is a person or entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control ("OFAC") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking

Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) or other similar governmental action. Tenant further represents and warrants that it is not and is not acting on behalf of (i) an "employee benefit plan" within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), (ii) a "plan" within the meaning of Section 4975 of the Internal Revenue Code of 1986, as amended, or (iii) an entity deemed to hold "plan assets" within the meaning of 29 C.F.R. §2510.3-101 of any such employee benefit plan or plans.

37. **Confidentiality.** Tenant shall keep the terms and conditions of this Lease and any information, plans or other materials provided to Tenant or its employees, agents or contractors pursuant to Article 4 or Article 8 or the Work Letter confidential and shall not (a) disclose to any third party any terms or conditions of this Lease or any other Lease-related document (including subleases, assignments, work letters, construction contracts, letters of credit, subordination agreements, non-disturbance agreements, brokerage agreements or

estoppels) or (b) provide to any third party an original or copy of this Lease (or any Lease-related document). Landlord shall not release to any third party any non-public financial information or non-public information about Tenant's ownership structure that Tenant gives Landlord. Notwithstanding the foregoing, confidential information under this Section may be released by Landlord or Tenant under the following circumstances: (w) if required by Applicable Laws or in any judicial proceeding; provided that the releasing party has given the other party reasonable notice of such requirement, if feasible, (x) to a party's attorneys, accountants, brokers, lenders and other bona fide consultants or advisers (with respect to this Lease only); provided such third parties agree to be bound by this Section, (y) to bona fide prospective assignees or subtenants of this Lease or (z) to bona fide prospective acquirers of or investors or partners in Tenant; provided they agree in writing to be bound by this Article.

38. **Notices.** Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given hereunder shall be in writing and shall be given by (a) personal delivery, (b) overnight delivery with a reputable international overnight delivery service, such as FedEx, or (c) email transmission, so long as such transmission is followed within one (1) business day by delivery utilizing one of the methods described in Subsection (a) or (b) above. Any such notice, consent, demand, invoice, statement or other communication shall be deemed delivered (x) upon receipt, if given in accordance with Subsection (a); (y) one (1) business day after deposit with a reputable international overnight delivery service, if given in accordance with Subsection (b); or (z) upon transmission, if given in accordance with Subsection (c). Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given pursuant to this Lease shall be addressed to Tenant and Landlord at the respective addresses shown in Article 2 above. Either party may, by notice to the other given



pursuant to this Article, specify additional or different addresses for notice purposes.

**39. Miscellaneous.**

39.1. Landlord reserves the right to change the name of the Building or the Property in its sole discretion.

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39.2. To induce Landlord to enter into this Lease, Tenant agrees that it shall furnish to Landlord, from time to time, within ten (10) business days after receipt of Landlord's written request, the most recent year-end unconsolidated financial statements and that it shall cause any Guarantor to furnish to Landlord, from time to time, within ten (10) business days after receipt of Landlord's written request, the most recent year-end unconsolidated financial statements reflecting such Guarantor's current financial condition, in each case audited by a nationally recognized accounting firm. Tenant shall, within ninety (90) days after the end of Tenant's financial year, furnish Landlord with a certified copy of Tenant's year-end unconsolidated financial statements for the previous year and shall cause any Guarantor to furnish Landlord with a certified copy of Tenant's year-end unconsolidated financial statements for the previous year, in each case audited by a nationally recognized accounting firm. Tenant represents and warrants that all financial statements, records and information furnished by Tenant to Landlord in connection with this Lease are true, correct and complete in all respects and that all financial statements, records and information furnished by Guarantor to Landlord in connection with this Lease are true, correct and complete in all respects. If audited financials are not otherwise prepared, unaudited financials complying with generally accepted accounting

principles and certified by the chief financial officer of Tenant or Guarantor (as applicable) as true, correct and complete in all respects shall suffice for purposes of this Section. The provisions of this Section shall not apply at any time while Tenant or Guarantor (as applicable) is a corporation whose shares are traded on any nationally recognized stock exchange.

39.3. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease or otherwise until execution by and delivery to both Landlord and Tenant.

39.4. The terms of this Lease and all exhibits, addenda and riders attached hereto are intended by the parties as a final, complete and exclusive expression of their agreement with respect to the terms that are included herein, and may not be contradicted or supplemented by evidence of any other prior or contemporaneous agreement.

