# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 10-Q

Mart One				=	
Mark One) ⊠	QUARTERLY REP	ORT PURSUANT TO SEC	TION 13 OR 15(d) OF	THE SECURITIES EXCHAN	GE ACT OF 1934
		For the quarter	ly period ended Septemb or	per 30, 2023	
	TRANSITION REP	ORT PURSUANT TO SEC	<del>-</del>	THE SECURITIES EXCHAN	GE ACT OF 1934
		For the transitio	n period from	to	
		Commis	sion File Number: 001-3	7620 -	
			NCOLOG registrant as specified in	•	
(Sta	<b>Delay</b> ate or other jurisdiction of i	ware ncorporation or organization)		61-1547851 (I.R.S. Employer Identifica	ntion No.)
127	30 High Bluff Drive, S (Address of principa	·	(858) 500-8800 celephone number, including an	92130 (Zip Code) rea code)	
		Securities register	red pursuant to Section 12(l	b) of the Act:	
	Title of each class		Trading Symbol(s)	Name of each exchar	nge on which registered
Comm	on Stock, par value \$0.	0001 per share	KURA	The Nasdaq Glo	bal Select Market
			•	ion 13 or 15(d) of the Securities I d (2) has been subject to such filing	9
	_			le required to be submitted pursual was required to submit such files).	9
	9	o a		ccelerated filer, a smaller reporting ny," and "emerging growth compan	
Larş	ge accelerated filer	×	Accel	erated filer	
Non	-accelerated filer		Small	er reporting company	
			Emerg	ging growth company	
		by check mark if the registrar rsuant to Section 13(a) of the Ex		extended transition period for con	mplying with any new or revised
ndicate by check	mark whether the registra	ant is a shell company (as define	ed in Rule 12b-2 of the Excha	ange Act). Yes □ No ⊠	
s of the close of	f business on October 26,	2023, the registrant had 74,272,	111 shares of Common Stock	x, \$0.0001 par value, outstanding.	

## KURA ONCOLOGY, INC. TABLE OF CONTENTS

#### PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (unaudited)	
Condensed Balance Sheets - As of September 30, 2023 (unaudited) and December 31, 2022	1
<u>Condensed Statements of Operations and Comprehensive Loss – Three and Nine Months Ended September 30, 2023 and 2022 (unaudited)</u>	2
Condensed Statements of Stockholders' Equity – Three and Nine Months Ended September 30, 2023 and 2022 (unaudited)	3
Condensed Statements of Cash Flows – Nine Months Ended September 30, 2023 and 2022 (unaudited)	5
Notes to Condensed Financial Statements (unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures about Market Risk	22
Item 4. Controls and Procedures	22
PART II. OTHER INFORMATION	
<u>Item 1. Legal Proceedings</u>	23
Item 1A. Risk Factors	23
Item 5. Other Information	70
<u>Item 6. Exhibits</u>	72
<u>Signatures</u>	

#### PART I. FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

#### KURA ONCOLOGY, INC.

Condensed Balance Sheets (In thousands, except par value data)

	Se	ptember 30, 2023	December 31, 2022		
	(	Unaudited)		_	
Assets					
Current assets:					
Cash and cash equivalents	\$	28,740	\$	51,802	
Short-term investments		423,853		386,183	
Prepaid expenses and other current assets		7,324		8,441	
Total current assets		459,917		446,426	
Property and equipment, net		2,057		2,540	
Operating lease right-of-use assets		7,281		3,842	
Other long-term assets		4,516		3,498	
Total assets	\$	473,771	\$	456,306	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	25,843	\$	21,739	
Current operating lease liabilities	<u> </u>	1,682	Ψ	2,318	
Total current liabilities		27,525		24,057	
Long-term debt, net		9,289		9,158	
Long-term operating lease liabilities		6,453		2,548	
Other long-term liabilities		567		265	
Total liabilities		43,834		36,028	
Stockholders' equity:		.5,65		30,020	
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares issued and outstanding		_		_	
Common stock, \$0.0001 par value; 200,000 shares authorized; 74,251 and 68,314 shares issued and outstanding as of		7		7	
September 30, 2023 and December 31, 2022, respectively		7		7	
Additional paid-in capital		1,112,118		997,111	
Accumulated other comprehensive loss		(3,535)		(8,032)	
Accumulated deficit		(678,653)		(568,808)	
Total stockholders' equity	ф.	429,937	φ.	420,278	
Total liabilities and stockholders' equity	\$	473,771	\$	456,306	

See accompanying notes to unaudited condensed financial statements.

#### KURA ONCOLOGY, INC.

#### Condensed Statements of Operations and Comprehensive Loss (In thousands, except per share data) (Unaudited)

	Three Months Ended			Nine Months Ended			
	September 30,			Septem		ber 30	),
	 2023		2022		2023		2022
Operating Expenses:	_						
Research and development	\$ 29,328	\$	24,973	\$	82,702	\$	70,144
General and administrative	13,145		11,621		36,340		34,565
Total operating expenses	 42,473		36,594	-	119,042	-	104,709
Other Income (Expense):	 						
Interest and other income, net	4,275		1,090		10,352		1,983
Interest expense	(404)		_		(1,155)		_
Total other income, net	 3,871		1,090		9,197		1,983
Net Loss	\$ (38,602)	\$	(35,504)	\$	(109,845)	\$	(102,726)
	(0 <b>=</b> 0)	4	(0 <b>=</b> 0.)	_	(4 <b>=</b> 0.)		
Net loss per share, basic and diluted	\$ (0.50)	\$	(0.53)	\$	(1.53)	\$	(1.54)
Weighted average number of shares used in computing net loss per share, basic and diluted	 77,241		66,889		71,845		66,723
Comprehensive Loss:							
Net loss	\$ (38,602)	\$	(35,504)	\$	(109,845)	\$	(102,726)
Other comprehensive income (loss):							
Unrealized gain (loss) on marketable securities and foreign currency	1,687		(1,601)		4,497		(7,627)
Comprehensive Loss	\$ (36,915)	\$	(37,105)	\$	(105,348)	\$	(110,353)

See accompanying notes to unaudited condensed financial statements.

#### KURA ONCOLOGY, INC.

## Condensed Statements of Stockholders' Equity (In thousands) (Unaudited)

			Additional	Accumulat ed Other Comprehe	Accumulat	Total Stockholde
_	Commo	n Stock	Paid-In	nsive	ed	rs'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2022	68,314	\$ 7	\$ 997,111	\$ (8,032)	\$ (568,808)	\$ 420,278
Share-based compensation expense	_		6,838		_	6,838
Issuance of common stock under equity plans	125	_		_		_
Other comprehensive income				2,136		2,136
Net loss	<u> </u>				(34,069)	(34,069)
Balance at March 31, 2023	68,439	7	1,003,949	(5,896)	(602,877)	395,183
Issuance of common stock, net of offering costs	5,661	_	60,919	_	_	60,919
Issuance of pre-funded warrants to purchase common stock, net of offering costs		_	32,658	_	_	32,658
Share-based compensation expense	_	_	6,987	_	_	6,987
Issuance of common stock under equity plans	43		431	<u> </u>	_	431
Other comprehensive income	_	<del>_</del>	<del></del>	674	<del></del>	674
Net loss	_	_	_	_	(37,174)	(37,174)
Balance at June 30, 2023	74,143	7	1,104,944	(5,222)	(640,051)	459,678
Share-based compensation expense	_		7,090	_		7,090
Issuance of common stock under equity plans	108	<del></del>	84	_	_	84
Other comprehensive income	_	_	_	1,687	_	1,687
Net loss	_				(38,602)	(38,602)
Balance at September 30, 2023	74,251	\$ 7	\$ 1,112,118	\$ (3,535)	\$ (678,653)	\$ 429,937

See accompanying notes to unaudited condensed financial statements.

# KURA ONCOLOGY, INC. Condensed Statements of Stockholders' Equity (In thousands) (Unaudited)

	Commo	n Stock	Additional Paid-In	Accumulat ed Other Comprehe nsive	Accumulat ed	Total Stockholde rs'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2021	66,572	\$ 7	\$ 941,359	\$ (1,789)	\$ (432,968)	\$ 506,609
Share-based compensation expense	· —	<del></del>	6,650	_	_	6,650
Issuance of common stock under equity plans	64	_	303	_	_	303
Other comprehensive loss	_	_	_	(4,859)	_	(4,859)
Net loss	_	_	_	_	(32,453)	(32,453)
Balance at March 31, 2022	66,636	7	948,312	(6,648)	(465,421)	476,250
Share-based compensation expense	_	_	6,508	_	_	6,508
Issuance of common stock under equity plans	202	_	2,669	_	_	2,669
Other comprehensive loss	<del></del>	<del></del>		(1,167)	_	(1,167)
Net loss	_	_		_	(34,769)	(34,769)
Balance at June 30, 2022	66,838	7	957,489	(7,815)	(500,190)	449,491
Share-based compensation expense	_	_	6,355	_		6,355
Issuance of common stock under equity plans	56	_	880	_	_	880
Other comprehensive loss				(1,601)		(1,601)
Net loss	<u> </u>				(35,504)	(35,504)
Balance at September 30, 2022	66,894	\$ 7	\$ 964,724	\$ (9,416)	\$ (535,694)	\$ 419,621

 $See\ accompanying\ notes\ to\ unaudited\ condensed\ financial\ statements.$ 

#### KURA ONCOLOGY, INC.

#### Condensed Statements of Cash Flows (In thousands) (Unaudited)

#### Nine Months Ended September 30,

Net loss         \$ (109,845)         \$ (102,726)           Adjustments to reconcile net loss to net cash used in operating activities:         20,915         19,513           Share-based compensation expense         20,915         19,513           Amortization of premium and accretion of discounts on marketable securities, net         (6,687)         2,264           Depreciation expense         635         553           Non-cash interest expense         635         553           Changes in operating assets and liabilities:         574         (4,287)           Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         75         167           Accounts payable and payable and accrued expenses         90,516         63,532           Net cash used in operating activities         75         167           Net cash used in operating activities         30,135         (164,532)           Muturities of marketable securities         310,135         (164,532)           Muturities of marketable securities         310,135         (614)           Net cash (used in) provided by investing activities         283,649         245,091           Purchases of proper		Septemi	er 50,		
Net loss         \$ (109,845)         \$ (102,726)           Adjustments to reconcile net loss to net cash used in operating activities:         20,915         19,513           Share-based compensation expense         20,915         19,513           Amortization of premium and accretion of discounts on marketable securities, net         (6,687)         2,264           Depreciation expense         635         553           Non-cash interest expense         635         553           Changes in operating assets and liabilities:         574         (4,287)           Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         75         167           Accounts payable and payable and accrued expenses         90,516         63,532           Net cash used in operating activities         75         167           Net cash used in operating activities         30,135         (164,532)           Muturities of marketable securities         310,135         (164,532)           Muturities of marketable securities         310,135         (614)           Net cash (used in) provided by investing activities         283,649         245,091           Purchases of proper		 2023		2022	
Adjustments to reconcile net loss to net cash used in operating activities:       20,915       19,513         Share-based compensation expense       20,915       19,513         Amortization of premium and accretion of discounts on marketable securities, net       66,687       2,264         Depreciation expense       635       553         Non-cash interest expense       358       —         Changes in operating assets and liabilities:       ***       ***         Prepaid expenses and other current assets       574       (4,287)         Operating lease right-of-use and other long-term assets       778       226         Accounts payable and accrued expenses       2,681       788         Other long-term liabilities       75       167         Net cash used in operating activities       (90,516)       (83,532)         Investing Activities         Purchases of marketable securities       (310,135)       (164,532)         Maturities of marketable securities       (310,135)       (164,532)         Met cash (used in) provided by investing activities       (26,633)       79,945         Financing Activities       93,577       —         Proceeds from issuance of common stock and pre-funded warrants, net of offering costs       93,577       —         Proceeds from issu	Operating Activities				
Share-based compensation expense         20,915         19,513           Amortization of premium and accretion of discounts on marketable securities, net         (6,687)         2,264           Depreciation expense         635         553           Non-cash interest expense         358         —           Changes in operating assets and liabilities:         Total (4,287)           Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         788           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities           Purchases of marketable securities         (310,135)         (164,532)           Maturities of marketable securities         (310,135)         (164,532)           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities           Proceeds from issuance of common stock and pre-funded warrants, net of offering costs         93,577         —           Proceeds fr	Net loss	\$ (109,845)	\$	(102,726)	
Amortization of premium and accretion of discounts on marketable securities, net         (6,687)         2,264           Depreciation expense         635         553           Non-cash interest expense         358         —           Changes in operating assets and liabilities:         874         (4,287)           Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         758           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities           Purchases of marketable securities         (310,135)         (164,532)           Mutrities of marketable securities         283,649         245,091           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities           Proceeds from issuance of common stock and pre-funded warrants, net of offering costs         93,577         —           Proceeds from issuance of stock under equity plans         515         3,852	Adjustments to reconcile net loss to net cash used in operating activities:				
marketable securities, net         (6,687)         2,264           Depreciation expense         635         553           Non-cash interest expense         358         —           Changes in operating assets and liabilities:         ***         ***           Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         758           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities         (310,135)         (164,532)           Purchases of marketable securities         (310,135)         (164,532)           Mutrities of marketable securities         283,649         245,091           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities           Proceeds from issuance of common stock and pre-funded warrants, net of offering costs         93,577         —           Proceeds from issuance of stock under equity plans         515         3,852	Share-based compensation expense	20,915		19,513	
Depreciation expense         635         553           Non-cash interest expense         358         —           Changes in operating assets and liabilities:         Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         758           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities         Purchases of marketable securities         (310,135)         (164,532)           Maturities of marketable securities         283,649         245,091           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities         Proceeds from issuance of common stock and pre-funded warrants, net of offering costs         93,577         —           Proceeds from issuance of stock under equity plans         515         3,852	•				
Non-cash interest expense         358         —           Changes in operating assets and liabilities:         Tenable of the current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         758           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities           Purchases of marketable securities         (310,135)         (164,532)           Maturities of marketable securities         283,649         245,091           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities           Proceeds from issuance of common stock and pre-funded warrants, net of offering costs         93,577         —           Proceeds from issuance of stock under equity plans         515         3,852	· ·	( , ,		2,264	
Changes in operating assets and liabilities:  Prepaid expenses and other current assets  Operating lease right-of-use and other long-term assets  Accounts payable and accrued expenses  Other long-term liabilities  Other long-term liabilities  Net cash used in operating activities  Investing Activities  Purchases of marketable securities  Auturities of marketable securities  Purchases of property and equipment  Net cash (used in) provided by investing activities  Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs  Proceeds from issuance of stock under equity plans  Total (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (4,287)  (614)  (83,532)  (83	Depreciation expense	635		553	
Prepaid expenses and other current assets         574         (4,287)           Operating lease right-of-use and other long-term assets         778         226           Accounts payable and accrued expenses         2,681         758           Other long-term liabilities         75         167           Net cash used in operating activities         (90,516)         (83,532)           Investing Activities         (310,135)         (164,532)           Maturities of marketable securities         283,649         245,091           Purchases of property and equipment         (152)         (614)           Net cash (used in) provided by investing activities         (26,638)         79,945           Financing Activities         93,577         —           Proceeds from issuance of stock under equity plans         515         3,852	Non-cash interest expense	358		_	
Operating lease right-of-use and other long-term assets778226Accounts payable and accrued expenses2,681758Other long-term liabilities75167Net cash used in operating activities(90,516)(83,532)Investing ActivitiesPurchases of marketable securities(310,135)(164,532)Maturities of marketable securities283,649245,091Purchases of property and equipment(152)(614)Net cash (used in) provided by investing activities(26,638)79,945Financing ActivitiesProceeds from issuance of common stock and pre-funded warrants, net of offering costs93,577—Proceeds from issuance of stock under equity plans5153,852	Changes in operating assets and liabilities:				
Accounts payable and accrued expenses Other long-term liabilities T5 167 Net cash used in operating activities  Investing Activities Purchases of marketable securities Auturities of marketable securities Purchases of property and equipment Purchases of property and equipment Other cash (used in) provided by investing activities  Financing Activities Proceeds from issuance of common stock and pre-funded warrants, net of offering costs Proceeds from issuance of stock under equity plans  2,681 758 (90,516) (83,532) (164,532) (310,135) (164,532) (310,135) (164,532) (614) (152) (614) (758) (7	Prepaid expenses and other current assets	574		(4,287)	
Other long-term liabilities75167Net cash used in operating activities(90,516)(83,532)Investing ActivitiesPurchases of marketable securities(310,135)(164,532)Maturities of marketable securities283,649245,091Purchases of property and equipment(152)(614)Net cash (used in) provided by investing activities(26,638)79,945Financing ActivitiesProceeds from issuance of common stock and pre-funded warrants, net of offering costs93,577—Proceeds from issuance of stock under equity plans5153,852	Operating lease right-of-use and other long-term assets	778		226	
Net cash used in operating activities    Purchases of marketable securities   (310,135)   (164,532)     Maturities of marketable securities   283,649   245,091     Purchases of property and equipment   (152)   (614)     Net cash (used in) provided by investing activities   (26,638)   79,945     Financing Activities   Proceeds from issuance of common stock and pre-funded warrants, net of offering costs   93,577   — Proceeds from issuance of stock under equity plans   515   3,852	Accounts payable and accrued expenses	2,681		758	
Investing Activities Purchases of marketable securities (310,135) (164,532) Maturities of marketable securities 283,649 245,091 Purchases of property and equipment (152) (614) Net cash (used in) provided by investing activities (26,638) 79,945  Financing Activities Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 — Proceeds from issuance of stock under equity plans 515 3,852	Other long-term liabilities	75		167	
Purchases of marketable securities (310,135) (164,532)  Maturities of marketable securities 283,649 245,091  Purchases of property and equipment (152) (614)  Net cash (used in) provided by investing activities (26,638) 79,945  Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 —  Proceeds from issuance of stock under equity plans 515 3,852	Net cash used in operating activities	 (90,516)		(83,532)	
Purchases of marketable securities (310,135) (164,532)  Maturities of marketable securities 283,649 245,091  Purchases of property and equipment (152) (614)  Net cash (used in) provided by investing activities (26,638) 79,945  Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 —  Proceeds from issuance of stock under equity plans 515 3,852	Investing Activities				
Purchases of property and equipment (152) (614)  Net cash (used in) provided by investing activities (26,638) 79,945  Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 —  Proceeds from issuance of stock under equity plans 515 3,852	Purchases of marketable securities	(310,135)		(164,532)	
Net cash (used in) provided by investing activities  Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs  Proceeds from issuance of stock under equity plans  515  3,852	Maturities of marketable securities	283,649		245,091	
Financing Activities  Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 —  Proceeds from issuance of stock under equity plans 515 3,852	Purchases of property and equipment	(152)		(614)	
Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 — Proceeds from issuance of stock under equity plans 515 3,852	Net cash (used in) provided by investing activities	 (26,638)		79,945	
Proceeds from issuance of common stock and pre-funded warrants, net of offering costs 93,577 — Proceeds from issuance of stock under equity plans 515 3,852	Financing Activities				
Proceeds from issuance of stock under equity plans 515 3,852		93,577		_	
		•		3,852	
11et Cash provided by illiancing activities 54,052 5,052	Net cash provided by financing activities	 94,092	-	3,852	
	Net (decrease) increase in cash and cash equivalents				
•	Cash and cash equivalents at beginning of period	· , ,			
	Cash and cash equivalents at end of period	\$ 	\$		

 $See\ accompanying\ notes\ to\ unaudited\ condensed\ financial\ statements.$ 

#### KURA ONCOLOGY, INC.

#### **Notes to Unaudited Condensed Financial Statements**

#### 1. Organization and Basis of Presentation

#### The Company

Kura Oncology, Inc. is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

References in these Notes to Unaudited Condensed Financial Statements to the "Company," "we," "our" or "us," refer to Kura Oncology, Inc.

#### **Basis of Presentation**

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on February 23, 2023, from which we derived our balance sheet as of December 31, 2022. The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited condensed financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of the unaudited condensed financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect the amounts reported on our unaudited condensed financial statements and accompanying notes. The amounts reported could differ under different estimates and assumptions. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

#### 2. Summary of Significant Accounting Policies

#### Reclassifications

The prior period restricted cash balance of approximately \$0.2 million has been reclassified to other long-term assets in the accompanying unaudited condensed financial statements. See Note 6, Leases, for further details.

#### Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, we first assess whether we intend to sell, or if it is more likely than not that we will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) on the unaudited condensed statements of operations and comprehensive loss.

We elected the practical expedient to exclude the applicable accrued interest from both the fair value and amortized costs basis of our available-for-sale securities for purposes of identifying and measuring an impairment. Accrued interest receivable on available-for-sale securities is recorded within prepaid expenses and other current assets on our unaudited condensed balance sheets. Our accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which we consider to be in the period in which we determine the accrued interest will not be collected by us.

#### Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We maintain deposits in federally insured financial institutions in excess of federally insured limits. We have established guidelines to limit our exposure to credit risk by placing investments with high credit quality financial institutions, diversifying our investment portfolio and placing investments with maturities that maintain safety and liquidity. We periodically review and modify these guidelines to maximize trends in yields and interest rates without compromising safety and liquidity.

#### **Employee Retention Credit**

Under the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, we were eligible to claim the employee retention credit, which is a refundable tax credit against certain employment taxes. For the nine months ended September 30, 2023, we recognized \$2.8 million of employee retention credits related to wages paid to our employees from July 2020 through September 2021 within operating expenses as a reduction to personnel costs in the unaudited condensed statements of operations and comprehensive loss. We filed for the credit with the Internal Revenue Service in the first quarter of 2023. As of September 30, 2023, an employee retention credit receivable of \$2.8 million was included within prepaid expenses and other current assets in the unaudited condensed balance sheets, and we expect to receive such credit in the form of a cash payment during the second half of 2023.

#### Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, which includes the shares related to outstanding pre-funded warrants (see Note 7), but excludes other potential common stock equivalents. Pre-funded warrants are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little or no additional consideration, and are fully vested and exercisable. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period. As we have reported net loss for the three and nine months ended September 30, 2023 and 2022, dilutive net loss per common share is the same as basic net loss per common share for those periods. Common stock equivalents outstanding are comprised of stock options, restricted stock units, performance-based restricted stock units, warrants and employee stock purchase plan rights and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. Common stock equivalents outstanding at September 30, 2023 and 2022 totaling approximately 12,664,000 and 9,111,000, respectively, were excluded from the computation of dilutive weighted-average shares outstanding because their effect would be anti-dilutive.

#### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that we adopt as of the specified effective date. We have evaluated recently issued accounting pronouncements and, based on our preliminary assessment, we do not believe any will have a material impact on our unaudited condensed financial statements or related footnote disclosures.