39.5. Neither party shall record this Lease or any memorandum or short form of this Lease.

39.6. Where applicable in this Lease, the singular includes the plural and the masculine or neuter includes the masculine, feminine and neuter. The words "include," "includes," "included" and "including" mean "'include,' etc., without limitation." The word "shall" is mandatory and the word "may" is permissive. The section headings of this Lease are not a part of this Lease and shall have no effect upon the construction or interpretation of any part of this Lease. Landlord and Tenant have each participated in the drafting and negotiation of this Lease, and the language in all parts of this Lease shall be in all cases construed as a whole according to its fair meaning and not strictly for or against either Landlord or Tenant.

39.7. Except as otherwise expressly set forth in this Lease, each party shall pay its own costs and expenses incurred in connection with this Lease and such party's performance under this Lease; provided that, if either party commences an action, proceeding,

demand, claim, action, cause of action or suit against the other party arising out of or in connection with this Lease, then the substantially prevailing party shall be reimbursed by the other party for all reasonable costs

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and expenses, including reasonable attorneys' fees and expenses, incurred by the substantially prevailing party in such action, proceeding, demand, claim, action, cause of action or suit, and in any appeal in connection therewith (regardless of whether the applicable action, proceeding, demand, claim, action, cause of action, suit or appeal is voluntarily withdrawn or dismissed).

39.8. Time is of the essence with respect to the performance of every provision of this Lease.

39.9. Notwithstanding anything to the contrary contained in this Lease, Tenant's obligations under this Lease are independent and shall not be conditioned upon performance by Landlord.

39.10. Notwithstanding anything in this Lease to the contrary, in every instance where Landlord's consent or approval is required, Landlord shall be entitled to withhold its consent if any party whose consent Landlord must obtain under any ground lease, master lease, or any Mortgage or any other financing denies consent to such request.

39.11. Any provision of this Lease that shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision hereof, and all other provisions of this Lease shall remain in full force and effect and shall be interpreted as if the invalid, void or illegal provision did not exist.

39.12. Each of the covenants, conditions and agreements herein contained shall inure to the benefit of and shall apply to and be binding upon the parties

hereto and their respective heirs; legatees; devisees; executors; administrators; and permitted successors and assigns. This Lease is for the sole benefit of the parties and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns, and nothing in this Lease shall give or be construed to give any other person or entity any legal or equitable rights. Nothing in this Section shall in any way alter the provisions of this Lease restricting assignment or subletting.

39.13. This Lease shall be governed by, construed and enforced in accordance with the laws of the state in which the Property is located, without regard to such state's conflict of law principles.

39.14. If a Guarantor is specified in Article 2 of the Lease, then simultaneously with Tenant's execution and delivery of this Lease, Tenant shall cause the Guarantor to execute and deliver to the Landlord the Guaranty of all of Tenant's obligations under this Lease in the form attached hereto.

39.15. This Lease may be executed by electronic signature process (such as DocuSign) and in one or more counterparts, each of which shall, for all purposes, be deemed an original and fully enforceable as an original. All such counterparts, taken together, shall constitute one and the same agreement even though all of the parties may have not executed the same counterpart of this Lease.

39.16. No provision of this Lease may be modified, amended or supplemented except by an agreement in writing signed by Landlord and Tenant.

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39.17. No waiver of any term, covenant or condition of this Lease shall be binding upon Landlord

unless executed in writing by Landlord. The waiver by Landlord of any breach or default of any term, covenant or condition contained in this Lease shall not be deemed to be a waiver of any preceding or subsequent breach or default of such term, covenant or condition or any other term, covenant or condition of this Lease.

39.18. TO THE EXTENT PERMITTED BY APPLICABLE LAWS, THE PARTIES WAIVE TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY THE OTHER PARTY HERETO RELATED TO MATTERS ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP BETWEEN LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, OR ANY CLAIM OF INJURY OR DAMAGE RELATED TO THIS LEASE OR THE PREMISES. TENANT HEREBY WAIVES ANY RIGHT TO FILE A NON-MANDATORY COUNTERCLAIM AGAINST LANDLORD IN ANY SUMMARY DISPOSSESSION OR SIMILAR PROCEEDING.