#### 3. Investments

We invest in available-for-sale securities consisting of money market funds, U.S. Treasury securities, corporate debt securities, commercial paper, U.S. Agency bonds and non-U.S. government debt securities. Available-for-sale securities are classified as either cash and cash equivalents or short-term investments on our unaudited condensed balance sheets.

The following tables summarize, by major security type, our short-term investments that are measured at fair value on a recurring basis, in thousands:

Amortized Cost \$ 9,012	Unrealized Gains	Unrealized Losses	Fair Value
\$ 9,012	\$ —		
\$ 9,012	s —		
	4	\$ —	\$ 9,012
292,274	_	(1,433)	290,841
80,622	_	(1,691)	78,931
24,294	_	(14)	24,280
15,273	3	(5)	15,271
15,000	_	(470)	14,530
427,463	3	(3,613)	423,853
\$ 436,475	\$ 3	\$ (3,613)	\$ 432,865
		427,463 3	427,463 3 (3,613)

		December 31, 2022							
	Maturities (years)	A	mortized Cost	U	nrealized Gains	_	realized Losses	Fa	nir Value
Cash equivalents:									
Money market funds	1 or less	\$	37,878	\$	_	\$	_	\$	37,878
U.S. Agency bonds	1 or less		9,956						9,956
Total cash equivalents			47,834						47,834
Short-term investments:									
U.S. Treasury securities	2 or less		183,051		16		(3,018)		180,049
Corporate debt securities	2 or less		115,763		_		(3,931)		111,832
Commercial paper	1 or less		52,941		_		_		52,941
U.S. Agency bonds	1 or less		16,192		11		(160)		16,043
Non-U.S. government and supranational debt securities	2 or less		26,268				(950)		25,318
Total short-term investments			394,215		27		(8,059)		386,183
Total		\$	442,049	\$	27	\$	(8,059)	\$	434,017

Short-term investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. As of September 30, 2023 and December 31, 2022, short-term investments of \$369.7 million and \$274.3 million, respectively, had maturities less than one year, and short-term investments of \$54.2 million and \$111.9 million, respectively, had maturities between one to two years. We had no realized gains or losses for the nine months ended September 30, 2023 and 2022.

As of September 30, 2023, 63 available-for-sale securities with a fair market value of \$404.3 million were in gross unrealized loss positions, \$139.2 million of which were in a continuous unrealized loss position for greater than 12 months. We do not intend to sell these available-for-sale securities, and it is not more likely than not that we will be required to sell these securities prior to recovery of their amortized cost basis. Based on our review of these available-for-sale securities, the unrealized losses at September 30, 2023 were primarily due to changes in interest rates and not due to increased credit risks associated with specific securities. We have no allowance for credit losses as of September 30, 2023 and December 31, 2022. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss.

Accrued interest receivable on available-for-sale securities was \$1.1 million and \$0.9 million as of September 30, 2023 and December 31, 2022, respectively. We have not written off any accrued interest receivables for the nine months ended September 30, 2023 and 2022.

#### 4. Fair Value Measurements

As of September 30, 2023 and December 31, 2022, we had cash equivalents and short-term investments measured at fair value on a recurring basis.

Available-for-sale securities consist of U.S. Treasury securities, which are measured at fair value using Level 1 inputs, and corporate debt securities, commercial paper, U.S. Agency bonds and non-U.S. government debt securities which are measured at fair value using Level 2 inputs. We determine the fair value of Level 2 related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. We validate the fair values of Level 2 financial instruments by comparing these fair values to a third-party pricing source.

The following tables summarize, by major security type, our cash equivalents and short-term investments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy, in thousands:

		September 30, 2023				
		Total		Level 1		Level 2
Cash equivalents:					, <u> </u>	
Money market funds	\$	9,012	\$	9,012	\$	_
Short-term investments:						
U.S. Treasury securities		290,841		290,841		_
Corporate debt securities		78,931		_		78,931
Commercial paper		24,280		_		24,280
U.S. Agency bonds		15,271		_		15,271
Non-U.S. government debt securities		14,530		<u> </u>		14,530
Total short-term investments		423,853		290,841		133,012
Total	\$	432,865	\$	299,853	\$	133,012
		Total		nber 31, 2022 Level 1		Level 2
Cash equivalents:		Total		Level 1		Level 2
Money market funds	\$	37,878	\$	37,878	\$	_
U.S. Agency bonds	Ψ	9,956	Ψ	<i>57</i> ,676	Ψ	9,956
Total cash equivalents		47,834		37,878		9,956
Total cush equivalents		47,004	_	37,070	_	3,330
Short-term investments:						
U.S. Treasury securities		180,049		180,049		_
Corporate debt securities		111,832		_		111,832
Commercial paper		52,941		_		52,941
U.S. Agency bonds		16,043		_		16,043
						0 = 040
Non-U.S. government and supranational debt securities		25,318		_		25,318
Non-U.S. government and supranational debt securities  Total short-term investments		25,318 386,183		180,049		25,318

We believe that our term loan facility bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the term loan facility approximates fair value. The fair value of our term loan facility is determined using Level 2 inputs in the fair value hierarchy.

#### 5. Balance Sheet Detail

Property and equipment consisted of the following, in thousands:

	Septemb	oer 30, 2023	De	cember 31, 2022
Laboratory and computer equipment	\$	1,657	\$	1,568
Leasehold improvements		1,543		1,543
Furniture and fixtures		1,095		1,032
Property and equipment, gross		4,295		4,143
Less: accumulated depreciation		(2,238)		(1,603)
Property and equipment, net	\$	2,057	\$	2,540

Accounts payable and accrued expenses consisted of the following, in thousands:

	Septem	ber 30, 2023	D	ecember 31, 2022
Accounts payable	\$	1,762	\$	1,533
Accrued clinical trial research and development expenses		4,889		2,440
Accrued other research and development expenses		8,071		5,030
Accrued compensation and benefits		9,068		10,300
Other accrued expenses		2,053		2,436
Total accounts payable and accrued expenses	\$	25,843	\$	21,739

#### 6. Leases

We currently have three operating leases for administrative and research and development office and lab space in San Diego, California and Boston, Massachusetts that expire between July 2024 and July 2031. Under the terms of the operating leases, we are required to pay our proportionate share of property taxes, insurance and normal maintenance costs. Two of our leases include renewal options for an additional five years, which were not included in the determination of the right-of-use, or ROU, asset or lease liability as the renewal was not reasonably certain at the inception of the lease. Our San Diego corporate headquarters lease and our San Diego lease for lab and office space provided for \$1.0 million and \$0.1 million, respectively, in reimbursements for allowable tenant improvements, which effectively reduced the total lease payments owed.

On August 30, 2023, we entered into an amendment to the lease agreement for office space in Boston, Massachusetts, or the Amendment, pursuant to which the term of the lease was extended by seven years, or the Extended Term, such that the lease will now expire in July 2031. The minimum rent payable during the Extended Term is approximately \$0.1 million per month for the first year, which amount will increase by 2% per year over the Extended Term. The Amendment provides (i) a rent credit in the amount of approximately \$0.5 million to be applied as a credit against the rent payments due for the months of August 2023 through July 2024, inclusive, and (ii) a tenant improvement allowance in an amount not to exceed approximately \$0.8 million, in each case subject to certain conditions. We elected to apply the tenant improvement allowance as a credit against the rent payments due for the months of August 2024 through March 2025, inclusive. Prior to the Amendment, we were required to maintain a standby letter of credit of approximately \$0.2 million during the term of the lease which was recorded as restricted cash in the prior period unaudited condensed balance sheets. Under the terms of the Amendment, we are required to maintain a cash deposit of approximately \$0.2 million during the term of the lease which was included within other long-term assets in the unaudited condensed balance sheet as of September 30, 2023.

Maturities of lease liabilities as of September 30, 2023 are as follows, in thousands:

#### Year Ending December 31,

2023 (remaining)	\$ 464
2024	1,545
2025	1,964
2026	1,344
2027	1,371
Thereafter	5,138
Total lease payments	11,826
Less: imputed interest	(3,691)
Total operating lease liabilities	\$ 8,135

As of September 30, 2023 and December 31, 2022, the weighted-average discount rate was 10.3% and 5.5%, respectively, and the weighted-average remaining lease term was 6.3 years and 2.3 years, respectively. Total cash paid for amounts included in the measurement of operating lease liabilities was \$1.7 million for both the nine months ended September 30, 2023 and 2022. During the nine months ended September 30, 2023, operating lease ROU assets of approximately \$4.7 million were obtained in exchange for operating lease liabilities. No operating lease ROU assets were obtained in exchange for operating lease liabilities for the nine months ended September 30, 2022. Total operating lease expense for the three months ended September 30, 2023 and 2022 was approximately \$0.5 million in both periods. Total operating lease expense for the nine months ended September 30, 2023 and 2022 was approximately \$1.5 million in both periods.

#### 7. Stockholders' Equity

In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of our common stock at a price of \$11.50 per share and pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of \$11.4999 per pre-funded warrant. The exercise price of each pre-funded warrant is \$0.0001 per share and the pre-funded warrants are exercisable from the date of issuance until fully exercised. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately \$93.6 million. In addition, the underwriters were granted a 30-day option to purchase up to 1,304,347 additional shares of our common stock, or the Overallotment Option, at the \$11.50 per share public offering price. The common stock, pre-funded warrants, and Overallotment Option met the accounting standards guidance for equity classification. The Overallotment Option expired without being exercised in July 2023. We measured the fair value of the Overallotment Option using the Black-Scholes valuation model, which represents a Level 3 fair value measurement, and determined that the value was not material.

#### 8. Share-Based Compensation

The following table summarizes share-based compensation expense for all share-based compensation arrangements, in thousands:

	Three Months Ended					Nine Months Ended						
	September 30,					Septem	ber 30,	,				
	<del> </del>	2023	2022			2023		2022				
Research and development	\$	3,223	\$	2,492	\$	9,430	\$	7,545				
General and administrative		3,867		3,863		11,485		11,968				
Total share-based compensation expense	\$	7,090	\$	6,355	\$	20,915	\$	19,513				

As of September 30, 2023, unrecognized estimated compensation expense related to stock options and restricted stock units was approximately \$42.0 million and \$10.8 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.6 years and 2.5 years for stock options and restricted stock units, respectively. On May 31, 2023, upon approval by our stockholders of an amendment to our Amended and Restated 2014 Equity Incentive Plan, we granted an aggregate of 1,313,100 performance-based restricted stock units, or PSUs, to certain executives. The PSUs vest in six equal tranches upon the achievement of certain milestones and service conditions. As of September 30, 2023, we determined that the vesting of the PSUs was not probable and have not been included in share-based compensation expense or unrecognized estimated compensation expense.

#### 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 should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial statements and notes thereto as of and for the fiscal year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on February 23, 2023.

This Quarterly Report includes forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections, that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "seek", "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our res

References to "we," "us" and "our" refer to Kura Oncology, Inc.

#### Overview

We are a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We are conducting clinical trials of three product candidates: ziftomenib, tipifarnib and KO-2806. We also have additional programs that are at a discovery stage. We own global commercial rights to all of our programs and product candidates. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

**Ziftomenib.** Our first product candidate, ziftomenib, is a potent, selective, reversible and oral small molecule inhibitor that blocks the interaction of two proteins, menin and the protein expressed by the Lysine K-specific Methyl Transferase 2A gene, or KMT2A gene (formerly referred to as the mixed-lineage leukemia 1 gene).

We received orphan drug designation for ziftomenib for the treatment of acute myeloid leukemia, or AML, from the U.S. Food and Drug Administration, or the FDA, in July 2019. We initiated our menin-KMT2A Phase 1/2 clinical trial of ziftomenib in relapsed or refractory AML, which we call the Kura Oncology MEnin-KMT2A Trial, or KOMET-001, in September 2019. In the Phase 1a dose-escalation portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all-comer population of 30 patients with relapsed/refractory AML. A total of 53 patients were treated in the Phase 1b portion of the study, which consisted of two randomized expansion cohorts, each comprised of nucleophosmin 1-, or NPM1-, mutant and KMT2A-rearranged AML patients. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the recommended Phase 2 dose, or RP2D.

On June 11, 2023, we presented updated clinical data from KOMET-001 during a late-breaking oral session at the 2023 European Hematology Association Annual Congress in Frankfurt, Germany, or EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed/refractory NPM1-mutant AML.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a complete remission, or CR, with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after hematopoietic cell transplantation, or HCT, and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with IDH co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an overall response rate of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The median duration of response, or DoR, for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M3271 was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of differentiation syndrome, or DS, was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed/refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The first of these studies, which we call KOMET-007, is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with cytarabine and daunorubicin, or 7+3, in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. On August 3, 2023, we announced that we are dosing patients in KOMET-007. We anticipate having preliminary data from 20 patients in the KOMET-007 study early in the first quarter of 2024.

The second ziftomenib combination study, which we call KOMET-008, is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with fludarabine, cytarabine, granulocyte-colony stimulating factor, or G-CSF, and idarubicin, or FLAG-IDA, or low-dose cytarabine, or LDAC, in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. We expect to dose the first patients in KOMET-008 in the first quarter of 2024.

We also intend to evaluate the use of ziftomenib as a maintenance therapy in patients with NPM1-mutant or KMT2A-rearranged AML who have undergone HCT. HCT represents the only potentially curative treatment for AML, yet the most common reason for long-term failure after HCT is disease relapse. We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy following HCT. We expect to initiate the post-transplant maintenance program in the first quarter of 2024.

*Tipifarnib.* Our second product candidate, tipifarnib, is a potent, selective and orally bioavailable farnesyl transferase inhibitor, or FTI, that has been previously studied in more than 5,000 cancer patients and demonstrated compelling and durable anti-cancer activity in certain patients with a manageable side effect profile.

In February 2021, tipifarnib was granted Breakthrough Therapy Designation from the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma, or HNSCC, with variant allele frequency  $\geq$  20% after disease progression on platinum-based chemotherapy, or high VAF.

In July 2021, we announced a clinical collaboration with Novartis Pharma AG, or Novartis, to evaluate the combination of tipifarnib and alpelisib, a PI3 kinase alpha inhibitor, in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification. In the fourth quarter of 2021, we commenced a Phase 1/2 open-label, biomarker-defined cohort study, which we call the KURRENT-HN trial, to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of the combination for the treatment of such patients. Under the terms of our collaboration agreement with Novartis, we sponsor the KURRENT-HN trial and supply tipifarnib, and Novartis supplies alpelisib. On December 16, 2021, we announced dose administration for the first patient in the PIK3CA cohort in KURRENT-HN. In October 2022, we reported the first demonstration of a durable clinical response with the combination of tipifarnib and alpelisib in a patient with PIK3CA-mutated squamous cell carcinoma of the tonsil. Since that time, we have continued dose escalation and have observed evidence of clinical activity at multiple doses, with no dose-limiting toxicities to date for the combination. We continue to evaluate patients in the dose-escalation study to inform the selection of the optimal biologically active dose, or OBAD, for the combination. Once we determine the OBAD, we will continue to evaluate whether the activity supports the development and commercialization of the combination in HNSCC.

On October 21, 2023, we presented the results of our Phase 2 AIM-HN study of tipifarnib in patients with recurrent/metastatic, or R/M, HRAS mutant HNSCC in a late-breaking oral session at the 2023 European Society for Medical Oncology Congress. As of the data cutoff on June 15, 2023, 59 patients with R/M HRAS mutant HNSCC were enrolled in the AIM-HN study, of whom 50 had high VAF and 38 were evaluable for efficacy. Responses were assessed by the investigators and an independent review facility, or IRF, in the modified intent to treat high VAF population. Both assessments by investigators and IRF observed one patient achieving a CR on treatment. Patients had a median of two prior lines of therapy (range 0-6) in the R/M setting and robust activity was seen in second line treatment and beyond with greater activity observed in the second line versus the third line and subsequent treatments. The objective response rate, or ORR, in second line treatment was 29% [0.13, 0.51] in the IRF assessment. The ORR for three FDA-approved therapies for the treatment of HNSCC in the second line range from 13-16%. Tipifarnib was generally well-tolerated with a manageable safety profile. The most common grade 3 or 4 treatment-related adverse events, or TRAEs, seen in at least 10% of patients were cytopenias and TRAEs led to discontinuation of treatment in 7% of patients. We believe the positive results from AIM-HN validate the therapeutic value of farnesyl transferase inhibition.

**KO-2806.** Our newest product candidate, KO-2806, is a next-generation FTI that we believe demonstrates improved potency, pharmacokinetic and physicochemical properties relative to earlier FTI drug candidates. In January 2023, we announced the clearance by the FDA of our investigational new drug, or IND, application for KO-2806 for the treatment of advanced solid tumors.

We have presented preclinical data in 2023 that we believe illustrate the potential to use FTIs as combination agents to prevent or delay emergence of resistance to certain classes of targeted therapies. In April 2023, we presented preclinical data at the American Association for Cancer Research Annual Meeting highlighting the potential use of FTIs in combination with two distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic tyrosine kinase inhibitor, or TKI, axitinib in cell- and patient-derived xenograft models of clear cell renal cell carcinoma, or ccRCC. The second poster reported regression of multiple models of KRAS inhibitor-resistant non-small cell lung cancer, or NSCLC, by addition of tipifarnib to adagrasib or sotorasib.

On September 28, 2023, we presented preclinical data in an oral session at the 5<sup>th</sup> RAS-Targeted Drug Development Summit supporting the development of KO-2806 in combination with KRAS<sup>G12C</sup> inhibitors to drive tumor regressions and durable responses in KRAS<sup>G12C</sup>-mutant NSCLC. KRAS<sup>G12C</sup> inhibitors have previously been shown to activate receptor tyrosine kinase signaling, leading to ERK-RSK and/or mTOR-S6 pathway reactivation. Our new preclinical data show that co-treatment of preclinical models of KRAS<sup>G12C</sup>-mutant NSCLC with KO-2806 and adagrasib deepens signaling inhibition at multiple nodes, including the mitogen-activated protein kinase and mTOR pathways, while decreasing cell proliferation. In both cell-derived, or CDX, and patient-derived, or PDX, xenograft models originating from NSCLC tumors, the combination of KO-2806 with adagrasib induced tumor regressions. In addition, the CDX and PDX models demonstrated enhanced duration and depth of antitumor response compared to adagrasib as a single-agent therapy.

On October 13, 2023, we presented preclinical data at the AACR-NCI-EORTC International Conference supporting the development of KO-2806 with targeted therapies, including TKIs, KRAS<sup>G12C</sup> inhibitors and KRAS<sup>G12D</sup> inhibitors. The first of

three posters illustrated that KO-2806 potentiates the antitumor activity of cabozantinib in ccRCC models. The second poster illustrated that KO-2806 blocks oncogenetic signaling at multiple nodes to enhance the antitumor activity of KRAS<sup>G12C</sup> inhibitor adagrasib in KRAS<sup>G12C</sup> NSCLC. The third poster illustrated that KO-2806 constrains compensatory signaling reactivation to deepen responses to KRAS<sup>G12D</sup> inhibition.

We believe these data support our rationale to combine KO-2806 with TKIs in ccRCC and with KRAS<sup>G12C</sup> inhibitors in NSCLC.

We are evaluating the safety, tolerability and preliminary antitumor activity of KO-2806 as a monotherapy and in combination with other targeted therapies in a Phase 1 first-in-human study, which we call the FIT-001 trial. On October 19, 2023, we announced that we dosed the first patient in the monotherapy portion of the FIT-001 trial. We anticipate initiation of dose escalation combination cohorts in advanced solid tumors, beginning with KRAS<sup>G12C</sup>-mutant NSCLC and ccRCC, by mid-2024. On November 2, 2023, we announced a clinical collaboration with Mirati Therapeutics, Inc., or Mirati, to evaluate the combination of KO-2806 and adagrasib, a KRAS<sup>G12C</sup> inhibitor, in patients with NSCLC whose tumors have a KRAS<sup>G12C</sup> mutation. Under the terms of the agreement, Mirati will supply us with adagrasib for the NSCLC combination cohort of the FIT-001 trial, and we will sponsor the trial.

#### **Liquidity Overview**

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$452.6 million. In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of common stock at a price of \$11.50 per share as well as pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of \$11.4999 per pre-funded warrant. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately \$93.6 million.

In February 2022, we entered into a Sales Agreement with SVB Securities LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co. under which we could offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million. We did not sell any shares of our common stock under the agreement. On November 2, 2023, we terminated the agreement with SVB Securities LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co.

On November 2, 2023, we entered into a new Sales Agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., or the ATM Facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million. We have not sold any shares of our common stock under the ATM facility.

On November 2, 2022, we entered into a loan and security agreement, or the Loan Agreement, with several banks and other financial institutions or entities party thereto, or collectively the Lenders, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, providing for up to \$125.0 million in a series of term loans, or Term Loans. Upon entering into the Loan Agreement, we borrowed \$10.0 million of an initial \$25.0 million tranche of Term Loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining \$15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to \$35.0 million at any time until March 15, 2024. We may borrow (i) an additional tranche of term loans in the amount of up to \$40.0 million which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of term loans in the amount of up to \$25.0 million, subject to the Lenders' investment committee approval in its sole discretion.

Also, on November 2, 2022, we entered into a securities purchase agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which BMS purchased 1,370,171 shares of our common stock in a registered direct offering, at a purchase price of approximately \$18.25 per share, for gross proceeds of approximately \$25.0 million.

To date, we have not generated any revenues from product sales, and we do not have any approved products. Since our inception, we have funded our operations primarily through equity and debt financings. We anticipate that we will require significant additional financing in the future to continue to fund our operations as discussed more fully below under the heading "Liquidity and Capital Resources."

#### **Financial Operations Overview**

#### Research and Development Expenses

We focus on the research and development of our pipeline programs. Our research and development expenses consist of costs associated with our research and development activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of September 30, 2023, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued development of our product candidates and our other pipeline programs. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. Our future research and development expenses will depend on the preclinical and clinical success of each product candidate that we develop, as well as ongoing assessments of the commercial potential of such product candidates. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Completion of clinical trials may take several years or more, and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of doses that patients receive;
- the number of patients that participate in the clinical trials;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of analyses and tests performed during the clinical trial;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate; and
- managing the impact of the COVID-19 pandemic and related precautions on the operation of our clinical trials.

#### General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, share-based compensation and other personnel costs for employees in executive, finance, business development and support functions. Other significant general and administrative expenses include the costs associated with obtaining and maintaining our patent portfolio, professional services for audit, legal, pre-commercial planning, investor and public relations, director and officer insurance premiums, corporate activities and allocated facilities.

#### Other Income, Net

Other income, net consists primarily of interest income and interest expense.

#### **Income Taxes**

We have incurred net losses and have not recorded any U.S. federal or state income tax benefits for the losses as they have been offset by valuation allowances.