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IN WITNESS WHEREOF, the parties hereto have executed this Lease as of the date first above written.

**WITNESS:**

/s/ Jennifer  
Armstrong  
Name: Jennifer  
Armstrong

**LANDLORD:**

Wexford-SCEC  
3675 Market  
Street, LLC, a  
Delaware limited  
liability company,

By: Wexford-  
SCEC 3675  
Market  
Street JV, LLC, a  
Delaware  
limited  
liability  
company, its  
managing  
member

By: SCEC  
Ventures,  
Inc., a  
Pennsylvania  
corporation,  
its  
member

Date:

November 7, By:

2022

by: \_\_\_\_\_

/s/ Monica  
Forbes Curt  
Hess

Monica Forbes

Name Curt  
Hess

Name:

Chief Financial Officer

Title Senior  
Vice  
President

Title:

By: LS 3675 Market  
Street JV,  
LLC, a Delaware  
limited  
liability company,  
its administrative  
member

(Principal Financial Officer)

By: Wexford 3675  
Member,  
LLC, a Delaware  
limited  
liability  
company, its  
administrative  
member

by: /s/ Mark  
Korczakowski  
Name Mark  
Korczakowski  
Title Senior Vice  
President

By: VTR Science &  
Technology, LLC  
A Maryland  
limited liability  
company,  
its member

by: /s/ Dave Liu  
Name Dave Liu  
Title Authorized  
Signatory

**WITNESS:**

**/s/ Kara Collins**

**Name: Kara Collins**

**TENANT:**

**CARISMA THERAPEUTICS  
INC.,**

**a Delaware corporation**

**By: /s/ Steven Kelly**

**Name: Steve Kelly**

**President and**

**Title: CEO**

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**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES**

**EXCHANGE ACT OF 1934,**

**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-  
OXLEY ACT OF 2002**

I, **Thomas R. Cannell, D.V.M., Steven Kelly**, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 of **Sesen Bio, Carisma Therapeutics Inc.**;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and



procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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: By:  
May 11,  
2023

/s/ Steven  
Kelly

\_\_\_\_\_

\_\_\_\_\_

**Date:** November 7, 2022

/s/  
Thomas  
R.  
Cannell,  
D.V.M.

Steven  
Kelly

**Name:**

Thomas  
R.  
Cannell,  
D.V.M.

President  
and Chief  
Executive

**Title:** Officer

(Principal  
Executive  
Officer)

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES  
EXCHANGE ACT OF 1934,**

**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-  
OXLEY ACT OF 2002**

I, Monica Forbes, Richard Morris, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 of Sesen Bio, Carisma Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all

material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023 By: /s/ Richard Morris

Date: November 7, 2022 By: /s/ Monica Forbes  
Richard Morris

**Name:** Monica  
Forbes

Chief  
Financial

**Title:** Officer

(Principal  
Financial  
Officer and  
Principal  
Accounting  
Officer)

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#### 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 the Quarterly Report on Form 10-Q of Sesen Bio, Carisma Therapeutics Inc. (the "Company") on Form 10-Q for the fiscal quarter period ended September 30, 2022 March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section § 1350, as adopted pursuant to Section § 906 of the Sarbanes-Oxley Act of 2002, 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.

that, to my knowledge:



(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.
Date:	By: /s/
May 11, 2023	Steven Kelly
Date November 7, 2022	Thomas R. Cannell, D.V.M.
©2023, Refinitiv. All rights reserved. Steven Kelly	
Name: Thomas R. Cannell, D.V.M.	

President and  
Chief Executive  
Title: Officer  
(Principal  
Executive  
Officer)

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 the Quarterly Report on Form 10-Q of Sesen Bio, Carisma Therapeutics Inc. (the "Company") on Form 10-Q for the fiscal quarter period ended September 30, 2022 March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section § 1350, as adopted pursuant to Section § 906 of the Sarbanes-Oxley Act of 2002, 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.

that, to my knowledge:

- (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.

Date: May 11, 2023 By: /s/ Richard Morris

Date: November 7, 2022 By: /s/ Monica Forbes Richard Morris

Name: Monica Forbes

Chief Financial

Title: Officer

(Principal Financial Officer and Principal Accounting Officer)

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