#### **Results of Operations**

The following table sets forth our results of operations for the periods presented, in thousands:

	Three Months Ended						Nine Mon				
	September 30,					September 30,					
	2023		2022		Change		2023		2022		Change
Research and development expenses	\$ 29,328	\$	24,973	\$	4,355	\$	82,702	\$	70,144	\$	12,558
General and administrative expenses	13,145		11,621		1,524		36,340		34,565		1,775
Other income, net	3,871		1,090		2,781		9,197		1,983		7,214

#### Comparison of the Three Months Ended September 30, 2023 and 2022

*Research and Development Expenses*. The following table illustrates the components of our research and development expenses for the periods presented, in thousands:

		Three Mon				
		Septem				
		2023	2022	Change		
Ziftomenib-related costs	\$	8,887	\$ 6,146	\$	2,741	
Tipifarnib-related costs		3,403	4,906		(1,503)	
KO-2806-related costs		2,817	1,867		950	
Discovery stage programs		1,331	819		512	
Personnel costs and other expenses		9,667	8,743		924	
Share-based compensation expense		3,223	2,492		731	
Total research and development expenses	\$	29,328	\$ 24,973	\$	4,355	

The increase in ziftomenib-related research and development expenses for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to increases in costs related to our registration-directed clinical trial of ziftomenib and the initiation of the ziftomenib combination trials. The decrease in tipifarnib-related research and development expenses for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to the closure of our registration-directed trial of tipifarnib. The increase in KO-2806-related research and development expenses for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to increased costs related to our Phase 1 clinical trial which was initiated in October 2023. The increase in discovery stage program research and development expenses for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to increased research activities for our preclinical-stage product candidates. Personnel costs and other expenses for the three months ended September 30, 2023 increased compared to the same period in 2022 to support our ongoing clinical trials and include employee salaries and related expenses, facilities expenses and overhead expenses. We expect our research and development expenses to increase in future periods as we continue clinical development activities for our ziftomenib and FTI programs.

*Other income, net.* The increase in other income, net for the three months ended September 30, 2023 compared to the same period in 2022 was primarily due to an increase in interest income.

#### Comparison of the Nine Months Ended September 30, 2023 and 2022

*Research and Development Expenses.* The following table illustrates the components of our research and development expenses for the periods presented, in thousands:

		Septem			
		2023	2022	(	Change
Ziftomenib-related costs	\$	23,681	\$ 17,503	\$	6,178
Tipifarnib-related costs		10,998	14,999		(4,001)
KO-2806-related costs		7,589	3,884		3,705
Discovery stage programs		3,649	1,791		1,858
Personnel costs and other expenses		27,355	24,422		2,933
Share-based compensation expense		9,430	7,545		1,885
Total research and development expenses	\$	82,702	\$ 70,144	\$	12,558

The increase in ziftomenib-related research and development expenses for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to increases in costs related to our registration-directed clinical trial of ziftomenib and the initiation of the ziftomenib combination trials. The decrease in tipifarnib-related research and development expenses for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to the closure of our registration-directed trial of tipifarnib. The increase in KO-2806-related research and development expenses for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to increased costs related to our Phase 1 clinical trial which we initiated in October 2023. The increase in discovery stage program research and development expenses for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to increased research activities for our preclinical-stage product candidates. Personnel costs and other expenses for the nine months ended September 30, 2023 increased compared to the same period in 2022 to support our ongoing clinical trials and include employee salaries and related expenses, facilities expenses and overhead expenses.

*Other income*, *net*. The increase in other income, net for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to an increase in interest income.

#### **Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through equity and debt financings. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities.

In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of common stock at a price of \$11.50 per share as well as pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of \$11.4999 per pre-funded warrant. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately \$93.6 million.

On November 2, 2022, we entered into the Loan Agreement with the Lenders and Hercules, in its capacity as agent, providing for up to \$125.0 million in a series of Term Loans. Under the terms of the Loan Agreement, we borrowed \$10.0 million of an initial \$25.0 million tranche of Term Loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining \$15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to \$35.0 million, or the Tranche 2 Loan, at any time until March 15, 2024. Thereafter, we may borrow (i) an additional tranche of Term Loans in the amount of up to \$40.0 million, or the Tranche 3 Loan, which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of Term Loans in the amount of up to \$25.0 million, or the Tranche 4 Loan, subject to the Lenders' investment committee approval in its sole discretion. All of the Term Loans have a maturity date of November 2, 2027, or the Maturity Date. Repayment of the Term Loans is interest only through (a) May 1, 2025, with the satisfaction of the Interest Only Milestone 1 Conditions (as defined in the Loan Agreement), (b) November 1, 2025, if we satisfy the Interest Only Milestone 2 Conditions (as defined in the Loan Agreement), and (c) November 1, 2026, if we satisfy the Approval Milestone (as defined in the Loan Agreement). After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%.

At our option, we may prepay all or any portion of the outstanding Term Loans at any time. Prepayments made on or prior to the third anniversary of the date of the Loan Agreement will be subject to a prepayment fee equal to 1.50% of the principal amount being prepaid. In addition, we paid a facility charge of approximately \$0.1 million upon closing, and we have accrued an additional \$0.2 million of facility charges as of September 30, 2023 due to the availability of the Tranche 2 Loan. Additional facility charges will be incurred upon the availability of the Tranche 3 Loan or Tranche 4 Loan, in each case in the amount of 0.50% of the amount of such tranche of loans. The Loan Agreement also provides for an end of term fee in an amount equal to the greater of approximately (i) \$1.5 million (which is 6.05% of the maximum amount of the first tranche of loans) or (ii) 6.05% of the aggregate principal amount of loan advances actually made under the Loan Agreement, which fee is due and payable on the earliest to occur of (i) the Maturity Date, (ii) the date we prepay the outstanding loans in full, and (iii) the date that the secured obligations become due and payable. Our obligations under the Loan Agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. Our intellectual property is subject to negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

On November 2, 2022, we entered into a securities purchase agreement with BMS pursuant to which BMS purchased 1,370,171 shares of our common stock in a registered direct offering, at a purchase price of approximately \$18.25 per share, for gross proceeds of approximately \$25.0 million.

On November 2, 2023, we entered into the ATM Facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million. We have not sold any shares of our common stock under the ATM Facility.

We have incurred operating losses and negative cash flows from operating activities since inception. As of September 30, 2023, we had an accumulated deficit of \$678.7 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, for reasons including, but not limited to, potential worsening global economic conditions, disruptions to, and volatility in, financial markets in the United States and worldwide, including those resulting from public health epidemics or outbreaks, bank failures, actual or perceived changes in interest rates and economic inflation, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of September 30, 2023, we had cash, cash equivalents and short-term investments of \$452.6 million. Based on our current plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses to mid-2026. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of establishing or contracting for sales, marketing and distribution capabilities if we obtain regulatory approvals to market our product candidates;
- the costs of securing and producing drug substance and drug product material for use in preclinical studies, clinical trials and for use as commercial supply;
- the costs of securing manufacturing arrangements for development activities and commercial production;
- the scope, prioritization and number of our research and development programs;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license other product candidates and technologies;
- the success of our current or future companion diagnostic test collaborations for companion diagnostic tests; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

To date, we have not generated any revenues from product sales, and we do not have any approved products. We do not know when, or if, we will generate any revenues from product sales. We do not expect to generate significant revenues from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We are subject to all of the risks incident in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, collaborations, strategic partnerships or licensing arrangements. Other than our term loan facility, we do not have any committed external source of funds. Additional capital may not be available on reasonable terms, if at all. Subject to limited exceptions, our term loan facility also prohibits us from incurring indebtedness without the prior written consent of the Lenders. To the extent that we raise additional capital through the sale of stock or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, including our other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, for reasons including, but not limited to, potential worsening global economic conditions, disruptions to, and volatility in, financial markets in the United States and worldwide, including those resulting from public health epidemics or outbreaks, bank failures, actual or perceived changes in interest rates and economic inflation, we may be unable to carry out our business plan. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and commercialize our product candidates even if we would otherwise prefer to develop and commercialize such product candidates ourselves, and our business, financial condition and results of operations would be materially adversely affected.

The following table provides a summary of our net cash flow activities for the periods presented, in thousands:

#### September 30, 2023 2022 Change Net cash used in operating activities \$ (90,516)(83,532)(6,984)(106,583)Net cash (used in) provided by investing activities (26,638)79,945 Net cash provided by financing activities 94,092 90.240 3,852

Nine Months Ended

*Operating Activities.* The increase in net cash used in operating activities for the nine months ended September 30, 2023 compared to the same period in 2022 was primarily due to increases of \$9.0 million in non-cash net accretion of discount on marketable securities and \$7.1 million in net loss, offset by changes in operating assets and liabilities of \$7.2 million and an increase of \$1.4 million in non-cash share-based compensation expense.

*Investing Activities.* Net cash used in investing activities for the nine months ended September 30, 2023 was primarily due to purchases of marketable securities. Net cash provided by investing activities for the nine months ended September 30, 2022 was primarily due to maturities of marketable securities.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2023 was primarily due to \$93.6 million in net proceeds from the sale of shares of our common stock and pre-funded warrants to purchase shares of our common stock in our June 2023 public offering. Net cash provided by financing activities for the nine months ended September 30, 2022 related to proceeds of \$3.9 million from the issuance of shares of common stock under our equity plans.

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

The following is a summary of our significant contractual obligations and commitments as of September 30, 2023, in thousands:

Payments Due by Period														
		Less than		Less than		Less than		Less than		1-3		3-5	M	ore than
Total	1 Year		1 Year Years		Years		5 Years							
\$ 11,826	\$	1,736	\$	3,241	\$	2,755	\$	4,094						
10,000		_		5,443		4,557		_						
4,718		1,108		1,797		1,813		_						
\$ 26,544	\$	2,844	\$	10,481	\$	9,125	\$	4,094						
¢.	10,000 4,718	Total 1  \$ 11,826 \$  10,000  4,718	Total         Less than 1 Year           \$ 11,826         \$ 1,736           10,000         —           4,718         1,108	Less than           Total         1 Year           \$ 11,826         \$ 1,736         \$           10,000         —           4,718         1,108	Less than         1-3           Total         1 Year         Years           \$ 11,826         \$ 1,736         \$ 3,241           10,000         —         5,443           4,718         1,108         1,797	Less than         1-3           Total         1 Year         Years           \$ 11,826         \$ 1,736         \$ 3,241         \$ 10,000           4,718         1,108         1,797	Less than         1-3         3-5           Total         1 Year         Years         Years           \$ 11,826         \$ 1,736         \$ 3,241         \$ 2,755           10,000         —         5,443         4,557           4,718         1,108         1,797         1,813	Total         1 Year         Years         Years         5           \$ 11,826         \$ 1,736         \$ 3,241         \$ 2,755         \$ 10,000           —         5,443         4,557           4,718         1,108         1,797         1,813						

- (1) Future minimum lease payments under our operating leases in San Diego, California and Boston, Massachusetts.
- (2) Principal payments under our term loan facility.
- (3) Interest payments on our term loan facility. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%. As of September 30, 2023, the interest rate on the Term Loans was 10.90%. In addition, an end of term fee will be due in an amount equal to the greater of approximately (i) \$1.5 million or (ii) 6.05% of the aggregate principal amount of loan advances actually made, payable on the earliest of the maturity date, acceleration or prepayment of the Term Loans.

We lease certain office and laboratory space under non-cancelable operating leases. The leases are also subject to additional variable charges for common area maintenance, property taxes, property insurance and other variable costs. See Note 6 of the unaudited condensed financial statements for additional details related to our lease obligations.

We enter into short-term and cancellable agreements in the normal course of operations with clinical sites and contract research organizations, or CROs, for clinical research studies, professional consultants and various third parties for preclinical research studies, clinical supply manufacturing and other services through purchase orders or other documentation. Such short-term agreements are generally outstanding for periods less than one year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice of 90 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

Excluded from the table above are milestone or contractual payment obligations contingent upon the achievement of certain milestones or events if the amount and timing of such obligations are unknown or uncertain. Our in-license agreements are cancelable by us with written notice within 180 days or less. We may be required to pay up to approximately \$79.9 million in milestone payments, plus sales royalties, in the event that regulatory and commercial milestones under the in-license agreements are achieved.

#### **Critical Accounting Policies and Management Estimates**

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed financial statements required estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the unaudited condensed financial statements. On an ongoing basis, we evaluate our critical accounting estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be 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. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Management Estimates," included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### **Interest Rate Risk**

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in money market funds, U.S. Treasury securities, corporate debt securities, commercial paper, U.S. Agency bonds and non-U.S. government debt securities. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For our short-term investments, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the unaudited condensed statements of operations and comprehensive loss. We believe that should a 10.0% change in interest rates were to have occurred on September 30, 2023, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Any changes would only be realized if we sold the investments prior to maturity.

We are also subject to interest expense fluctuations through our Term Loans which, as of September 30, 2023, bear interest at a rate equal to the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65% and are therefore exposed to changes in interest rates through their maturity date in November 2027.

#### **Inflation Risk**

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during any periods presented herein.

#### ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Exchange Act is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive and financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the quarter covered by this Quarterly Report.

#### Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with management's evaluation of such internal control that occurred during our most recent quarter ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position.

#### **ITEM 1A. RISK FACTORS**

#### **Risk Factor Summary**

We face many risks and uncertainties, as more fully described in this section under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

- We are highly dependent on the success of our lead product candidate, ziftomenib, which is still in clinical development, and we cannot give
  any assurance that ziftomenib or any of our other product candidates will receive regulatory approval, which is necessary before they can be
  commercialized.
- Our discovery, preclinical and clinical development is focused on the development of targeted therapeutics for patients with genetically
  defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs may never lead to
  marketable products.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.
- Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.
- Failure by us or our third-party collaborators to develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.
- We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and
  operating results will vary significantly from period to period.
- We will need to obtain substantial additional capital in connection with our continuing operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.
- We rely on third-party contractors and organizations to conduct, and/or to supply materials to conduct, our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the supply of materials and/or the completion of such clinical trials.
- Our ability to conduct our clinical trials has been and could continue to be adversely impacted by COVID-19, or other actual or threatened
  public health epidemics or outbreaks.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals in some or all planned regions, we will not be able to commercialize, or may be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- Any product candidate for which we obtain marketing approval will be subject to extensive post-approval regulatory requirements and could
  be subject to post-approval restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with
  regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

- If we are unable to, or if we do not, obtain and maintain intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.
- We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.
- Patent terms may be inadequate to protect our competitive position on our product candidates for a commercially meaningful length of time.
- We may not be successful in obtaining or maintaining necessary third-party intellectual property rights for our development pipeline through acquisitions and in-licenses.
- If we are unable to maintain the confidentiality of our trade secrets or other confidential information, our business and competitive position would be harmed.
- Even if any of our product candidates receives marketing approval, it 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.
- We currently have no sales or market access personnel. If we are unable to establish effective sales or market access capabilities or enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- We currently have a limited number of employees, and are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock.
- The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

#### Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the information included or incorporated by reference in this Quarterly Report and in our other public filings, you should carefully consider the risks described below in evaluating our company. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. We have marked with an asterisk (\*) those risk factors that reflect changes from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 23, 2023.

#### Risks Related to the Discovery and Development of Our Product Candidates

We are highly dependent on the success of our lead product candidate, ziftomenib, which is still in clinical development, and we cannot give any assurance that ziftomenib or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize, our lead product candidate, ziftomenib. Our business depends entirely on the successful development and commercialization of our product candidates. We have not completed the development of any product candidates; we currently generate no revenues from sales of any product, and we have not demonstrated that we can successfully develop a marketable product.

We may subsequently learn of certain information or data that the FDA may request, which may necessitate conducting additional preclinical studies or generating additional information at significant cost in terms of both time and expense, including under a clinical hold imposed on an IND. For example, if the FDA does not believe we have sufficiently demonstrated that the selected doses for our investigational products maximize not only the efficacy of the investigational product, but the safety and tolerability as well, our ability to initiate new studies may be delayed. Even if we conducted the additional studies or generated the additional information requested, the FDA could disagree that we have satisfied their requirements, all of which will cause significant delays and expense to our programs.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote any product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals. Although the scope of regulatory approval is similar in other countries, in some countries there are additional regulatory requirements and potential regulatory risks and we cannot predict success in these jurisdictions.

There is no guarantee that our clinical trials will be completed on time or at all. Prior to receiving approval, if any, to commercialize a product candidate in the United States or internationally, we must demonstrate to the satisfaction of the FDA and other regulatory authorities, that such product candidate is safe and effective for its intended use. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of a product candidate may not be replicated in subsequent clinical trials. Even if we believe the preclinical or clinical data are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. We maintain frequent, ongoing dialogue with the FDA and other regulatory bodies regarding our clinical trial designs, including the patient selection criteria, dosing plan and statistical analysis plans. There is a risk that the FDA or other regulatory agencies could at any time raise objections to the design or conduct of our clinical trials. Any such objections could delay the initiation or completion of our registration-directed clinical trial.

Although we believe there may be potential to pursue a path to accelerated approval for ziftomenib for the treatment of patients with particular subtypes of relapsed or refractory AML, we cannot guarantee that ziftomenib will demonstrate sufficient safety and tolerability and clinical activity in that subtype to support an application for accelerated approval. Even if ziftomenib demonstrates sufficient activity in one patient subtype, such as patients with NPM1-mutant AML, to support an application in that subset, there can be no assurance it will demonstrate sufficient activity to support an application for accelerated approval in other patient subsets. Even if the trial results from ziftomenib demonstrate a compelling clinical benefit, the FDA has substantial discretion in the approval process and may not grant approval based on data generated by us.

If the results of our trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant additional resources to conduct additional trials in support of potential approval of ziftomenib, tipifarnib, KO-2806 or our other product candidates.

We have not previously submitted a new drug application, or NDA, to the FDA, or similar product approval filings to comparable foreign authorities, or received marketing approval for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval for any indication. We cannot anticipate whether or when we will seek regulatory review of a product candidate for any other indications. If we do not receive regulatory approvals for and successfully commercialize any of our product candidates on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one of our product candidates, our revenues will be dependent, in part, on our third-party collaborator's ability to commercialize the companion diagnostic as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the market opportunities for the treatment of NPM1-mutant AML, KMT2A-rearranged AML, PIK3CA-dependent HNSCC and other diseases are not as significant as we estimate, our business and prospects may be harmed.

## Our discovery, preclinical and clinical development is focused on the development of targeted therapeutics for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs may never lead to marketable products.

The discovery and development of targeted therapeutics for patients with genetically defined cancers, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates, are a relatively new and rapidly evolving area of science. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. The patient populations for our product candidates are not completely defined but are substantially smaller than the general treated cancer population, and patients will need to be screened and identified in order to be eligible for our therapies. Successful identification of patients is dependent on several factors, including screening a sufficient number of patients to identify whether they harbor a particular genetic alteration or expression level, achieving certainty as to how specific genetic alterations or expression levels respond to our product candidates and developing companion diagnostics to identify such genetic alterations or expression levels. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations will be large enough to allow us to successfully commercialize any products for which we are able to obtain marketing approval and achieve profitability. Therefore, we do not know if our approach of treating patients with genetically defined cancers will be successful. If our approach is unsuccessful, our business will suffer.

In order to execute on our strategy of advancing the clinical development of our product candidates, we have designed our clinical trials, and expect to design future clinical trials of our product candidates, to include patients who harbor a particular attribute such as a particular genetic alteration, tumor histology or expression level that we believe contribute to or are associated with particular cancer subsets. Our goal in doing this is to enroll patients who have the highest probability of responding to our product candidate and in our Phase 1 and/or proof-of-concept Phase 2 clinical trials, to show early and statistically significant evidence of clinical efficacy. Potential molecular biomarkers we have identified in retrospective analyses of data from clinical trials of ziftomenib or tipifarnib in certain cancer indications may not be prospectively validated as biomarkers of ziftomenib or tipifarnib activity in future clinical trials that we may conduct in these indications. If we are unable to identify molecular or genetic alterations, or biomarkers, that are predictive of response to our product candidates, or we are unable to include patients who harbor the applicable genetic alterations or expression levels in our clinical trials, or if our product candidates fail to work as we expect, our ability to assess the therapeutic effect, seek participation in FDA expedited review and approval programs, including Breakthrough Therapy Designation, Fast Track Designation, Priority Review and Accelerated Approval, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised, resulting in longer development times, larger clinical trials and a reduced likelihood of obtaining regulatory approval.

## We may find it difficult to enroll patients in our clinical trials. Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment.

In addition to the potentially small populations for our clinical trials, the eligibility criteria of our clinical trials will further limit the pool of available trial participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a trial. Additionally, the process of finding and diagnosing patients may prove costly. For example, many physicians who treat HNSCC patients do not routinely screen their patients for genetic mutations, such as oncogenic mutations present in the HRAS gene. To seek to address these limitations, we have contracted with third-party laboratories to facilitate the genetic screening of patients for our clinical sites. However, there is no guarantee that these efforts will be effective.

We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under trial including the number and frequency of trial required procedures and tests, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. For example, with the approvals of immune therapy agents nivolumab and pembrolizumab, many HNSCC patients are now being treated with one of these agents in the first line in combination with chemotherapy and after failure of first-line treatments such as chemotherapy and/or cetuximab. If patients receiving immune therapy, or the physicians treating them, are unwilling or unable to participate in our studies for any reason, or if such patients experience positive results from such agents resulting in longer times to disease progression than originally anticipated, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed or we may not be able to successfully complete our studies. Further, if patients do not comply with clinical trial process and procedure and, for example, drop out, miss scheduled doses or follow-up visits, or fail to follow trial protocols, then the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities.

Additionally, in estimating the frequency of biomarkers, we rely on data published in the scientific literature as well as our experience and that of our collaborators. The technologies used to identify mutations in published datasets may be different from the technologies we are using currently, which may make it more difficult to compare results across clinical trials or we may experience lower rates of mutation or other alteration frequencies in our clinical trials than provided in the current scientific literature. Moreover, sample quality in academic studies of molecular biomarkers may not reflect standard clinical practice that is focused on pathological diagnosis.

Even if patients carrying specific mutations or other genetic characteristics are identified, the potential clinical benefit of a product candidate may be delayed or reduced due to increased durations in time to disease progression in patients treated with first-line therapies and the number of patients who could benefit from such product candidate may be reduced. Potential trial subjects may also be located at too great a distance to participate at our clinical trial sites. Any delay or failure by us or third-party collaborators to screen patients or identify patients for enrollment in our ongoing clinical trials could delay or prevent us from completing our clinical trials which could prevent us from obtaining regulatory approval or commercializing our product candidates on a timely or profitable basis, or at all.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition, and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates, including:

- unforeseen safety issues or adverse side effects;
- failure of our companion diagnostics to identify patients;
- modifications to protocols of our clinical trials resulting from the FDA or comparable foreign regulatory authorities or institutional review board, or IRB, decisions; and
- ambiguous or negative interim results of our clinical trials or results that are inconsistent with earlier results.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The risk of failure for our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive preclinical and clinical testing to demonstrate the safety and efficacy of our product candidates in humans. This testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results.

Results from clinical trials conducted at a single clinical site or a small number of clinical sites may not be predictive of results from additional clinical sites or from subsequent clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, the FDA previously issued a non-approval letter to Janssen Pharmaceutica NV, or Janssen, for tipifarnib as a treatment for elderly, untreated AML patients in June 2005. It is impossible to predict with certainty if or when any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

We may experience delays in our clinical trials, and we do not know whether ongoing or planned clinical trials will begin or enroll patients on time, need to be redesigned or be completed on schedule, if at all. If the FDA, comparable foreign regulatory authorities or IRBs have comments on our study plans for our clinical trials that we are required to address, such studies may be delayed, or may not start at all. Clinical trials may be delayed, suspended or prematurely terminated at any time by us or by the FDA or other similar regulatory agency if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including risk of death, or if compounds are not manufactured in compliance with current good manufacturing practice, or cGMP, regulations or with acceptable quality. There can be no assurance that the FDA or other similar regulatory agency will not put any of our product candidates on clinical hold in the future. For example, on November 24, 2021, we reported that the FDA had placed the KOMET-001 trial on a partial clinical hold. The partial clinical hold was initiated following our report to the FDA of a Grade 5 serious adverse event potentially associated with DS, a known adverse event related to differentiating agents in the treatment of AML. Patients who were enrolled in the Phase 1b expansion cohorts at the time of the partial clinical hold were permitted to continue to receive ziftomenib, although no additional patients were to be enrolled until the partial clinical hold was lifted. On January 20, 2022, we announced that the FDA had lifted the partial clinical hold on the KOMET-001 trial following agreement on our mitigation strategy for DS, and that the study would resume screening and enrollment of new patients. 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 our product candidates. Clinical trials may be delayed, suspended or premat

- failure to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute:
- delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a clinical trial;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow-up;
- delay or failure in determining an acceptable dose and schedule for a product candidate in a clinical trial;
- clinical sites and investigators deviating from clinical trial protocol, failing to conduct the clinical trial in accordance with regulatory requirements or dropping out of a clinical trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to redesign or modify our clinical trial protocols, conduct additional 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;
- we may experience delays or difficulties in the enrollment of patients whose tumors harbor the specific genetic alterations that our product candidates are designed to target;

- our 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 have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- 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; or
- there may be changes in governmental regulations or administrative actions.

In addition, our clinical trials have been and may continue to be affected by COVID-19. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward COVID-19. Current or potential patients in our ongoing or planned clinical trials may also choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting COVID-19. Further, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

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 clinical trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- 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 that could reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-approval restrictions and/or 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 testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical 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.

Preclinical and clinical testing of tipifarnib that has been conducted to date may not have been performed in compliance with applicable regulatory standards, which could lead to increased costs or material delays for their further development.

We licensed the rights to develop tipifarnib from Janssen in December 2014, and the development of tipifarnib prior to our license was conducted wholly by Janssen or any third parties with which it had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. Because we had no input on Janssen's development activities relating to tipifarnib, we may discover that certain elements of the clinical development or manufacturing activities that Janssen performed were not performed in compliance with applicable regulatory standards or have otherwise been deficient, particularly relative to current requirements as development of tipifarnib began in the 1990s. Any such deficiency in the prior development of tipifarnib may adversely affect our ability to obtain regulatory approval for tipifarnib.

We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.\*

We are currently developing our product candidates, and may develop future product candidates, for use in combination with one or more other cancer therapies, such as venetoclax, azacitidine, cytarabine, daunorubicin, gilteritinib, fludarabine, G-CSF, and idarubicin in the case of ziftomenib, alpelisib in the case of tipifarnib, and cabozantinib and adagrasib in the case of KO-2806, or other drugs, both approved and unapproved. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with another drug or biologic will depend on our ability, or the ability of third-party clinical trial sites on which we rely, to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that we, or third-party clinical trial sites on which we rely, will be able to secure a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure by us, or by third-party clinical trial sites on which we rely, to secure a steady supply of such drugs or biologics may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

In the event that any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products from any future collaborator or supplier be interrupted, delayed or otherwise be unavailable, our clinical trials may be delayed. In the event we are unable to source an alternative supply or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

In addition, to the extent a third-party clinical trial site on which we rely sources a combination therapy itself and does not submit the costs of such therapy to government programs or patients' insurance, the costs of such therapy may be passed on to us, which could harm our business, financial condition, results of operations, stock price and prospects.

#### Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.\*

If our product candidates are associated with unacceptable side effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Any observed, drug-related side effects could affect the ability of patients to tolerate potentially therapeutically effective doses of the drug, which in turn could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Additionally, if results of our ongoing or planned clinical trials reveal an unacceptable frequency and severity of serious adverse events or side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory agencies could require us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of those compounds. Any of these occurrences may significantly harm our business, financial condition and prospects.

Continuous daily dosing of ziftomenib was well tolerated in the Phase 1b portion of our KOMET-001 trial, with no evidence of drug-induced QTc prolongation. The on-target effect of DS was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event. Grade  $\geq$ 3 treatment-emergent adverse events were reported in 17 patients (85%), and included anemia (25%) and thrombocytopenia (20%). Grade  $\geq$ 3 treatment-related adverse events were reported in six patients (30%).

Tipifarnib has been studied in more than 5,000 oncology patients and was generally well tolerated and exhibited a manageable side effect profile. The most common hematologic adverse events of any grade were neutropenia, or low white blood cell count, anemia and thrombocytopenia, or low platelet count. The most common non-hematologic adverse events of any grade were gastrointestinal system disorders such as nausea, anorexia, diarrhea and vomiting, fatigue and rash. Treatment discontinuation across the prior tipifarnib clinical studies has been in the range of approximately 20-25%. The side effects observed so far in our ongoing clinical trials of tipifarnib have been generally consistent with the prior observations; however, there is no guarantee that additional or more severe side effects will not be identified through further clinical studies.

Additionally, we may evaluate our product candidates in combination with third-party drugs or biologics, and safety concerns arising during a combination trial could negatively affect the individual development program of each candidate, as the FDA or comparable foreign regulatory authorities may require us to discontinue single-candidate trials until the contribution of each product candidate to any safety issues is better understood.

## We may expend our limited resources to pursue a specific 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 must focus on a limited number of research programs and product candidates and on 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 preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

## Failure by us or our third-party collaborators to develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.

One of the central elements of our business strategy is to screen and identify subsets of patients with molecular or genetic alterations who may derive meaningful clinical benefit from our product candidates. Successful identification of these patient subsets depends on the development of sensitive, accurate and cost-effective molecular and other diagnostic tests and the widespread adoption and use of these tests at clinical sites to screen a sufficient number of patients to identify whether they are appropriate candidates for treatment with one of our product candidates.

As we do not have in-house diagnostic testing capabilities, we rely extensively on third-party collaborators for the development, validation and regulatory approval of these diagnostic tests. We and our third-party collaborators may encounter difficulties in developing, validating and obtaining regulatory approval for these diagnostic tests. We may also experience difficulties in having these diagnostic tests adopted and used by oncologists, both during the clinical development phase and if and when approved as a companion diagnostic for commercial sale.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has frequently required a premarket approval application of companion diagnostics for cancer therapies. We presently anticipate that approved companion diagnostics will be required in order to obtain approval for ziftomenib in NPM1-mutant AML and KMT2A-rearranged AML and for tipifarnib in PIK3CA-dependent HNSCC. We and our third-party collaborators may encounter difficulties in developing, validating and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop, validate or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

Even if we or our companion diagnostic collaborators successfully obtain regulatory approval for the companion diagnostics for our product candidates, our collaborators:

- may not perform their obligations as expected;
- may not pursue commercialization of companion diagnostics for our therapeutic product candidates that achieve regulatory approval;
- may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of such product or products; and
- · may terminate their relationship with us.

Additionally, we or our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, affect the ease of use, affect the price or have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community.

If companion diagnostics for use with our product candidates fail to gain market acceptance, our ability to derive revenues from sales of our product candidates could be harmed. If insurance reimbursement to the laboratories who perform the companion diagnostic tests is inadequate, utilization may be low, and patient tumors may not be comprehensively screened for the presence of the genetic markers that predict response to our product candidates. If we or our collaborators fail to commercialize these companion diagnostics, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with our product candidates or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of our product candidates.

## Our ability to conduct our clinical trials has been and could continue to be adversely impacted by COVID-19, or other actual or threatened public health epidemics or outbreaks.\*

COVID-19 has adversely impacted, and could continue to adversely impact, our ability to conduct our clinical trials. The COVID-19 pandemic has delayed and may continue to delay startup of new clinical trial sites and enrollment in our clinical trials due to staffing challenges, prioritization of hospital resources toward the pandemic, requirements for working remotely and restrictions in travel. Some patients may be unwilling to enroll in our current and future clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. Increased demand at clinical trial sites and quarantined doctors and staff may reduce personnel and other available resources at clinical trial sites needed to conduct our clinical trials and may cause the screening of new patients or clinical trial operations to be delayed or paused. Trial sites have in some cases limited and may continue to limit or prohibit on-site dosing and monitoring to decrease potential exposure of doctors, staff and patients to COVID-19, which may require us to adopt remote monitoring and other procedures to ensure verifiable trial execution. Although we continue to enroll patients in our clinical studies, there is the potential that we may experience significant delays or other material adverse effects from the COVID-19 pandemic with regard to the conduct of our clinical trials and the COVID-19 pandemic could potentially decrease the implementation of protocol required trial activities and the quality of source data verification at clinical trial sites. Additionally, if a clinical trial site is not capable of remote clinical trial capabilities, we may be required to find and engage new clinical trial investigative sites. Any negative impact of the COVID-19 pandemic on patient enrollment or treatment could delay our clinical trial timelines and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines. We remain in active dialog with our CROs and clinical sites to minimize the impact of the COVID-19 pandemic to our clinical trials without adversely affecting the safety of patients, the quality of clinical data and overall integrity of our clinical trials. Despite our best efforts, it may prove difficult to continue to treat patients in a timely manner and activation of new sites could be delayed, particularly for our clinical trial sites in areas with high rates of community spread.

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

#### We expect to incur losses over the next several years and may never achieve or maintain profitability.\*

To date, we have financed our operations primarily through equity and debt financings. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially if and as we:

- continue research and development of our product candidates;
- initiate new clinical trials for our product candidates;
- seek marketing approvals for our product candidates;
- enter into collaboration arrangements for combination drugs or biologics for our product candidates;
- enter into collaboration arrangements for companion diagnostics for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- incur increased costs as a result of continued operations as a public company; and
- manage the risks associated with COVID-19 or any other similar health emergencies.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, successfully developing companion diagnostics, obtaining marketing approval from the FDA and other global regulatory authorities for these product candidates, and the manufacturing, marketing and selling of these products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or even sufficient to achieve profitability. 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 could decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

The COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation have caused volatility in the global financial markets and threatened a slowdown in the global economy, which may have a material adverse effect on our ability to raise additional capital on attractive terms or at all.

## We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and operating results will vary significantly from period to period.\*

We are a clinical-stage company that has incurred losses since our inception and expect to continue to incur substantial losses in the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We expect our actual financial condition and operating results to fluctuate significantly from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- the success of our clinical trials through all phases of clinical development;
- delays in the commencement, enrollment and completion of clinical trials;
- our ability to secure and maintain collaborations, licensing or other strategic partnerships for the future development and/or commercialization of our product candidates, as well as meet the terms of those arrangements;
- our and our third-party collaborators' ability to develop and validate companion diagnostics for our product candidates;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop our product candidates;
- the results of clinical trials or marketing applications for other product candidates that may compete with our portfolio of product candidates;
- competition from existing products or new products that may receive marketing approval;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- any delays in regulatory review and approval of our product candidates;
- our ability to identify and develop additional product candidates;
- · the ability of patients or healthcare providers to obtain sufficient coverage and adequate reimbursement for our products;
- our ability, and the ability of third parties, such as CROs, to adhere to clinical trial and other regulatory requirements;
- the ability of third-party manufacturers to manufacture our product candidates and the ability to obtain key ingredients needed to produce materials for clinical trial material in order to conduct clinical trials and, if approved, successfully produce commercial products;
- the costs to us, and our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of any future intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;

- changes in governmental regulations, healthcare policy, pricing and reimbursement systems and our ability to set and maintain prices in the United States and other territories; and
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with a clinical-stage company, many of which are outside of our control, and past operating or financial results should not be relied on as an indication of future results. Fluctuations in our operating and financial results could cause our share price to decline. It is possible that in some future periods, our operating results will be above or below the expectations of securities analysts or investors, which could also cause our share price to decline.

### 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 are a clinical-stage company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and acquiring potential product candidates, undertaking preclinical, clinical and regulatory development of our product candidates and conducting pre-commercial and diagnostic related activities for our product candidates. We have not yet demonstrated our ability to successfully complete clinical trials or the development of companion diagnostics in support of FDA approval, obtain marketing approvals, manufacture a product at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Medicines, on average, take 10 to 15 years to be developed from the time they are discovered to the time they receive marketing approval. Consequently, any predictions you make about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We may in the future need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need to obtain substantial additional capital in connection with our continuing operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.\*

Until such time, if ever, as we can generate sufficient product revenues to fund our operations, we will need to raise additional capital in connection with our continuing operations. We expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships or licensing arrangements. Additional capital may not be available on reasonable terms, if at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of our stockholders as a common stockholder. Debt financing and 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 additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, including our other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. As a result of the COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive.

On November 2, 2023, we entered into the ATM Facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million. We have not sold any shares of our common stock under the ATM Facility.

In November 2022, we entered into a loan and security agreement, or the Loan Agreement, with several banks and other financial institutions or entities party thereto, or collectively the Lenders, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, providing for up to \$125.0 million in a series of term loans, or Term Loans. Upon entering into the Loan Agreement, we borrowed \$10.0 million of an initial \$25.0 million tranche of Term Loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining \$15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to \$35.0 million at any time until March 15, 2024. Thereafter, we may borrow (i) an additional tranche of Term Loans in the amount of up to \$40.0 million which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of term loans in the amount of up to \$25.0 million, subject to the Lenders' investment committee approval in its sole discretion. Other than our term loan facility, we do not have any committed external source of funds. While any amounts are outstanding under our term loan facility, we are subject to affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness, transactions with affiliates and a minimum cash covenant, among other customary covenants. If we default under our term loan facility, the Lenders may accelerate our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the Lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could accelerate our obligations under the Loan Agreement upon the occurrence of an event of default, which includes, among other things, our failure to satisfy our payment obligations under the Loan Agreement, the breach of certain of our other covenants under the Loan Agreement or the occurrence of a material adverse change, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Subject to limited exceptions, our term loan facility also prohibits us from incurring indebtedness without the prior written consent of the Lenders. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

# Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions could adversely affect our current financial condition and projected business operations.\*

Events involving limitations to liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or FDIC, was appointed as receiver. Subsequently, the FDIC announced that all deposits with SVB are fully insured. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each placed into receivership and on May 1, 2023, First Republic Bank was placed into receivership. We regularly maintain cash balances at third-party financial institutions in excess of the FDIC standard insurance limit, with balances concentrated at a small number of financial institutions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or with which we do business, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. In addition, if any of our partners or parties with whom we conduct business are unable to access funds due to the status of their financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

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

We rely on third-party contractors and organizations to conduct, and/or to supply materials to conduct, our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the supply of materials and/or the completion of such clinical trials.\*

We rely, and expect to continue to rely, on third-party contractors, CROs, clinical data management organizations, independent contractors, medical institutions and clinical investigators to support our preclinical development activities and conduct our clinical trials. These agreements may terminate for a variety of reasons, including a failure to perform by the third parties. If we are required to enter into alternative arrangements, our product development activities could be delayed.

We compete with many other companies, some of which may be our business competitors, for the resources of these third parties. Large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may have the right to terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third-party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which could result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Our reliance on third parties to conduct our clinical trials 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 clinical trial. Moreover, the FDA and other regulatory authorities require us to comply with good clinical practice guidelines 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 clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, such as ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and criminal sanctions.

Additionally, we rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance that these third parties will pass FDA or other regulatory audits, which could delay or prevent regulatory approval.

For our KURRENT-HN trial, in addition to relying upon third-party service providers, we depend upon Novartis to supply alpelisib in accordance with the terms of our collaboration agreement. If Novartis does not perform in accordance with the agreement, or the agreement is terminated, the KURRENT-HN trial, and our development plans for tipifarnib in combination with alpelisib, could be materially adversely impacted. Similarly, we depend on Mirati to supply adagrasib for the NSCLC combination cohort of our FIT-001 trial. If Mirati does not perform in accordance with the agreement, or the agreement is terminated, the NSCLC combination cohort of our FIT-001 trial, and our development plans for KO-2806 in combination with adagrasib, could be materially adversely impacted.

If these third parties do not successfully carry out their contractual duties, meet expected timelines, conduct our clinical trials or supply clinical trial materials in accordance with regulatory requirements, our agreements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, the ability of these third parties to conduct certain of their operations, including monitoring of clinical sites, as applicable, may be limited by actual or threatened public health epidemics or outbreaks, and to the extent that such third parties are unable to fulfill their contractual obligations as a result of such events or government orders in response to such events, we may have limited or no recourse under the terms of our contractual agreements with such third parties. Further, if any of the third parties with whom we engage were to experience shutdowns or other substantial disruptions due to actual or threatened public health epidemics or outbreaks, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

We depend on third parties for the manufacture of our product candidates for preclinical 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 at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.\*

We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of clinical supplies of ziftomenib, tipifarnib and KO-2806 for preclinical and clinical testing. We expect to rely on third parties as well for commercial manufacture if any of our product candidates receive marketing approval. 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 also expect to rely on other third parties to package and label the drug product as well as to store and distribute drug supplies for our clinical trials.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of drug formulation and manufacturing techniques and process controls. Manufacturers of active pharmaceutical ingredients, or APIs, and pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

If we are unable to develop formulations of our product candidates with acceptable stability and sterility characteristics, or experience an unexpected delay or loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues, geopolitical events, actual or threatened public health epidemics or outbreaks, or otherwise, our business may be harmed and we may experience delays, disruptions, suspensions or terminations of, or we may be required to restart or repeat, any pending or ongoing clinical trials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, we may be required to manufacture additional supplies of our product candidates to the extent our estimates of the amounts required prove inaccurate, we suffer unexpected losses of product candidate supplies, or to the extent that we are required to have fresh product candidate supplies manufactured to satisfy regulatory requirements or specifications. Any significant delay or discontinuation in the supply of a product candidate, or the raw material components thereof, due to the need to replace a supplier, contract manufacturer or other third-party manufacturer, could considerably harm our business and delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. Any performance failure on the part of our existing or future manufacturers, suppliers or distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue. If 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 qual

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;
- catastrophic events at the third-party organization;
- the possible breach of the manufacturing agreement by the third party;
- 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.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that will be conducted after an NDA is submitted to the FDA. We are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of both the active drug substances and finished drug product for ziftomenib, tipifarnib, KO-2806 and our other product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture our products, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside 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 wh

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

We and our collaboration partners have been able to continue to supply our clinical products to our patients and currently do not anticipate any interruptions in supply. To the extent our third-party manufacturers and supply chain suppliers are negatively impacted by geopolitical events such as the military action initiated by Russia against Ukraine (and responses by the United States and certain other countries, including significant sanctions and trade actions against Russia), as well as actual or threatened public health epidemics or outbreaks, we may not be able to provide continuous drug supply to our clinical sites and our clinical trials may be delayed or may not be completed which would have a material adverse effect on our business operations and performance.

### Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals in some or all planned regions, we will not be able to commercialize, or may be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.\*

Our product candidates must be approved by the FDA pursuant to an NDA in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, 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. In addition, public health epidemics or outbreaks could also potentially affect the business of the FDA, the EMA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our product candidates may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. 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 also cause delays in or prevent the approval of an application.

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.

# We may not be able to benefit from available regulatory exclusivity periods for tipifarnib if another company obtains regulatory approval for tipifarnib before we do.

The composition of matter patents covering tipifarnib expired in the United States and in countries in Europe in 2016. Our commercial strategy for tipifarnib relies on obtaining method of use and method of treatment patents, including those directed to specific indications and biomarkers, other patents related to tipifarnib, and method of treatment patents related to farnesyl transferase inhibitors including tipifarnib, and on non-patent regulatory exclusivity. In the United States, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon FDA approval of an NDA for a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any abbreviated new drug application seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that the FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

We may not be able to obtain orphan drug exclusivity for the product candidates for which we seek it, which could limit the potential profitability of such product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan designation subsequently receives the first marketing approval for the indication for which it receives the designation, then the product is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the same indication during the exclusivity period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may 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 drug to meet the needs of patients with the rare disease or condition.

In July 2019, the FDA granted orphan drug designation to ziftomenib for the treatment of AML. If ziftomenib receives marketing approval for an indication broader than AML, ziftomenib may no longer be eligible for marketing exclusivity. Furthermore, orphan drug exclusivity may not effectively protect ziftomenib from the competition of different drugs for the same orphan condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same condition if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. The failure to obtain an orphan designation for any product candidates we may develop for the treatment of rare cancers, and/or the inability to maintain that designation for the duration of the applicable exclusivity period, could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

If we obtain an orphan designation and FDA approval of any of our product candidates for an oncology indication, we would be entitled to seven years of marketing exclusivity for that orphan indication. However, if a competitor obtained approval of a generic form of such product candidate for another indication, physicians would not be prevented from prescribing the generic drug for the orphan indication during the period of marketing exclusivity. Such prescribing practices could adversely affect the sales of our product candidates for the orphan indication.

# A Breakthrough Therapy Designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

We have received Breakthrough Therapy Designation from the FDA on tipifarnib for the treatment of patients with recurrent or metastatic HRAS mutant HNSCC with variant allele frequency  $\geq$  20% after disease progression on platinum-based chemotherapy. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs that have been designated as Breakthrough Therapies are eligible for priority review by the FDA, rolling submission of portions of the NDA and FDA's organizational commitment involving senior management to provide guidance to the company to help determine the most efficient route to approval. Such interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. However, the reduced timelines may introduce significant chemistry, manufacturing and controls challenges for product development.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

### Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party 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 and different criteria for approval. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the 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 our third-party collaborators 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. However, failure to obtain marketing approval in some countries or jurisdictions may compromise 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 market.

Any product candidate for which we obtain marketing approval will be subject to extensive post-approval regulatory requirements and could be subject to post-approval restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities. These requirements include, without limitation, submissions of safety and other post-approval information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, restrictions or requirements regarding the distribution of samples to physicians, tracking and reporting of payments to physicians and other healthcare providers, and recordkeeping requirements.

The FDA may also impose requirements for costly post-approval studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations 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 adverse events or other problems with our products, 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 on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-approval studies or clinical trials;
- warning 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;
- refusal to permit the import or export of our products;

- · product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal data can also lead to significant penalties and sanctions.

# The FDA and other regulatory agencies may require more extensive or expensive trials for combination product candidates than may be required for single agent pharmaceuticals.

In the event that we seek regulatory approval for a combination product candidate, we may be required to show that each active pharmaceutical ingredient in the product candidate makes a contribution to the combined product candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy. As a result, we may be required to conduct clinical trials comparing each component drug with the combination. This could require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of a combination drug than of a new drug containing only a single active pharmaceutical ingredient.

Our relationships with healthcare professionals, customers and third-party payors and our general business operations may be subject to applicable fraud and abuse laws, including anti-kickback and false claims laws, transparency laws, privacy laws and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative and civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens, on behalf of the government, through whistleblower actions, and civil monetary penalties laws which prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information on covered entities which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of certain drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians or their immediate family; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing
  arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private
  insurers.

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 may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, and/or drug pricing. Some state and local laws also require the registration of pharmaceutical sales representatives.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse business consequences.\*

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process personal data, including data we collect about participants in our clinical trials, and other sensitive third-party data, including proprietary and confidential business data, trade secrets and intellectual property. Our data processing activities subject us to numerous data privacy and security obligations, such as laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices, affording California residents certain rights related to their personal data, and requiring businesses subject to the CCPA to implement certain measures to effectuate California residents' personal data rights. The CCPA allows for civil penalties for noncompliance (up to \$7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act, or CPRA, went into effect on January 1, 2023, and expands the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states, such as Virginia, Colorado, Utah and Connecticut, have also passed comprehensive privacy laws, and similar laws are being considered in several other states. In addition, data privacy and security laws have been proposed at the federal and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR (collectively, GDPR) and Canada's Personal Information Protection and Electronic Documents Act, or PIPEDA, impose strict requirements for processing personal data. For example, under the GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR/17.5 million British Pounds under the UK GDPR, or 4% of annual global revenue, whichever is greater. Further, the GDPR provides for private litigation related to the processing of personal data that can be brought by classes of data subjects or consumer protection organizations authorized at law to represent the data subjects' interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. For example, the European Economic Area, or EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer data from the EEA, UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we may face significant adverse consequences, including the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, limiting our ability to collaborate with parties subject to European and other data protection laws, or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Our employees and personnel may use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply. Any such standards could negatively impact our operations by requiring us to change our processes and procedures or otherwise modify how we handle data or produce our products. We also publish privacy policies, and other statements regarding data privacy and security. If these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party service provider to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operat

# Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.\*

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, improve quality, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates and our business are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. Certain changes to the ACA, such as the removal of the ACA's individual health insurance mandate by federal tax legislation, a delay in the implementation of certain ACA-mandated fees, and other changes to the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," were recently enacted or implemented, and the effect of these changes is unknown. Furthermore, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. We cannot predict the ultimate content, timing or effect of healthcare reform legislation or regulation or the impact of potential legislation or regulation on us.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, that due to subsequent legislative amendments, will stay in effect until 2032. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and other potential legislation may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. As a result, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law. The IRA, among other things, (1) extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, (2) directs HHS to negotiate, subject to a specified cap, the price of a set number of certain single-source drugs and biologics covered under Medicare each year starting in 2026, (3) imposes rebates under Medicare Part B and Medicare Part D to penalize manufacturers for price increases that outpace inflation, and (4) makes several changes to the Medicare Part D benefit, including by significantly lowering the beneficiary maximum annual out-of-pocket costs, and through a change in manufacturer liability under the program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued, and will continue to issue and update, guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry and could negatively affect our business and financial condition. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures have increasingly passed legislation and implemented 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. Future legislation could potentially change drug pricing dynamics. We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business.

We expect that healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Foreign legislative changes may also affect our ability to commercialize our product candidates.

### Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some 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 product. 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. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

# If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials and a pollution liability policy, this insurance may not provide adequate coverage against potential liabilities. Other than our pollution liability policy, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our discovery, preclinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

### **Risks Related to Our Intellectual Property**

If we are unable to, or if we do not, obtain and maintain intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.\*

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, confidentiality agreements, and license agreements to protect the intellectual property related to our current product candidates and development programs. If the breadth or strength of protection provided by any patents, patent applications or future patents we may own, license, or pursue with respect to any of our current or future product candidates or products is threatened, it could threaten our ability to commercialize any of our current or future product candidates or products. For example, our patent rights may not protect our patent-protected products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights. Further, if we encounter delays in our development efforts, the period of time during which we could market any of our current or future product candidates or products under any patent protection we obtain would be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates or products, patents protecting such candidates might expire before or shortly after such product candidates or products are commercialized.

### Ziftomenib

We have issued patents in the United States, Europe, China, Japan and other foreign jurisdictions covering the composition of matter of ziftomenib and certain structurally related compounds and methods of using the compounds for treating cancers. Although these patents are currently in force, there is no guarantee that a court would agree that any of the patents are valid or enforceable.

We are pursuing additional U.S. and foreign patents for ziftomenib; however, there is no guarantee that any such patents will be granted or that, if granted, would provide protection against third parties.

Patent term extension may be available in the United States to account for regulatory delays in obtaining marketing approval for a product candidate; however, only one patent may be extended per marketed compound. The applicable authorities, including the U.S. PTO and the FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, our competitors who obtain the requisite regulatory approval can offer products with the same API as ziftomenib so long as the competitors do not infringe any patents that we may hold. Competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We expect that following expiration of patents and any regulatory exclusivity we are able to obtain for ziftomenib, competitors may manufacture and sell generic versions of ziftomenib, at a lower price, which would reduce ziftomenib's revenues. In certain jurisdictions, legislation mandates generic substitution for brand name drugs.

### Tipifarnib

Our patent rights in tipifarnib are limited in ways that affect our ability to exclude third parties from competing against us. In particular, the patent term for the composition of matter patents covering the API of tipifarnib expired in the United States and countries in Europe in 2016. Composition of matter patents on APIs are generally considered to be the strongest form of intellectual property protection because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used.

Patents directed to the method of treatment of certain cancers using tipifarnib or a farnesyl transferase inhibitor have been issued to us in a number of jurisdictions, including the United States, Europe, China and Japan. Although these patents are currently in force, there is no guarantee that a court would agree that any of the patents are valid or enforceable. Further, if a competitor were to develop tipifarnib for use in an indication other than that claimed by the patents, we would not be able to prevent the competitor from marketing tipifarnib for such indication in the United States or other jurisdictions based on our currently issued patents. We are pursuing additional U.S. and foreign method of treatment patents for tipifarnib and farnesyl transferase inhibitors, however there is no guarantee that any such patents will be granted or that, if granted, would provide protection against third parties.

Under our license agreement with Janssen for tipifarnib, we and Janssen agree to cooperate in obtaining available patent term extensions. We and Janssen may not reach agreement and no patent term extension may be obtained. Additionally, the applicable authorities, including the U.S. PTO and the FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, our competitors who obtain the requisite regulatory approval can offer products with the same API as tipifarnib so long as the competitors do not infringe any method of use patents that we may hold. Competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We expect that following expiration of patents and any regulatory exclusivity we are able to obtain, competitors may manufacture and sell generic versions of tipifarnib, at a lower price, which would reduce tipifarnib's revenues. In certain jurisdictions, legislation mandates generic substitution for brand name drugs.

### KO-2806

We have filed patent applications in the United States, and under the Patent Cooperation Treaty, covering the composition of matter of KO-2806 and certain structurally related compounds and methods of using KO-2806 for treating cancers. However, there is no guarantee that patents will be granted from such applications or that, if granted, would provide protection against third parties.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.\*

We have licensed patent rights from third parties for some of our development programs, including compounds in our menin-KMT2A program from the University of Michigan and tipifarnib from Janssen. As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

With respect to the patent portfolio for tipifarnib, which is in-licensed from Janssen, Janssen retains rights to prosecute and maintain patents and patent applications within the portfolio as well as to assert such patents against infringers within and outside the scope of our license, and to defend such patents against claims of invalidity and unenforceability. Although we have rights to consult with Janssen on actions taken as well as back-up rights of prosecution and enforcement, rights to tipifarnib granted to another licensee, could potentially influence Janssen's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us.

# If we breach any of the agreements under which we license from third parties the commercialization rights to our product candidates, we could lose license rights that are important to our business and our operations could be materially harmed.\*

We have in-licensed rights to ziftomenib and other compounds in our menin-KMT2A program from the University of Michigan. We have also inlicensed from Janssen use, development and commercialization rights in all indications other than virology, for tipifarnib. Additionally, we have an
exclusive worldwide license from Memorial Sloan Kettering Cancer Center to a patent family pertaining to a method of use of FTIs, including tipifarnib.
As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of the University of Michigan license
agreement and the Janssen license agreement and the rights we license under such agreements and our other in-license agreements. The University of
Michigan license agreement and the Janssen license agreement each provides that we are subject to diligence obligations relating to the commercialization
and development of the respective product candidates, milestone payments, royalty payments and other obligations. If we fail to comply with any of the
conditions or obligations or otherwise breach the terms of our license agreement with University of Michigan, or Janssen, or other license agreements we may enter into on which our business or product candidates are dependent, University of Michigan, or Janssen, or
other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and
intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. The loss of the rights licensed to us
under our license agreement with University of Michigan, or Janssen, or our other license agreements or any future license agreement that we may enter
granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product
candidates and would materially harm our business, prospects, financial condition and results of operations.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic 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, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- 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 priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or 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 product candidates.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent position of biotechnology and pharmaceutical 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 laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Certain inventions that are patentable in the United States may not be patentable in other countries and vice versa. Further, our ability to enforce our patent rights in foreign jurisdictions may not be as effective as in the United States. For example, some foreign countries, such as India and China, may not allow or enforce patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that 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. Our pending and future patent applications may not result in patents being issued which protect our technology or products, 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 or narrow the scope of our patent protection, or eliminate our patent protection completely.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO, or become involved in patent office post-grant proceedings, such as opposition, derivation, 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 products 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and 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. Even if our owned and licensed patents might provide such protection or competitive advantage, we may not have the resources to effectively enforce our rights under such patents, which can be expensive and time-consuming. Further, our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and 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 products. Given the amount of time required for 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

# Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.\*

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For instance, under the Unitary Patent Court system that has been implemented in Europe, European patent applications have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unified Patent Court, or UPC. This is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

#### Patent terms may be inadequate to protect our competitive position on our product candidates for a commercially meaningful length of time.\*

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its effective U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patents have expired, we may be open to competition from competitive products. Given the amount of time required for 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 duration of rights to exclude others from commercializing products similar or identical to ours.

# Obtaining and maintaining our 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 fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside annuity provider firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

# We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.\*

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming to pursue. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

# Third parties may initiate legal proceedings alleging that we are infringing 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 the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. 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. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

### We may not be successful in obtaining or maintaining necessary third-party intellectual property rights for our development pipeline through acquisitions and in-licenses.\*

Presently we have rights to intellectual property under an exclusive worldwide license from the University of Michigan for all therapeutic indications for ziftomenib and other compounds in our menin-KMT2A program, an exclusive license from Janssen to develop tipifarnib in all fields other than virology, and an exclusive worldwide license from Memorial Sloan Kettering Cancer Center to a patent family pertaining to a method of use of FTIs, including tipifarnib. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Additionally, a companion diagnostic may require that we or a third-party collaborator developing the diagnostic acquire proprietary rights held by third parties, which may not be available. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we may collaborate with U.S. and foreign academic and other research institutions to accelerate our discovery and preclinical development work under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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 license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

# If we are unable to maintain the confidentiality of our trade secrets or other confidential information, 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, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, 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 manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants; however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, to third parties, and we may not be able to obtain adequate remedies for such breaches. 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 the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, 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, our competitive position would be harmed.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based manufacturing companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.\*

Although we do not currently own issued patents or pending patent applications that have been generated through the use of U.S. government funding, our license agreement with the University of Michigan includes intellectual property rights unrelated to ziftomenib that have been generated through the use of U.S. government funding or grants, and we may acquire or license additional intellectual property rights from one or more entities that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that; (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our intellectual property rights generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

### We may not be able to protect our intellectual property rights throughout the world.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Even if any of our product candidates receives marketing approval, it 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.

If any of our product candidates receives marketing approval, it 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 like immunotherapy, chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues 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 safety and potential advantages and disadvantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- 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 our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- our ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the acceptance and utilization of diagnostics to identify appropriate patients;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

We currently have no sales or market access personnel. If we are unable to establish effective sales or market access capabilities or enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

We currently do not have sales or market access teams for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates continue to progress toward regulatory approval, we intend to establish sales, marketing, analytics and market access teams with expertise to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Capable managers with commercial experience may need to be identified and successfully recruited to our company. Any failure or delay in the development of our commercial capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

### We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies, which may directly compete with ziftomenib, tipifarnib, KO-2806 and any other future product candidates. In the case of ziftomenib, one of our clinical-stage competitors has published preliminary clinical data demonstrating that their inhibitor of the menin-KMT2A interaction was able to drive clinical benefit, including objective responses, in relapsed or refractory patients with NPM1-mutated and KMT2A-rearranged AML. Based on these data, that competitor has indicated that they plan to complete an NDA submission for relapsed or refractory KMT2A-rearranged acute leukemias under FDA's real-time oncology review by the end of 2023, while having previously received Fast Track Designation from the FDA for relapsed or refractory NPM1-mutant or KMT2A-rearranged acute leukemias, orphan drug designation from the FDA and European Commission for AML and Breakthrough Therapy Designation from the FDA for relapsed or refractory KMT2A-rearranged acute leukemia. If any competitor is able to advance their clinical program more quickly than ours, our commercial opportunity for ziftomenib could be reduced.

Our commercial opportunity also 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 alone or in combination with other drugs or biologics. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or slow our regulatory approval. 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.

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, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries 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.

The insurance coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain coverage and adequate reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of coverage and reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Further, any companion diagnostic that we or our collaborators develop will be subject to separate coverage and reimbursement determinations by third-party payors.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. We or our collaborators may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective.

Reimbursement agencies in countries other than the United States may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. In addition, drug-pricing by pharmaceutical companies has come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and provide an explanation of the reasons for the increase, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

Further, we or our collaborators will be required to obtain coverage and reimbursement for companion diagnostic tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. There is significant uncertainty regarding our and our collaborators' ability to obtain coverage and adequate reimbursement for any companion diagnostic test for the same reasons applicable to our product candidates. If insurance coverage and reimbursement for companion diagnostic tests for our product candidates is inadequate, utilization may be low, and patient tumors may not be comprehensively screened for the presence of the genetic markers that predict response to our product candidates.

### Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of 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. If we cannot successfully defend ourselves 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;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Our current product liability insurance coverage 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 we commence 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.

### Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

We currently have a limited number of employees, and are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.\*

We are a clinical-stage company with a limited operating history, and, as of September 30, 2023, we had 131 full-time employees. We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with 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, sales and market access personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees, and recruiting additional 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 regulatory 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 pharmaceutical and biotechnology 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 and preclinical 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. 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, regulatory, medical affairs and marketing capabilities and potentially implement sales and market access 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 in the areas of development, regulatory affairs, operations, medical affairs, sales, marketing and market access. 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. 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. The expansion of our operations may 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.

### Third-party expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

In recent years, there has been an increased focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Third-party providers of ESG ratings and reports on companies have increased in number, resulting in varied and, in some cases, inconsistent standards. Topics taken into account in such assessments include, among others, the company's efforts and impacts with respect to climate change and human rights, ethics and compliance with the law, and the role of the company's board of directors in supervising various sustainability issues. In addition to the topics typically considered in such reviews, in our industry, the public's ability to access our medicines is of particular importance.

Some investors may use third-party ESG ratings and reports to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our desirability as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to adequately pursue or fulfill any goals and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could expose us to additional regulatory, social or other scrutiny of us, the imposition of unexpected costs, or damage to our reputation, which in turn could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

### Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.\*

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. From time to time, including recently as a result of the COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation, global financial markets have experienced volatility and uncertainty. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.\*

Our business requires collecting, manipulating, analyzing, storing and otherwise processing large amounts of data, including proprietary data, sensitive data, personal data and other confidential information. We, and third parties acting on our behalf, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. In addition, we rely on an enterprise software system to operate and manage our business. Our business, including our ability to manufacture drug products and conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources and those of third parties acting on our behalf, including computer hardware, software, networks, Internet servers and related infrastructure.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Any of these threats, particularly during times of international conflict, could materially disrupt our systems, operations and supply chain. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third-party information technology systems that support us and our services. Remote work poses increased risks to our information technology systems and data, as employees who work from home utilize network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. An intentional or accidental security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standards or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have not always been able in the past and may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Thus, despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

### Our business and operations would suffer in the event of system failures.\*

Despite the implementation of security measures, our internal computer systems and those of our CROs, collaborators and third parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies.

While we have not experienced any system failures, accidents or security breaches to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

# Actual or threatened public health epidemics or outbreaks may adversely impact our industry, including our clinical trials, our supply chain, our liquidity and access to capital markets and our business development activities.\*

While many health organizations have declared that the COVID-19 pandemic has ended, the pandemic and previous actions to slow its spread had an adverse impact on our operations, including our ability to conduct our clinical trials, and we cannot predict if or when other similar disease outbreaks will emerge that cause similar disruptions.

The extent to which future pandemics may impact our clinical trials, our supply chain, our access to capital and our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the timing and duration of future pandemics, the transmissibility and severity of illness caused by future pandemics, the efforts by governments and businesses to contain the spread of future pandemics, business closures or business disruptions and the impact on the economy and capital markets.

# Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity and other events beyond our control, the occurrence of which could materially harm our business.

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power, and any future blackouts could disrupt our operations. We are vulnerable to a major earthquake, wildfire and other natural disasters, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. We do not carry any business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could cause our business to materially suffer.

### Risks Related to Ownership of our Common Stock

### Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock.\*

Our common stock has been listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol "KURA" since November 5, 2015. The high and low price per share of our common stock as reported by Nasdaq during the period from November 5, 2015 through September 30, 2023, were \$43.00 and \$2.50, respectively. We cannot predict the extent to which investor interest in our company will sustain an active trading market on Nasdaq or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if an active trading market is not sustained or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

#### The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.\*

The market for our common stock could fluctuate substantially due to a variety of factors, some of which may be beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- changes in the structure of healthcare payment systems;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates:
- our dependence on third parties, including CROs as well as our potential partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results, liquidity or other indicators of our financial condition;
- failure to meet or exceed the estimates and projections of the investment community;

- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- market conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including as a result of the COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. These events may also lead to securities litigation, which can be expensive and time-consuming to defend, regardless of the merit or outcome. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

### We have broad discretion in the use of our cash and may not use our cash effectively, which could adversely affect our results of operations.

Our management has broad discretion in the application of our cash resources. Because of the number and variability of factors that will determine our use of our cash resources, our management might not apply our cash in ways that ultimately increase the value of our common stock. The failure by our management to apply our cash effectively could harm our business. Pending their use, we may invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

### FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

The Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

The resale of shares covered by our effective shelf registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We filed a shelf registration statement with the SEC, which has been declared effective, to register the resale of 13,947,599 shares of our common stock. The shelf registration statement permits the resale of these shares at any time, subject to restrictions under applicable law. The resale of a significant number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to the shelf registration statement, the selling stockholders named in such registration statement will continue to offer shares covered by the shelf registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the shelf registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we have incurred and will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, as well as rules implemented by the SEC or Nasdaq or any other stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with certain aspects of Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to, among other things, conduct an annual review and evaluation of their internal controls over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that requires frequent evaluation. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Future sales and issuances of our common stock or rights to purchase or acquire common stock, including pursuant to our equity incentive plans, outstanding stock options, restricted stock units, performance-based restricted stock units, warrants, pre-funded warrants or otherwise, could result in dilution to the percentage ownership of our stockholders and could cause our stock price to fall.\*

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time.

If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders or the perception that such sales could occur could cause the market price of our common stock to decline. On November 2, 2023, we entered into the ATM Facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million. We have not sold any shares of our common stock under the ATM Facility.

Pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of September 30, 2023, we had 3,775,895 shares of common stock available for grant under the 2014 Plan, options to purchase up to an aggregate of 10,284,251 shares of common stock outstanding, 967,017 unvested restricted stock units outstanding and 1,313,100 unvested performance-based restricted stock units outstanding. On January 1, 2023, an automatic increase pursuant to the 2014 Plan occurred, resulting in 2,732,559 additional shares available for future grant under the 2014 Plan. In May 2023, our stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares available for future grant by 4,050,000 shares and remove the automatic annual 4% increase to the number of shares available for future grant.

In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2015 Employee Stock Purchase Plan, or ESPP. As of September 30, 2023, we had 691,409 shares of common stock reserved for future issuance under the ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year through January 1, 2025 by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2022, the compensation committee of the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in 2023.

In addition, as of September 30, 2023, (i) warrants to purchase up to (a) 33,988 shares of our common stock at an exercise price of \$3.31 per share and (b) 26,078 shares of our common stock at an exercise price of \$14.38 per share and (ii) pre-funded warrants to purchase up to 3,034,782 shares of our common stock at an exercise price of \$0.0001 per share were outstanding.

Any future grants of options, restricted stock units, performance-based restricted stock units, warrants, pre-funded warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, as amended, and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- division of our board of directors into three classes;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than  $66\frac{2}{3}\%$  of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 66<sup>2</sup>/<sub>3</sub>% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation;
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock; and

• a requirement that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation, as amended, and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our charter documents provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation, as amended, and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive-forum provisions in our amended and restated certificate of incorporation, as amended, and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

# Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, we expect an increase in our net deferred tax assets and an offsetting similarly sized increase in our valuation allowance over these amortization periods. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur and whether we conduct our research and development activities inside or outside the United States.

### Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

### We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any payment of cash dividends in the future would depend on our financial condition, contractual restrictions, including under our term loan facility, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our board of directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

### **General Risk Factors**

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

### Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. 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. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundam

### Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.\*

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharma companies have experienced significant stock price volatility in recent years. Even if we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to our management and may lead to an unfavorable outcome that could adversely impact our financial condition and prospects.

Our employees, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and CROs may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by our employees and other third parties may also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by our 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 or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anticorruption and anti-money laundering laws and regulations, including the Foreign Corrupt Practices Act, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products internationally once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

### ITEM 5. OTHER INFORMATION

### **Entry into New Sales Agreement**

On November 2, 2023, we entered into a sales agreement, or Sales Agreement, with Leerink Partners LLC and Cantor Fitzgerald & Co., or collectively, the Agents, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million through the Agents as our sales agents, or ATM Offering.

The Agents may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on the Nasdaq Global Select Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. The Agents will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may

impose). We will pay the Agents a commission of up to 3.0% of the gross sales proceeds of any common stock sold through the Agents under the Sales Agreement, and we have also provided the Agents with customary indemnification rights.

We are not obligated to make any sales of our common stock under the Sales Agreement. The offering of shares of common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which is filed as Exhibit 10.4 to this Quarterly Report on Form 10-Q.

The shares of common stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to an automatic shelf registration statement on Form S-3 and prospectus relating to the ATM Offering that we will file with the SEC.

This Quarterly Report on Form 10-Q shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

## **Termination of Prior Sales Agreement**

On November 2, 2023, we and Leerink Partners LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co., or collectively, the Prior Agents, agreed to terminate the sales agreement, or Prior Sales Agreement, that we entered into with the Prior Agents on February 24, 2022, effective November 2, 2023. Under the Prior Sales Agreement, we were permitted to offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to \$150.0 million through the Prior Agents by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. We did not sell any shares of our common stock under the Prior Sales Agreement.

#### **Trading Plans**

During the three months ended September 30, 2023, certain of our officers adopted or terminated contracts, instructions or written plans for the purchase or sale of our securities as noted below:

		_	Trading A	rrangement	_	
		<del>-</del>		Non-Rule 10b5-	<b>Total Shares to be</b>	
	Action	Date	Rule 10b5-1*	1**	Sold	<b>Expiration Date</b>
					ESPP net shares to be	
Teresa Bair, Chief Legal Officer	Adoption	September 22, 2023	X		purchased	May 31, 2024
Kathleen Ford, Chief Operating Officer	Adoption	August 29, 2023	X		136,261	September 15, 2024

<sup>\*</sup> Intended to satisfy the affirmative defense of Rule 10b5-1(c)

<sup>\*\*</sup> Not intended to satisfy the affirmative defense of Rule 10b5-1(c)

## **ITEM 6. EXHIBITS**

## INDEX TO EXHIBITS

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.		8-K (Exhibit 3.1)	6/14/2017	001-37620
3.2	Amended and Restated Bylaws of the Registrant.		8-K (Exhibit 3.2)	6/14/2017	001-37620
4.1	Form of Common Stock certificate.		8-K (Exhibit 4.1)	3/12/2015	000-53058
4.2	Warrant to Purchase Stock issued by Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
4.3	Form of Warrant Agreement issued by the Registrant on November 2, 2022 to certain Lenders.		10-K (Exhibit 4.3)	2/23/2023	001-37620
4.4	Amended and Restated Warrant Agreement, dated as of November 29, 2022, by and between the Registrant and Hercules Capital, Inc.		10-K (Exhibit 4.4)	2/23/2023	001-37620
4.5	Warrant Agreement, dated as of November 29, 2022, by and between the Registrant and Hercules Capital IV, L.P.		10-K (Exhibit 4.5)	2/23/2023	001-37620
4.6	Form of Pre-Funded Warrant		8-K (Exhibit 4.1)	6/14/2023	001-37620
10.1+	Executive Employment Agreement, effective as of August 14, 2023, by and between the Registrant and Brian Powl.	X			
10.2	First Amendment to Lease, dated as of August 30, 2023, by and between the Registrant and East Office Operating Limited Partnership.	X			
10.3	First Amendment to Loan and Security Agreement, dated as of October 2, 2023, by and between the Registrant and Hercules Capital, Inc.	X			
10.4	Sales Agreement, dated November 2, 2023, by and among the Registrant, Leerink Partners LLC and Cantor Fitzgerald & Co.	X			
31.1	Certification of Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certifications of Principal Executive and Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.	X			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
	72				

Exhibit Number	Description	Filed Herewith	Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101.INS).	X			

<sup>+</sup> Indicates management contract or compensatory plan.

<sup>\*</sup> The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

## **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.

Kura Oncology, Inc.

Date: November 2, 2023

By: /s/ Troy E. Wilson, Ph.D., J.D.

Troy E. Wilson, Ph.D., J.D.
President and Chief Executive Officer
(Principal Executive and Financial Officer)

# EXECUTIVE EMPLOYMENT AGREEMENT FOR BRIAN POWL

This Executive Employment Agreement (the "*Agreement*"), entered into between Kura Oncology, Inc. (the "*Company*") and **B**RIAN **PowL** (the "*Executive*") (collectively, the "*Parties*"), is effective as of August 14, 2023 (the "*Effective Date*").

**W**HEREAS, the Company desires Executive to provide employment services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services; and

**W**HEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits.

**Now, Therefore**, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

## 1. Employment by the Company.

- **1.1 Position.** Executive will serve as the Chief Commercial Officer of the Company. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies.
- **1.2 Duties and Location.** Executive will perform such duties as are required by the Company's **CHIEF EXECUTIVE OFFICER** to whom Executive will report. Executive's primary office location will be the Company's San Diego office. The Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, and to require reasonable business travel. The Company may modify Executive's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time.
- **1.3 Policies and Procedures.** The employment relationship between the Parties will be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement will control.

## 2. Compensation.

- **2.1 Salary.** For services to be rendered hereunder, Executive will receive a base salary at the rate of **\$475,000.00** per year (the "*Base Salary*") payable in installments in accordance with the Company's regular payroll schedule.
- **2.2 Bonus.** Executive will be eligible for an annual discretionary bonus of up to **40**% of Executive's Base Salary (the "**Annual Bonus**"). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors ("**Board**") in its sole discretion based upon the Company's and Executive's achievement of objectives and milestones to be determined on an annual basis by the Board. Executive must remain an active employee through the end of any given calendar year in order to earn an Annual Bonus for that year and any such bonus will be paid prior to March 15 of the

year following the year in which such bonus was earned. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before the end of the calendar year.

## 2.3 Equity.

- **3. OPTIONS.** The Board, as further consideration for Executive's continued employment under the terms of this Agreement, previously grated Executive an option to purchase 200,000 shares of the Company's common stock ("Common Stock") on Grant date.
- **4. STANDARD COMPANY BENEFITS.** Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.
- **5. PAID TIME OFF.** Executive will be entitled to accrue and use paid time off in accordance with the terms of the Company's paid time off policy and practices, provided, however, that in no event will Executive's paid time off accrual rate be lower than 4 weeks per year.
- **6. Expenses.** The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.
  - 7. TERMINATION OF EMPLOYMENT; SEVERANCE.
- **7.1 At-Will Employment.** Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause or advance notice.

## 7.2 Termination Without Cause; Resignation for Good Reason.

(a) Not in Connection with a Corporate Transaction. In the event Executive's employment with the Company is terminated by the Company without Cause (other than by reason of death or disability), or Executive resigns for Good Reason, then provided such termination or resignation constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "Separation from Service"), the Separation from Service occurs more than 59 days prior to or 12 months after the closing of a Corporate Transaction, the Company shall pay Executive's base salary and accrued and unused vacation benefits earned through the date of termination, at the rate in effect at the time of termination, less standard deductions and withholdings. In addition, if Executive provides a signed release of claims in a form reasonably satisfactory to the Company (the "Release") and allows such Release to become irrevocable and effective no later than 60 days following Executive's Separation from Service, and provided that Executive remains in compliance with the terms of this Agreement, the Company will provide Executive with the following severance benefits:

(i) a cash lump-sum payment in an amount equal to **12** months of Executive's annual base salary at the rate in effect on the effective date of Executive's Separation from Service, ignoring any decrease in base salary that forms the basis for Good Reason, payable on the 60th day following Executive's Separation from Service.

(ii) Provided Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will pay the COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable), subject to withholding if deemed necessary to comply with applicable laws, through the period (the "COBRA Premium Period") starting on the Executive's Separation from Service and ending on the earliest to occur of: (i) 12 months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

**(b)** In Connection with a Corporate Transaction. In the event Executive's employment with the Company is terminated by the Company without Cause (other than by reason of death or disability), or Executive resigns for Good Reason, and provided such termination or resignation constitutes a Separation from Service and such the Separation from Service occurs within 59 days prior to, on or within 12 months following the closing of a Corporate Transaction, the Company shall pay Executive's base salary and accrued and unused vacation benefits earned through the date of termination, at the rate in effect at the time of termination, less standard deductions and withholdings. In addition, if Executive provides a signed Release and allows such Release to become irrevocable and effective no later than 60 days following Executive's Separation from Service, and provided that Executive remains in compliance with the terms of this Agreement, the Company will provide Executive with the following severance benefits:

(i) A cash lump-sum payment in an amount equal to 12 months of Executive's annual base salary at the rate in effect on the effective date of Executive's Separation from Service, ignoring any decrease in base salary that forms the basis for Good Reason, less standard deductions and withholdings, payable on the 60th day following Executive's Separation from Service.

(ii) A cash lump-sum payment in an amount equal to the Executive's full target bonus amount for services to be performed during the year in which the Corporate Transaction occurs, less standard deductions and withholdings, payable on the 60th day following Executive's Separation from Service.

(iii) Provided Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will pay the COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable), subject to withholding if deemed necessary to comply with applicable laws, through the period (the "COBRA Premium Period") starting on the Executive's Separation from Service and ending on the earliest to occur of: (i) 12 months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

**(iv)** One hundred percent of any equity held by Executive will be deemed vested and exercisable (if applicable) as of Executive's last day of employment, provided, however, that with respect to any performance based vesting equity awards held by Executive that

have multiple vesting levels depending upon the level of performance, such equity awards will vest at the target level.

(c) <u>COBRA</u>. Notwithstanding Sections 6.2(a)(ii) and 6.2(b)(iii), if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether the Executive or the Executive's qualifying family members elect COBRA continuation coverage (the "*Health Care Benefit Payment*"). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Premium Period, but determined without regard to whether or not the Executive continues to be eligible for COBRA coverage.

**7.3 Resignation Without Good Reason; Termination for Cause; Death or Disability.** If Executive resigns without Good Reason, or the Company terminates Executive's service for Cause, or upon a termination due to Executive's death or disability, then all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and Executive will not be entitled to any severance benefits under Section 6.2(a) or Section 6.2(b).

## 8. Section 280G.

If any payment or benefit Executive would receive from the Company or otherwise ("Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

- **8.2** In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.
- **8.3** Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Corporate Transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Corporate Transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.
- **8.4** The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

#### 9. Section 409A.

- **9.1** It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Code Section 409A.
- **9.2** A termination of employment will not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a Separation from Service and, for purposes of any such provision of this Agreement, references to a "termination," "termination of service" or like terms will mean Separation from Service. If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered deferred compensation under Code Section 409A payable on account of a Separation from Service, such payment or benefit will be made or provided at the date which is the earlier of (A) the expiration of the six-month period measured from the date of such Separation from Service of Executive, and (B) the date of Executive's death, to the extent required under Code Section 409A. Upon the expiration of the foregoing delay period, all payments and benefits delayed pursuant to this Section 8.2 (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) will be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due under this Agreement will be paid or provided in accordance with the normal payment dates specified for them herein.
- **9.3** To the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Code Section 409A, (A)

all expenses or other reimbursements hereunder will be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by Executive, (B) any right to reimbursement or in-kind benefits will not be subject to liquidation or exchange for another benefit, and (C) no such reimbursement, expenses eligible for reimbursement, or in-kind benefits provided in any taxable year will in any way affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

**9.4** For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days, the actual date of payment within the specified period will be within the sole discretion of the Company. Notwithstanding any other provision of this Agreement to the contrary, in no event will any payment under this Agreement that constitutes "nonqualified deferred compensation" for purposes of Code Section 409A be subject to offset by any other amount unless otherwise permitted by Code Section 409A.

#### 10.DEFINITIONS.

- **10.1** "Cause" with respect to Executive means Executive has: (a) been convicted of or pled guilty or *nolo contendere* to a felony or any crime involving moral turpitude or dishonesty; (b) participated in a fraud or act of dishonesty against the Company; (c) materially breached any agreement between such Executive and the Company or any written policy of the Company, and not cured such breach within five days of the Company's written notice of such breach; (d) engaged in conduct that demonstrates gross unfitness to serve; or (e) engaged in willful misconduct or refused to comply with any lawful directive of the Company, and not cured such noncompliance within five days of the Company's written notice of such noncompliance.
  - **10.2** *"Code"* means the Internal Revenue Code of 1986, as amended.
- **10.3** "*Good Reason*" will exist for Executive's resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent:
- **(a)** a material reduction in Executive's base salary, unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees;
  - **(b)** a material reduction in Executive's duties (including responsibilities and/or authorities);
- **(c)** a material reduction in the authority, duties, or responsibilities of the supervisor to whom Executive is required to report, including a requirement that Executive report to an employee of the Company instead of the Chief Executive Officer;
- **(d)** relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than 50 miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; or
- **(e)** any other action or inaction that constitutes a material breach by the Company of this Agreement or any agreement under which Executive provides services.

Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within 30 days following the first occurrence of the condition that Executive considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within 30 days following such written notice, and (ii) the Executive terminates employment within 90 days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.

- **10.4** "Corporate Transaction" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:
- (a) a sale, lease or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its subsidiaries;
- **(b)** a merger, consolidation, or similar transaction of the Company following which such entity is not the surviving entity;
- **(c)** a merger, consolidation or similar transaction of the Company following which such entity is the surviving entity but the shares outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

Notwithstanding the foregoing, the term Corporate Transaction will not include (i) a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, or (ii) the acquisition of securities of the Company by an investor or any affiliate thereof that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities. In addition, to the extent required for compliance with Code Section 409A, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

## 11. Proprietary Information Obligations.

- **11.1 Confidential Information Agreement.** As a condition of employment, Executive will execute and abide by the Company's standard form of Proprietary Information and Invention Assignment Agreement (the "Confidentiality Agreement") and Arbitration Agreement.
- 11.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment with the Company, except as expressly authorized by that third party. During Executive's employment with the Company, Executive will use in the performance of Executive's duties only information which is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

## 12. Outside Activities During Employment.

**12.1 Non-Company Business.** Except with the prior written consent of the Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any employment, occupation or business enterprise, other than ones in which Executive is a passive investor or as permitted under Section 11.2. Executive shall be entitled to serve on the board of directors of such other companies as may be approved in advance by the Chief Executive Officer, in each case, so long as Executive remain in compliance with Section 11 and such service does not interfere with Executive's duties under this Agreement. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

**12.2 No Adverse Interests.** Except with the prior written consent of the Chief Executive Officer, Executive will not during the term of Executive's employment with the Company acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise, provided that this does not prohibit Executive's continued involvement in any existing investments or ownership, for investment purposes only, of not more than 3% of the outstanding stock of any company listed on a national securities exchange, or actively traded in a national over-the-counter market.

**13.**Non-Solicitation. Executive agrees that during the period of employment with the Company and for 12 months after the date Executive's employment is terminated for any reason, Executive will not, either directly or through others, solicit or encourage or attempt to solicit or encourage any employee, independent contractor, or consultant of the Company to terminate his or her relationship with the Company in order to become an employee, consultant or independent contractor to or for any other person or entity.

**14.**Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, Executive's employment, or the termination of Executive's employment, including but not limited to statutory claims, will be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in San Diego, California, conducted by JAMS, Inc. ("JAMS") under the then applicable JAMS rules (which can be found at the following web address: http://www.jamsadr.com/rulesclauses). By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator will: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator will be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company will pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of the Executive if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

#### 15. General Provisions.

- **15.1 Notices.** Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.
- **15.2 Severability.** Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.
- **15.3 Waiver.** Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it will not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.
- **15.4 Complete Agreement.** This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.
- **15.5 Counterparts.** This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.
- **15.6 Headings.** The headings of the paragraphs hereof are inserted for convenience only and will not be deemed to constitute a part hereof nor to affect the meaning thereof.
- **15.7 Successors and Assigns.** This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which will not be withheld unreasonably.
- **15.8 Choice of Law.** All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

## KURA ONCOLOGY, INC.

By: /s/ Troy Wilson

Name: Troy Wilson
Title: President and CEO

EXECUTIVE

/s/ Brian Powl

Brian Powl

10.

## First Amendment to Lease

This First Amendment to Lease (this "**Amendment**"), is made as of the 30<sup>th</sup> day of August, 2023, by and between EAST OFFICE OPERATING LIMITED PARTNERSHIP, a

Massachusetts limited partnership, with an address c/o Pembroke Real Estate LLC, 255 State Street, Boston, Massachusetts 02109 (the "**Landlord**") and KURA ONCOLOGY, INC, a Delaware corporation, with an address of 12730 High Bluff Drive, Suite 400, San Diego, California 92130 (the "**Tenant**").

## WITNESSETH:

Reference is hereby made to the following facts:

A.Landlord and Tenant entered into that certain lease (the "Existing Lease"), dated as of March 24, 2020, for certain premises (the "Premises") comprised of 16,541 square feet of Rentable Area located on the eighth (8th) floor of the building commonly known as Seaport East located at Two Seaport Lane in Boston, Massachusetts (all as more particularly described in the Existing Lease, the "Building"). The Existing Lease as amended and modified by this Amendment is referred to herein as the "Lease." All capitalized words and phrases used in this Amendment and not otherwise defined herein shall have the meanings ascribed to them in the Existing Lease.

B.Landlord and Tenant have agreed to extend the term of the Existing Lease, and to modify and amend the Existing Lease, all in the manner hereinafter set forth.

NOW THEREFORE, in consideration of Ten Dollars (\$10.00) and other good and valuable consideration, the receipt, sufficiency and delivery of which are hereby acknowledged, the parties agree that the Existing Lease is hereby amended as follows:

1. Extension of Term. The term of the Lease is hereby extended to expire on July 31, 2031 (the "Expiration Date"), unless sooner terminated, in accordance with and subject to the terms and conditions set forth in the Lease. The period of time commencing on August 1, 2024 (the "Extension Term Commencement Date") and continuing through the Expiration Date is referred to in this Amendment as the "Extension Term." Without limitation, all references in the Existing Lease to the "Term" and "Lease Term" shall be deemed to include the Extension Term in all respects. The demise and use of the Premises for the Extension Term shall be upon and subject to all of the terms and conditions of the Existing Lease, except as expressly set forth in this Amendment.

2.<u>Rent for the Extension Term</u>. (a) For and with respect to the Extension Term, Tenant shall pay Annual Fixed Rent, all Additional Rent, including, without limitation, Tenant's Tax Percentage of the Tax Excess and Tenant's Office Percentage of the Operating Costs Excess, and all other charges and fees payable pursuant to the Existing Lease, in accordance with and subject to the terms and provisions of the Existing Lease. All such amounts shall be payable in accordance with the terms and provisions of the Existing Lease.

The Annual Fixed Rent and Monthly Fixed Rent payable by Tenant during the Extension Term shall be as follows:

Period of Time	Annual Fixed Rent	Monthly Fixed Rent
August 1, 2024 – July 31, 2025	\$1,306,739.00	\$108,894.91
August 1, 2025 – July 31, 2026	\$1,332,873.78	\$111,072.81
August 1, 2026 – July 31, 2027	\$1,359,531.25	\$113,294.27
August 1, 2027 – July 31, 2028	\$1,386,721.88	\$115,560.15
August 1, 2028 – July 31, 2029	\$1,414,456.31	\$117,871.35
August 1, 2029 – July 31, 2030	\$1,442,745.44	\$120,228.78
August 1, 2030 – July 31, 2031	\$1,471,600.35	\$122,633.36

(b) Subject to and in accordance with the provisions of this Section 2(b), Landlord shall provide Tenant with a credit (the "**Rent Credit**") in the total amount of

\$544,474.58 to be applied against the Monthly Fixed Rent payable under the Existing Lease, provided that all of the following conditions are satisfied: (i) the Lease is in full force and effect; and (ii) no Event of Default then exists under the Lease. The Rent Credit may be applied by Tenant as a credit, in equal monthly installments, against the Monthly Fixed Rent payments required to be made by Tenant for the months of August, 2023 through July, 2024, inclusive. The right to receive the Rent Credit is for the exclusive benefit of Tenant, and in no event shall such right be otherwise assigned to or be enforceable by or for the benefit of any third party. Any amount of the Rent Credit which has not been applied by December 31, 2024 shall be forfeited, waived, and released, and of no further force or effect, and Tenant shall have no further right or claim thereto.

(c) Throughout the Extension Term, Tenant shall pay all Additional Rent, including, without limitation, Tenant's Tax Percentage of the Tax Excess, and Tenant's Office Percentage of the Operating Costs Excess, in accordance with and subject to the terms and conditions of the Existing Lease, including, without limitation, the provisions of Section 4.2 of the Existing Lease. For purposes of determining the Tax Excess during the Extension Term, the Base Taxes shall be an amount equal to the Taxes payable for tax fiscal year 2025, commencing on July 1, 2024 and expiring on June 30, 2025. For purposes of determining the Operating Costs Excess during the Extension Term, the Base Operating Costs shall be an amount equal to the Operating Costs payable for calendar year 2024.

3.As-Is Condition. Tenant acknowledges that pursuant to the Existing Lease, through and including the date of this Amendment, the Premises have been under its control, subject to and in accordance with the terms and conditions of the Existing Lease. Tenant has had a full and complete opportunity to review and inspect all aspects of the Premises and the condition thereof. Notwithstanding any provision contained in the Existing Lease to the contrary, Tenant shall lease the Premises for the Extension Term "as-is", "where is", and in all respects in the condition in which the Premises are in as of the date of this Amendment, without any obligation on the part of Landlord to prepare or construct the Premises for Tenant's occupancy, or, excepting only Landlord's Extension Term Contribution (as hereinafter defined), to provide any allowances or inducements, or to construct any additional work or improvements therein or in the Building and without any representation or warranty (express or implied) on the

part of Landlord as to the condition of the Premises. Tenant shall, at its own cost and expense (excepting only to the extent funded by the Landlord's Extension Term Contribution), in accordance with and subject to the terms and provisions of the Lease, perform or cause to be performed any and all work and improvements necessary to prepare the Premises for occupancy by Tenant during the Extension Term. All of such work and improvements shall be considered to be Alterations, and shall be performed in accordance with the applicable terms and conditions of the Lease, including, without limitation, Section 6.2.5 of the Existing Lease.

## 4. Landlord's Extension Term Contribution.

- (a) After the Extension Term Commencement Date, Landlord shall provide to Tenant a tenant improvement allowance (the "Landlord's Extension Term Contribution") in an amount not to exceed \$827,050.00 to reimburse Tenant for the costs of performing Alterations in and to the Premises, provided that (i) as of the date on which Landlord is required to make payment thereof, the Lease is in full force and effect; (ii) as of both the date of the respective Contribution Request Notice (as hereinafter defined), and as of the respective date on which Landlord is required to make payment thereof, no Event of Default then exists; and (iii) Tenant shall provide not less than thirty (30) days prior notice (each, a "Contribution Request Notice") of its request for payment of all or a portion of the Landlord's Extension Term Contribution. Tenant shall pay all costs of constructing all Alterations in and to the Premises to the extent such costs exceed the Landlord's Extension Term Contribution. The Landlord's Extension Term Contribution shall be payable, at the election of Tenant in its sole discretion, either (x) in accordance with Section 4(b) of this Amendment, on account of hard construction costs and "soft costs" incurred by Tenant in connection with Tenant's work in the Premises, which may include architectural, design engineering services, networking, wiring, project management, IT, and telecommunication consultants, permit application fees, and other direct moving expenses fees incurred by Tenant; or (y) in accordance with Section 4(c) of this Amendment, as a credit against the Monthly Fixed Rent payable under the Lease. Notwithstanding any provision contained herein to the contrary, from and after the first (1st) anniversary of the Extension Term Commencement Date, any amount of the Landlord's Extension Term Contribution for which Tenant has not submitted a requisition for payment shall be retained by Landlord and Tenant shall have no further rights or claims thereto.
- (b) Landlord shall make progress payments on account of Landlord's Extension Term Contribution to Tenant on a monthly basis, for the work performed during the previous month. Each of Landlord's progress payments shall be limited to an amount equal to the aggregate amounts theretofore paid by Tenant (as certified by a duly authorized officer of Tenant) to Tenant's contractors, subcontractors and material suppliers which have not been subject to previous disbursements from Landlord's Extension Term Contribution, multiplied by a fraction the numerator of which is the amount of Landlord's Extension Term Contribution, and the denominator of which is the total contract price (or, if there is no specified or fixed contract price for the Alterations, then Landlord's reasonable estimate thereof) for the performance of all of the Alterations shown on all plans and specifications approved by Landlord, provided that in no event shall such fraction be greater than one. Such progress payments shall be made within thirty (30) days next following the delivery to Landlord of requisitions therefor. Each requisition shall be executed by a duly authorized officer of Tenant, and shall be accompanied by (i) with the exception of the first requisition, copies of partial waivers of lien from all contractors,

subcontractors, and material suppliers covering all work and materials which were the subject of previous progress payments by Landlord and Tenant, (ii) a certification from Tenant's architect that the work for which the requisition is being made has been performed substantially in accordance with the plans and specifications approved by Landlord, and (iii) such other documents and information as Landlord or its Mortgagee may reasonably request. Landlord shall disburse the final requisition upon submission by Tenant to Landlord of Tenant's requisition therefor accompanied by all documentation required under the foregoing provisions of this Section 4(b), together with (A) proof of the satisfactory completion of all required inspections and issuance of any required approvals, permits and sign-offs for the Alterations by Governmental Authorities having jurisdiction thereover, (B) final "as-built" plans and specifications for the Alterations as required pursuant to Section 5.1(c) of the Lease, and (C) issuance of final lien waivers by all contractors, subcontractors and material suppliers covering all of the Alterations. The right to receive Landlord's Extension Term Contribution is for the exclusive benefit of Tenant, and in no event shall such right be assigned to or be enforceable by or for the benefit of any third party, including any contractor, subcontractor, materialman, laborer, architect, engineer, attorney or other person or entity.

(c)In lieu of the progress payments pursuant to the foregoing Section 4(b), upon request made by Tenant, the Landlord's Extension Term Contribution may be applied as a credit on a monthly basis against payments required to be made by Tenant to Landlord on account of the Monthly Fixed Rent payable under the Lease, provided that all of the following conditions are satisfied: (i) the Lease is in full force and effect; (ii) no Event of Default then exists under the Lease; and (iii) Tenant shall provide not less than thirty (30) days prior notice of its request that all or a portion of the Landlord's Extension Term Contribution be applied as a credit against the Fixed Rent payable under the Lease, which notice shall specify the amount of such credit and the applicable installments of Fixed Rent to which such amount of the Landlord's Extension Term Contribution is to be applied.

5. <u>Reference Information</u>. Section 1.1 of the Existing Lease is hereby amended as follows:

(i) by deleting the definition of "**Original Notice Address of Tenant**", and replacing said definition with the following:

Kura Oncology, Inc. 12730 High Bluff Drive, Suite 400 San Diego, CA 92130 Attn: Chief Operating Officer

(ii) by inserting the following after the definitions of "Annual Fixed Rent Rate and Monthly Fixed Rent Rate," "Base Operating Costs, "Base Taxes," respectively:

"For and with respect to the Extension Term, the Annual Fixed Rent Rate and the Monthly Fixed Rent Rate shall be as follows:

Period of Time	Annual Fixed Rent	<b>Monthly Fixed Rent</b>
August 1, 2024 – July 31, 2025	\$1,306,739.00	\$108,894.91
August 1, 2025 – July 31, 2026	\$1,332,873.78	\$111,072.81
August 1, 2026 – July 31, 2027	\$1,359,531.25	\$113,294.27
August 1, 2027 – July 31, 2028	\$1,386,721.88	\$115,560.15
August 1, 2028 – July 31, 2029	\$1,414,456.31	\$117,871.35
August 1, 2029 – July 31, 2030	\$1,442,745.44	\$120,228.78
August 1, 2030 – July 31, 2031	\$1,471,600.35	\$122,633.36

Base Operating Costs for the

Extension Term: An amount equal to the Operating Costs payable for calendar year 2024.

Base Taxes for the

Extension Term: An amount equal to the Taxes payable for fiscal year 2025, which will commence on July 1,

2024

and expire on June 30, 2025.

(iii) by deleting the definition of "Expiration Date", and replacing said definition with the following

Expiration Date: July 31, 2031; or, if the Original Term shall have been extended for one

(1) period of five (5) years in

accordance with Section 2.3, July 31, 2036.

6.<u>Extension Option</u>. Section 2.3(a) of the Lease is hereby amended by deleting the phrase "such Extension Term to begin immediately upon the expiration of the Original Term of this Lease" from the first sentence of said section and replacing the phrase with the following "commencing on August 1, 2031 and expiring on July 31, 2036."

## 7. <u>Right of First Offer</u>.

- (a)Section 2.4 of the Existing Lease (titled "ROFO Right") shall remain in full force and effect, in accordance with and subject to the terms and conditions thereof.
- (b)All references in Section 2.4 of the Existing Lease to the "Expiration Date" shall mean and refer to the Expiration Date (as defined in Section 1 of this Amendment).
- (c)Section 2.4(a) of the Existing Lease is hereby amended by deleting the phrase "contiguous to the Premises" from the first sentence of said section.
  - 8. <u>Termination Option</u>.

(a)Subject to the full and complete satisfaction of the Termination Conditions Precedent (as hereinafter defined), in accordance with the provisions of this Section 7, Tenant shall have the one-time irrevocable option to terminate the Lease (a "Termination"). The conditions precedent (the "Termination Conditions Precedent") to the effectiveness of such Termination shall be as follows: (i) the effective date of such Termination shall be December 31, 2029 (the "Termination Date"); (ii) Tenant shall deliver written notice (a "Termination Notice") of such Termination to Landlord by not later than December 31, 2028; (iii) concurrent with the delivery of the Termination Notice, Tenant shall pay to Landlord, without deduction or offset, the Termination Fee (as hereinafter defined); and (iv) on the Termination Date no Event of Default of Tenant shall have occurred under the Lease. Said Termination Fee shall be Additional Rent and shall be in addition to, and not in lieu of, any other payments due under the Lease. The "Termination Fee" shall be an amount equal to \$857,827.30, which amount represents the sum of: (x) the Unamortized Portion (as hereinafter defined) as of the Termination Date of the Rent Credit, Landlord's Extension Term Contribution, and all brokerage commissions paid by Landlord to both Landlord's broker and Tenant's broker in connection with this Amendment, plus (y) the amount of Fixed Rent payable with respect to the last three (3) months of the Extension Term immediately preceding the Termination Date. The "Unamortized Portion" shall mean the amounts in the foregoing clause (x), amortized on a straight-line basis over the Extension Term, together with interest thereon at the rate of 8% per annum, compounded monthly in advance.

(b)Provided that all of the Termination Conditions Precedent have been fully and completely satisfied, then effective as of the Termination Date, the Lease, and the rights of the Tenant with respect to the Premises, shall terminate and expire with the same force and effect as if such Termination Date had originally been specified as the Expiration Date. Prior to the Termination Date, Tenant shall comply with all of the terms and provisions of the Lease and shall perform all of its obligations thereunder, including, without limitation, the obligation to pay when due all Fixed Rent and other Additional Rent. By not later than the Termination Date, Tenant shall surrender and yield-up the Premises in good and broom-clean order, repair and condition, free of all tenants and occupants, and otherwise in the condition in which the Premises are required to be surrendered pursuant to the terms and conditions of the Lease at the expiration of the Term. All property and Alterations of any kind, nature or description remaining in the Premises after the Termination Date shall be and become the property of Landlord and may be disposed of by Landlord, without payment from Landlord and without the necessity to account therefor to Tenant.

(c)Without limiting the foregoing, if Tenant fails to yield up and surrender the Premises by the Termination Date, then Tenant shall pay a holdover charge at the rate set forth in Section 6.1.9 of the Lease. Nothing herein contained shall constitute a release, waiver, limitation, or restriction of any rights or remedies of Landlord on account of Tenant's failure to surrender the Premises by the Termination Date, including any rights or remedies afforded to Landlord in Section 6.1.9 of the Lease.

(d)The foregoing provisions shall be self-operative; provided, however, on the request of either party, Landlord and Tenant will enter into a mutually satisfactory customary termination agreement evidencing said Termination of the Lease.

(e) Time is of the essence of this Section 8.

9. Security Deposit. Article 11 of the Existing Lease is hereby deleted in the entirety and replaced with the following:

## SECURITY DEPOSIT

- 11.1. <u>Security Deposit</u>. Concurrent with the execution of this Amendment, (i) Tenant has delivered to Landlord a cash security deposit (the "**Security Deposit**") in the amount of
- \$210,000.00 (the "Security Deposit Amount"), as security for the faithful performance and observance by Tenant of the terms, covenants and conditions of this Lease, and (ii) Landlord has returned to Tenant the previously-delivered letter of credit. Tenant covenants and agrees to maintain the Security Deposit in the Security Deposit Amount throughout the Term of this Lease.
- 11.2. Application of Security. If (a) an Event of Default by Tenant occurs under this Lease, or (b) Tenant files a voluntary petition under any Federal or state bankruptcy or insolvency code, law or proceeding, then Landlord shall have the right to use, apply, or retain the whole or any part of the Security Deposit to the extent required for the payment of any Rent or any other sum as to the payment of which Tenant is in default including (i) any sum which Landlord may expend or may be required to expend by reason of such Event of Default, and/or (ii) any damages to which Landlord is entitled pursuant to this Lease, whether such damages accrue before or after summary proceedings or other reentry by Landlord. If Landlord applies or retains any part of the Security Deposit, then Tenant, upon demand, shall deliver additional cash security in the amount so applied or retained such that Landlord shall have a cash Security Deposit in the Security Deposit Amount on hand at all times during the Term. If Tenant shall comply with all of the terms, covenants and conditions of this Lease, the Security Deposit, or remaining balance thereof, as the case may be, shall be returned to Tenant promptly after (x) the Expiration Date, (y) the surrender and yield-up of possession of the Premises to Landlord in the manner required by this Lease, and (z) the curing of any outstanding Events of Default under this Lease.
- 11.3. <u>Transfer</u>. Landlord, its successors and assigns, may, at any time and without notice to Tenant and without first obtaining Tenant's consent thereto, transfer (one or more times) the Security Deposit to the holder of any mortgage upon the Building or any other successor landlord in connection with a transfer of the Building, as a part of the assignment by Landlord to such mortgagee or successor landlord of its rights and interests in and to this Lease. In the event of a transfer of Landlord's interest in the Building, Landlord shall transfer the Security Deposit, to the transferee and thereupon Landlord shall without any further agreement between the parties, be released by Tenant from all liability therefor. The provisions of this Section 11.3 shall apply to every transfer or assignment of the whole or any portion of the Security Deposit to a new landlord.
- 11.4.<u>Landlord's Right to Draw Upon Security Deposit</u>. The use, application or retention of the Security Deposit, or any portion thereof, by Landlord shall not prevent Landlord

from exercising any other right or remedy provided by this Lease or by any applicable law, it being intended that Landlord shall not first be required to proceed against the Security Deposit, and shall not operate as a limitation on any recovery to which Landlord may otherwise be entitled. Tenant agrees and acknowledges that in the event Tenant becomes a debtor under any chapter of the Bankruptcy Code, neither Tenant, any trustee, nor Tenant's bankruptcy estate shall have any right to restrict or limit Landlord's claim and/or rights to the Security Deposit by application of Section 502(b)(6) of the U. S. Bankruptcy Code or otherwise.

10.<u>Inapplicable Lease Provision</u>. Section 2.1(e) (relocation) of the Existing Lease is hereby deleted in the entirety, and shall be of no further force or effect.

11.<u>Brokerage</u>. Tenant warrants and represents to Landlord, and Landlord warrants and represents to Tenant, that it has dealt with no broker or agent in connection with this Amendment, other than Colliers International New England, LLC ("Colliers") and Newmark of Massachusetts LLC ("Newmark"). Each of Tenant and Landlord shall indemnify and hold harmless the other from and against any and all loss, cost and expense (including reasonable attorneys' fees) arising out of or resulting from any breach of said warranty and representation by the indemnifying party, including, without limitation, any claims for a brokerage commission, finder's fee or similar compensation made by any person other than Newmark, arising out of or in connection with this Amendment. Landlord shall be responsible for payment of all fees payable to Newmark in connection with this Amendment, pursuant to a separate agreement.

12. Miscellaneous. This Amendment may be executed by electronic signatures, each of which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation, in addition to electronically produced signatures, "electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via PDF) of an original signature. This Amendment may be executed in multiple counterparts (which counterparts may be executed and delivered by PDF or another file sent by email) which shall together constitute a single document. Any executed counterpart of this Amendment delivered by PDF or another file sent by email shall be equally effective as an original counterpart for all purposes. Tenant hereby represents and warrants to Landlord as follows: (i) the execution and delivery of this Amendment by Tenant has been duly authorized by all requisite corporate action; (ii) neither the Existing Lease nor the interest of Tenant therein has been assigned, sublet, encumbered or otherwise transferred; (iii) there are no defenses or counterclaims to the enforcement of the Existing Lease or the liabilities and obligations of Tenant thereunder; (iv) Tenant is not entitled to any offset, abatement or reduction of rent under the Existing Lease; (vi) Landlord has performed all work and constructed all improvements required pursuant to the Existing Lease, and has provided all allowances and contributions required pursuant to the Existing Lease; and

(vii) Landlord has made no representations or warranties, except as expressly and specifically set forth in the Existing Lease and this Amendment. The submission of drafts of this document for examination and negotiation does not constitute an offer to lease, or a reservation of or option for, the Extension Term or any of the other terms and conditions set forth in this Amendment, and this Amendment shall not be binding upon Landlord or Tenant unless and until Landlord shall have executed and delivered a fully executed copy of this Amendment to Tenant. Except as

expressly and specifically set forth in this Amendment, the Existing Lease is hereby ratified and confirmed, and all of the terms, covenants, agreements and provisions of the Existing Lease shall remain unaltered and unmodified and in full force and effect throughout the balance of the term of the Lease, as extended hereby. Except as expressly set forth herein, all of the covenants, representations and warranties made by Tenant contained in the Existing Lease are hereby remade, reaffirmed and ratified as of the date hereof.

[Signatures on following page]

EXECUTED as an instrument under seal as of the date first above-written.

## EAST OFFICE OPERATING LIMITED PARTNERSHIP, a Massachusetts limited partnership

By: Commonwealth Flats Development East Corp., its general

partner

By: /s/ Katherine Hedrick

Name: Katherine Hedrick
Title: Vice President

## KURA ONCOLOGY, INC, a Delaware corporation

By: /s/ Kathleen Ford

Name: Kathleen Ford

Title: COO

Hereunto duly authorized

#### FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of October 2, 2023 (the "Amendment Effective Date"), is entered into by and between Kura Oncology, Inc., a Delaware corporation, together with any Subsidiaries from time to time party to the Loan Agreement (collectively referred to as "Borrower"), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as "Lender") that are party hereto and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, "Agent").

A. Borrower, Lender and Agent are parties to that certain Loan and Security Agreement, dated as of November 2, 2022 (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). Borrower, Lender and Agent have agreed to certain amendments to the Loan Agreement upon the terms and conditions more fully set forth herein.

#### **SECTION 1Definitions; Interpretation.**

- (a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.
- (b) **Rules of Construction**. The rules of construction that appear in <u>Section 1.3</u> of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

## SECTION 2Amendments to the Loan Agreement.

- (a) The Loan Agreement shall be amended as follows effective as of the date hereof (except as otherwise noted):
- (i) The following defined terms are hereby added, in appropriate alphabetical order, or amended and restated, as applicable, in <u>Section 1.1</u> of the Loan Agreement, as set forth below:

"First Amendment" means that certain First Amendment to Loan and Security Agreement, dated as of October 2, 2023 by and among Borrower, Lender and Agent.

"First Amendment Effective Date" means October 2, 2023.

"Tranche 2 Facility Charge" means one half of one percent (0.50%) of the Tranche 2 Commitment, which is fully earned and due and payable to the Lenders on the Tranche 2 Milestone Date.

"**Tranche 3 Facility Charge**" means one half of one percent (0.50%) of the Tranche 3 Commitment, which is fully earned and due and payable to the Lenders on the Tranche 3 Milestone Date.

- (ii) The following new Section 2.10 is inserted immediately following Section 2.09 thereof:
- "2.10 Facility Charge. Each of the Tranche 2 Facility Charge and the Tranche 3 Facility Charge shall be due and payable at such times set forth in the definitions thereof. For the avoidance of doubt, the Tranche 4 Facility Charge shall be payable pursuant to Section 4.2(g)."
- (b) **References Within Loan Agreement**. Each reference in the Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment. This Amendment shall be a Loan Document. Any failure by Borrower to perform any obligation under this Amendment shall constitute an Event of Default under the Loan Agreement.

**SECTION 3Conditions to Effectiveness**. The effectiveness of this Amendment shall be subject to satisfaction of each of the following conditions precedent:

(a) Agent shall have received this Amendment, executed by Agent, Lender, and Borrower.

#### **SECTION 4Miscellaneous.**

- (a) Loan Documents Otherwise Not Affected; Reaffirmation. Except as expressly amended pursuant hereto or referenced herein, the Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. Borrower hereby reaffirms the security interest granted pursuant to the Loan Documents and hereby reaffirms that such grant of security in the Collateral granted as of the Closing Date continues without novation and secures all Secured Obligations under the Loan Agreement and the other Loan Documents. Borrower acknowledges and agrees that it does not have any defense, set-off, counterclaim or challenge against the payment of any sums owing under the Loan Agreement and the other Loan Documents, or the enforcement of any of the terms or conditions thereof.
- (b) **Conditions**. For purposes of determining compliance with the conditions specified in <u>Section 3</u>, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the date hereof specifying its objection thereto.
- (c) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lender that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.
  - (d) Binding Effect. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.
- (e) **Governing Law.** This Amendment and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.
- (f) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.
- (g) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.
- (h) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.
- (i) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a

paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

- (j) **Inconsistencies**. To the extent of any inconsistency between the terms and conditions of this Amendment and the terms and conditions of the Loan Agreement and the other Loan Documents, the terms and conditions of this Amendment shall prevail.
  - (k) Fees. Each party shall be responsible for their own attorneys' fees.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

## **BORROWER**:

KURA ONCOLOGY, INC.

Signature: /s/ Troy Wilson

Print Name: Troy Wilson

Title: President and Chief Executive Officer

[Signature Page to First Amendment to Loan and Security Agreement]

## AGENT:

## HERCULES CAPITAL, INC.

Signature: /s/ Seth H. Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

## LENDERS:

## HERCULES CAPITAL, INC.

Signature: /s/ Seth H. Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

## HERCULES CAPITAL IV, L.P.

By: Hercules Technology SBIC

Management, LLC, its General Partner

By: Hercules Capital, Inc., its Manager

Signature: /s/ Seth H. Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

[Signature Page to First Amendment to Loan and Security Agreement]

## LENDERS:

## HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth H. Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

## HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth H. Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

[Signature Page to First Amendment to Loan and Security Agreement]

#### KURA ONCOLOGY, INC.

## \$150,000,000

## **COMMON STOCK**

## **SALES AGREEMENT**

November 2, 2023

Leerink Partners LLC 1301 Avenue of the Americas, 12<sup>th</sup> Floor New York, New York 10019

Cantor Fitzgerald & Co. 110 E. 59th Street New York, NY 10022

Ladies and Gentlemen:

Kura Oncology, Inc., a Delaware corporation (the "<u>Company</u>"), Leerink Partners LLC ("<u>Leerink Partners</u>"), as lead sales agent, and Cantor Fitzgerald & Co. ("<u>Cantor</u>", and together with Leerink Partners, the "<u>Agents</u>"), as sales agent, confirm their agreement (this "<u>Agreement</u>") as follows:

1. <u>Issuance and Sale of Shares</u>. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agents, each acting as agent and/or principal, shares (the "<u>Placement Shares</u>") of the Company's common stock, par value \$0.0001 per share (the "<u>Common Stock</u>"), having an aggregate offering price of up to \$150,000,000. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this <u>Section 1</u> on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and the Agents shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through the Agents will be effected pursuant to the Registration Statement (as defined below) filed by the Company with the Securities and Exchange Commission (the "<u>Commission</u>"), which became effective upon filing with the Commission, although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Placement Shares.

The Company has prepared and will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "Securities Act"), with the Commission an "automatic shelf registration statement" (as defined under Rule 405 of the Securities Act) of the Company on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "Exchange Act"). The Company has prepared a prospectus supplement specifically relating to the Placement Shares to be issued from time to time pursuant to this Agreement (the "Prospectus Supplement") to the base prospectus included as part of such registration statement. The Company has furnished to the Agents, for use by the Agents, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently

filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, is herein called the "Registration Statement." The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement or by any additional prospectus supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act regulations ("Rule 433"), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the "Prospectus." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval system ("EDGAR").

<u>Placements</u>. Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a "Placement"), it will 2. notify an Agent (the "Designated Agent") by email notice (or other method mutually agreed to in writing by the parties) (a "Placement Notice") containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as <u>Schedule 1</u>. The Placement Notice shall originate from any of the individuals from the Company set forth on <u>Schedule 2</u> (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from such Designated Agent set forth on Schedule 2, as such Schedule 2 may be amended from time to time by sending a written notice containing a revised **Schedule 2** to the other party in the manner provided in **Section 12** (including by email correspondence to each of the individuals of the Company set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto reply). The Placement Notice shall be effective upon receipt by such Designated Agent unless and until (i) in accordance with the notice requirements set forth in Section 4, such Designated Agent declines to accept the terms contained therein for any reason, in its sole discretion, within two Trading Days of the date the Designated Agent receives the Placement Notice, (ii) in accordance with the notice requirements set forth in Section 4, such Designated Agent suspends sales under the Placement Notice for any reason in its sole discretion, (iii) the entire amount of the Placement Shares have been sold, (iv) in accordance with the notice requirements set forth in Section 4, the Company suspends sales under or terminates the Placement Notice for any reason, in its sole discretion, (v) the Company issues a subsequent Placement Notice and explicitly indicates that its parameters supersedes those contained in the earlier dated Placement Notice, or (vi) this Agreement has been terminated under the provisions of Section 11. The amount of any discount, commission or other compensation to be paid by the Company to such Designated Agent in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 3. It is expressly acknowledged and agreed that neither the Company nor the Agents will have any obligation whatsoever with respect to a Placement or any Placement

Shares unless and until the Company delivers a Placement Notice to a Designated Agent and such Designated Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by the Designated Agent. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, including Section 5(c), upon the Designated Agent's acceptance of the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Designated Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market, Inc. ("Nasdaq") to sell such Placement Shares up to the amount specified in such Placement Notice, and otherwise in accordance with the terms of such Placement Notice. The Designated Agent will provide written confirmation to the Company and the other Agent (including by email correspondence to each of the individuals of the Company set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which the Designated Agent has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. The Designated Agent may sell Placement Shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation, sales made through Nasdaq or on any other existing trading market for the Common Stock or to or through a market maker. If expressly authorized by the Company in a Placement Notice, the Designated Agent may also sell Placement Shares in negotiated transactions. Notwithstanding the provisions of Section 6(hh), the Designated Agent shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Designated Agent will be successful in selling Placement Shares, (ii) the Designated Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by such Designated Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of Nasdaq to sell such Placement Shares as required under this Agreement and (iii) the Designated Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement unless the Company and the Designated Agent enter into a separate written agreement setting forth the terms of such sale. For the purposes hereof, "Trading Day" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

## 4. <u>Suspension of Sales</u>.

(a) The Company or the Designated Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on <u>Schedule 2</u>, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on <u>Schedule 2</u>), suspend any sale of Placement Shares; *provided*, *however*, that such suspension shall not affect or impair either

party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this <u>Section 4</u> shall be effective against the other unless it is made to one of the individuals named on <u>Schedule 2</u> hereto, as such schedule may be amended from time to time, to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on <u>Schedule 2</u>, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto reply).

- (b) Notwithstanding any other provision of this Agreement, during any period in which the Company is, or could be deemed to be, in possession of material non-public information, the Company and the Designated Agent agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares and shall cancel any effective Placement Notices instructing the Designated Agent to make sales, and (iii) the Designated Agent shall not be obligated to sell or offer to sell any Placement Shares.
- (c) If either the Designated Agent or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c) (1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, the Designated Agent or the Company shall promptly notify the other party, and the Designated Agent may, at its sole discretion, suspend sales of the Placement Shares under this Agreement.

## 5. <u>Settlement and Delivery of Placement Shares.</u>

- (a) <u>Settlement of Placement Shares</u>. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2<sup>nd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "<u>Settlement Date</u>" and the first such settlement date, the "<u>First Delivery Date</u>"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "<u>Net Proceeds</u>") will be equal to the aggregate gross sales price received by the Designated Agent at which such Placement Shares were sold, after deduction of (i) the Designated Agent's commission, discount or other compensation for such sales payable by the Company pursuant to <u>Section 2</u> hereof, (ii) any other amounts due and payable by the Company to the Designated Agent hereunder pursuant to <u>Section 7(g)</u> (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.
- (b) <u>Delivery of Placement Shares</u>. On or before each Settlement Date, the Company will issue the Placement Shares being sold on such date and will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting the Designated Agent's or its designee's account (provided the Designated Agent shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System ("<u>DWAC</u>") or by such other means of delivery as may be mutually agreed upon by the parties hereto, which in all cases shall be duly authorized, freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, the Designated Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Designated Agent shall be responsible for providing DWAC instructions or other instructions for delivery by other means with regard to the transfer of the Placement Shares being sold. In addition to and in no way limiting the rights and obligations set forth in Section 9(a) hereto, the Company agrees that if the Company or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized, freely

tradeable, transferable, registered Placement Shares in good deliverable form by 2:30 P.M., New York City time, on a Settlement Date (other than as a result of a failure by the Designated Agent to provide instructions for delivery), the Company will (i) take all necessary action to cause the full amount of any Net Proceeds that were delivered to the Company's account with respect to such settlement, together with any costs incurred by the Designated Agent and/or its clearing firm in connection with recovering such Net Proceeds, to be immediately returned to the Designated Agent or its clearing firm no later than 5:00 P.M., New York City time, on such Settlement Date, by wire transfer of immediately available funds to an account designated by the Designated Agent or its clearing firm, (ii) indemnify and hold the Designated Agent and its clearing firm harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (iii) pay to the Designated Agent (without duplication) any commission, discount or other compensation to which it would otherwise have been entitled absent such default. Certificates for the Placement Shares, if any, shall be in such denominations and registered in such names as the Designated Agent may request in writing one Business Day (as defined below) before the applicable Settlement Date. Certificates for the Placement Shares, if any, will be made available by the Company for examination and packaging by the Designated Agent in New York City not later than 12:00 P.M., New York City time, on the Business Day prior to the applicable Settlement Date.

- Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any (c) Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate number or gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of: (i) the number or dollar amount of Common Stock registered pursuant to, and available for offer and sale under, the Registration Statement pursuant to which the offering of Placement Shares is being made, (ii) the number of authorized but unissued Common Stock of the Company (less Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (iii) the number or dollar amount of Common Stock permitted to be offered and sold by the Company under Form S-3 (including General Instruction I.B.6. thereof, if such instruction is applicable), (iv) the number or dollar amount of Common Stock the Company's board of directors or a duly authorized committee thereof authorizes the Company to issue and sell from time to time, or (v) the dollar amount of Common Stock for which the Company has filed the Prospectus Supplement. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors or a duly authorized committee thereof. Notwithstanding anything to the contrary contained herein, the parties hereto acknowledge and agree that compliance with the limitations set forth in this Section 5(c) on the number or dollar amount of Placement Shares that may be issued and sold under this Agreement from time to time shall be the sole responsibility of the Company, and that the Designated Agent shall have no obligation in connection with such compliance.
- 6. <u>Representations and Warranties of the Company</u>. The Company represents and warrants to, and agrees with, the Agents that, as of the date of this Agreement, and as of (i) each Representation Date (as defined in <u>Section 7(m)</u>), (ii) each date on which a Placement Notice is given, (iii) any date on which Placement Shares are sold hereunder and (iv) each Settlement Date:

- (a) <u>Compliance with Registration Requirements</u>. The Registration Statement and any Rule 462(b) Registration Statement have been declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.
- (b) No Misstatement or Omission. The Prospectus, when filed, complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each of the Settlement Dates, if any, complied in all material respects with the Securities Act and did not and, as of each Settlement Date, if any, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each of the Settlement Dates, if any, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agents furnished to the Company in writing by the Agents expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.
- (c) <u>Offering Materials Furnished to the Agents</u>. The Company has delivered to the Agents one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as the Agents have reasonably requested.
- (d) <u>Not an Ineligible Issuer</u>. The Company currently is not an "ineligible issuer," as defined in Rule 405 of the rules and regulation of the Commission. The Company agrees to notify the Agents promptly upon the Company becoming an "ineligible issuer."
- (e) Renewal Deadline. (i) At the time of filing the Registration Statement, (ii) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Securities Act (whether such amendment was by post-effective amendment, incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or form of prospectus), and (iii) at the time the Company or any person acting on its behalf (within the meaning, for this clause only, of Rule 163(c) under the Securities Act) made any offer relating to the Common Stock in reliance on the exemption of Rule 163 under the Securities Act, the Company is a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act, including not having been an "ineligible issuer" as defined in Rule 405

under the Securities Act. The Registration Statement is an "automatic shelf registration statement," as defined in Rule 405 under the Securities Act, that initially became effective within three years of the date hereof. If immediately prior to the third anniversary (the "Renewal Deadline") of the initial effective date of the Registration Statement, any of the Common Stock remains unsold by the Agents, the Company will, prior to the Renewal Deadline file, if it has not already done so and is eligible to do so, a new automatic shelf registration statement relating to the Common Stock, in a form satisfactory to the Agents. If the Company is no longer eligible to file an automatic shelf registration statement, the Company will, prior to the Renewal Deadline, if it has not already done so, file a new shelf registration statement relating to the Common Stock, in a form satisfactory to the Agents, and will use its best efforts to cause such registration statement to be declared effective within 180 days after the Renewal Deadline. The Company will take all other action necessary or appropriate to permit the public offering and sale of the Common Stock to continue as contemplated in the expired Registration Statement. References herein to the Registration Statement shall include such new automatic shelf registration statement or such new shelf registration statement, as the case may be.

The Company has not received from the Commission any notice pursuant to Rule 401(g)(2) under the Securities Act objecting to the use of the automatic shelf registration form. If at any time when Common Stock remains unsold by the Agents the Company receives from the Commission a notice pursuant to Rule 401(g)(2) under the Securities Act or otherwise ceases to be eligible to use the automatic shelf registration statement form, the Company will (i) promptly notify the Agents, (ii) promptly file a new registration statement or post-effective amendment on the proper form relating to the Common Stock, in a form satisfactory to the Agents, (iii) use its best efforts to cause such registration statement or post-effective amendment to be declared effective as soon as practicable, and (iv) promptly notify the Agents of such effectiveness. The Company will take all other action necessary or appropriate to permit the public offering and sale of the Common Stock to continue as contemplated in the Registration Statement that was the subject of the notice under Rule 401(g)(2) or for which the Company has otherwise become ineligible. References herein to the Registration Statement relating to the Common Stock shall include such new registration statement or post-effective amendment, as the case may be.

- (f) <u>Distribution of Offering Material by the Company</u>. The Company has not distributed and will not distribute, prior to the completion of the Agents' distribution of the Placement Shares, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.
- (g) <u>Sales Agreement</u>. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.
- (h) <u>Authorization of the Common Stock</u>. The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly authorized, validly issued, fully paid and nonassessable.
- (i) <u>No Applicable Registration or Other Similar Rights</u>. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the

Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

- No Material Adverse Change. Except as otherwise disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change on the business, properties, management, financial position, stockholders' equity, results of operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change is called a "Material Adverse Change"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business: and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for regular quarterly dividends publicly announced by the Company or dividends paid to the Company or other subsidiaries, by any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.
- (k) <u>Independent Accountants</u>. Ernst & Young LLP, who has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission or incorporated by reference as a part of the Registration Statement and included in the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Exchange Act.
- (l) Preparation of the Financial Statements. The financial statements filed with the Commission as a part of or incorporated by reference in the Registration Statement and included in the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in or incorporated in the Registration Statement. The financial data, if any, set forth or incorporated in the Prospectus fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained, incorporated or deemed to be incorporated in the Registration Statement.
- (m) <u>XBRL Reporting</u>. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- (n) <u>Incorporation and Good Standing of the Company and its Subsidiaries</u>. Each of the Company and its subsidiaries has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction in which it is chartered or organized with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Prospectus, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except where the failure to be so qualified or in good standing would not reasonably be expected, individually or in the

aggregate, to result in a Material Adverse Change. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the most recently ended fiscal year and other than (i) those subsidiaries not required to be listed on Exhibit 21.1 by Item 601 of Regulation S-K under the Exchange Act and (ii) those subsidiaries formed since the last day of the most recently ended fiscal year.

- (o) <u>Capital Stock Matters</u>. The Common Stock conforms in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with federal and state securities laws. None of the outstanding shares of Common Stock were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those accurately described in all material respects in the Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.
- Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor (p) any of its subsidiaries is in violation of its charter or by-laws or is in default (or, with the giving of notice or lapse of time, would be in default) ("Default") under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of the property or assets of the Company or any of its subsidiaries is subject (each, an "Existing **Instrument**"), except for such Defaults as would not, individually or in the aggregate, result in a Material Adverse Change. The Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws of the Company or any subsidiary, (ii) will not conflict with or constitute a breach of, or Default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except for such conflicts, breaches, Defaults, liens, charges or encumbrances as would not, individually or in the aggregate, result in a Material Adverse Change and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any subsidiary. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act, the listing rules of Nasdaq, applicable state securities or blue sky laws and from the Financial Industry Regulatory Authority ("FINRA").
- (q) <u>No Material Actions or Proceedings</u>. There is no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the

Company or any of its subsidiaries or its or their respective property is pending or, to the best knowledge of the Company, is being threatened that (i) could reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of any of the transactions contemplated hereby or (ii) could reasonably be expected to result in a Material Adverse Change, except as set forth in or contemplated in the Prospectus (exclusive of any supplement thereto).

- (r) All Necessary Permits, etc. The Company and each subsidiary possess such valid and current certificates, authorizations or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses, other than those the failure to possess or own would not result in a Material Adverse Change, and neither the Company nor any subsidiary has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, could result in a Material Adverse Change.
- (s) Regulatory Matters. The Company and its subsidiaries have operated at all times and are currently in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by the Company and its subsidiaries ("Applicable Regulatory Laws") of the United States Food and Drug Administration of the U.S. Department of Health and Human Services ("FDA") and comparable regulatory agencies outside of the United States to which they are subject (collectively, the "Regulatory Authorities"), except where the failure to so comply would not, individually or in the aggregate, result in a Material Adverse Change. Neither the Company nor any of its subsidiaries has received any written notices, correspondence or other communications from, nor do they have knowledge that any of their collaboration partners has received, any written notices, correspondence or other communications from Regulatory Authorities alleging or asserting material non-compliance with any Applicable Regulatory Laws. The Company has not failed to file with Regulatory Authorities any required material filing, declaration, listing, registration, report or submission with respect to the Company's products that are described in the Registration Statement and the Prospectus; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with Applicable Regulatory Laws when filed; and no material deficiencies regarding compliance with Applicable Regulatory Law have been asserted by any Regulatory Authority with respect to any such filings, declarations, listings, registrations, reports or submissions.
- (t) Tests and Preclinical and Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Regulatory Laws, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder (collectively, "FFDCA"); the descriptions of the results of such studies, tests and trials contained in the Registration Statement and the Prospectus are, to the Company's knowledge, accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement and the Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement and the Prospectus when viewed in the context in which

such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement or the Prospectus, the Company has not received any notices or correspondence from the FDA or any governmental authority requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company, other than ordinary course communications with respect to modifications in connection with the design and implementation of such trials, copies of which communications have been made available to the Agents.

- (u) Tax Law Compliance. There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Placement Shares. The Company has filed all tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure to file would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.
- (v) <u>Company Not an "Investment Company"</u>. The Company has been advised of the rules and requirements under the Investment Company Act of 1940, as amended (the "<u>Investment Company Act</u>"). The Company is not, and after receipt of payment for the Common Stock will not be, an "investment company" within the meaning of Investment Company Act.
- (w) Insurance. The Company and each of its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the businesses in which they are engaged; all policies of insurance insuring the Company or any of its subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any such subsidiary has been refused any insurance coverage sought or applied for; and neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to result in a Material Adverse Change.
- (x) <u>No Price Stabilization or Manipulation</u>. The Company has not taken, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.
- (y) <u>Related Party Transactions</u>. There are no business relationships or related-party transactions involving the Company or any subsidiary or any other person required to be described in the Prospectus which have not been described as required.
- (z) <u>No Associated Persons; FINRA Matters</u>. Neither the Company nor, to the Company's knowledge, any of its affiliates (within the meaning of FINRA Rule 5121(f)(1)) directly or

- indirectly controls, is controlled by, or is under common control with, or is an associated person (within the meaning of Article I, Section 1(ee) of the By-laws of FINRA) of, any member firm of FINRA. In accordance with FINRA Conduct Rule 5110(j)(6), the Placement Shares have been registered with the Commission on Form S-3 under the Securities Act.
- (aa) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (bb) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that could result in a violation or a sanction for violation by such persons of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder; and the Company and its subsidiaries have instituted and maintain policies and procedures designed to ensure compliance therewith. No part of the proceeds of the offering will be used, directly or indirectly, in violation of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder.
- (cc) <u>Compliance with Money Laundering Laws</u>. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "<u>Money Laundering Laws</u>") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (dd) Compliance with OFAC. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries (i) is, or is controlled or 50% or more owned in the aggregate by or is acting on behalf of, one or more individuals or entities that are currently the subject of any sanctions administered or enforced by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the U.S. Department of State or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, a member state of the European Union (including sanctions administered or enforced by Her Majesty's Treasury of the United Kingdom) or other relevant sanctions authority (collectively, "Sanctions" and such persons, "Sanctioned Persons" and each such person, a "Sanctioned Person"), (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that

country or territory (collectively, "Sanctioned Countries" and each, a "Sanctioned Country") or (iii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity in any manner that would result in a violation of any Sanctions by, or could result in the imposition of Sanctions against, any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise). Neither the Company nor any of its subsidiaries has engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country.

- (ee) <u>Company's Accounting System</u>. The Company maintains a system of "internal control over financial reporting" (as such term is defined in Rule 13a-15(f) of the General Rules and Regulations under the Exchange Act (the "<u>Exchange Act Rules</u>")) that complies with the requirements of the Exchange Act and has been designed by their respective principal executive and principal financial officers, or under their supervision, to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company's internal control over financial reporting is effective in all material respects. Except as described in the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.
- (ff) <u>Disclosure Controls</u>. The Company and its subsidiaries maintain "disclosure controls and procedures" (as such term is defined in Rule 13a- 15(e) under the Exchange Act). Such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company and its subsidiaries is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company and its subsidiaries have conducted evaluations of the effectiveness of their disclosure controls as required by Rule 13a-15 of the Exchange Act; such disclosure controls and procedures are effective.
- (gg) Compliance with Environmental Laws. The Company and its subsidiaries are (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"), (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) have not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. Except as set forth in the Prospectus, neither the Company nor any of the subsidiaries has been named as a

"potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended. In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and its subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

- (hh) Intellectual Property. The Company owns, possesses, has license rights or has other rights to use, or to the Company's knowledge can acquire on reasonable terms rights to, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") necessary for the conduct of the Company's business as now conducted by the Company or, to the Company's best knowledge, as are necessary for the business as proposed to be conducted, in each case as described in the Prospectus, except where the failure to own, possess or license such rights would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. Except as set forth in the Prospectus and to the knowledge of the Company, (i) the conduct of its business has not infringed, misappropriated or otherwise violated any Intellectual Property of others in any material respect and (ii) no third party has any rights to or has infringed, misappropriated or otherwise violated any Intellectual Property of the Company that relates to the Company's product candidates or processes, in any material respect. Except as set forth in the Prospectus, there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim (i) challenging the Company's rights in or to any of the Intellectual Property that relates to the Company's product candidates or processes; (ii) alleging that the Company has materially infringed, misappropriated or otherwise violated or conflicted with any Intellectual Property of any third party; or (iii) challenging the validity, scope or enforceability of any Intellectual Property of the Company that relates to the Company's product candidates or processes, and in the case of each of (i), (ii) and (iii), the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim.
- (ii) <u>Title to Real and Personal Property.</u> The Company and each of its subsidiaries have good and marketable title in and (in the case of real property) to, or have valid and marketable rights to lease or otherwise use, all items of real or personal property which are material to the business of the Company and its subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that (i) do not, singularly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries or (ii) could not reasonably be expected, singularly or in the aggregate, to have a Material Adverse Change.
- (jj) <u>Data Privacy and Cybersecurity</u>. The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), and

databases (collectively, "IT Systems") are adequate in all material respects for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change, to the Company's knowledge, there has been no security breach or attack or other compromise of or relating to any of the Company's and its subsidiaries' IT Systems. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data ("Personal Data")) and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification. Neither the Company nor its subsidiaries have received any written notice of any claims, investigations, or alleged violations of law with respect to Personal Data.

- (kk) <u>Forward-Looking Statements</u>. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Prospectus or Prospectus Supplement has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith; *provided that* for documents incorporated by reference in the Prospectus or Prospectus Supplement, forward-looking statements speak only as to the date they were made.
- (ll) <u>Statistical and Market Data</u>. The statistical and market related data included in the Registration Statement and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate, and such data agree in all material respects with the sources from which they are derived.
- (mm) <u>Listing</u>. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and is listed on Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing.
- (nn) <u>Brokers</u>. Except for the Agents, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.
- (oo) <u>No Outstanding Loans or Other Indebtedness</u>. Except as described in the Prospectus, there are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of the immediate family members of any of them.
- (pp) No Reliance. The Company has not relied upon the Agents or legal counsel for the Agents for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

- (qq) The Agents' Purchases. The Company acknowledges and agrees that the Agents have informed the Company that the Agents may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for their own account while this Agreement is in effect, *provided*, *that* (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent the Agents may engage in sales of Placement Shares purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agents.
- (rr) <u>Compliance with Laws</u>. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not be reasonably expected to result in a Material Adverse Change.
- (ss) <u>Labor</u>. No labor problem or dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, that could reasonably be expected to result in a Material Adverse Change.
- (tt) Compliance with ERISA. None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended ("ERISA"), and the regulations and published interpretations thereunder with respect to a Plan, determined without regard to any waiver of such obligations or extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company or any of its subsidiaries that could reasonably be expected to result in a Material Adverse Change; or (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company or any of its subsidiaries that could reasonably be expected to result in a Material Adverse Change. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company and its subsidiaries compared to the amount of such contributions made in the most recently completed fiscal year of the Company and its subsidiaries; (ii) a material increase in the "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) of the Company and its subsidiaries compared to the amount of such obligations in the most recently completed fiscal year of the Company and its subsidiaries; (iii) any event or condition giving rise to a liability under Title IV of ERISA that could reasonably be expected to result in a Material Adverse Change; or (iv) the filing of a claim by one or more employees or former employees of the Company or any of its subsidiaries related to their employment that could reasonably be expected to result in a Material Adverse Change. For purposes of this paragraph, the term "Plan" means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company or any of its subsidiaries may have any liability.

- (uu) <u>Sarbanes-Oxley Act</u>. There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "<u>Sarbanes-Oxley Act</u>"), including Section 402 relating to loans and Sections 302 and 906 relating to certifications, that are in effect and with which the Company is required to comply.
- (vv) <u>Significant Subsidiaries</u>. The Company does not have any significant subsidiaries as defined by Rule 1-02 of Regulation S-X.
- (ww) Compliance with Regulatory Laws. The Company and its subsidiaries have operated at all times and are currently in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by the Company and its subsidiaries ("Applicable Regulatory Laws") of the U.S. Food and Drug Administration and comparable regulatory agencies outside of the United States to which they are subject (collectively, the "Regulatory Authorities"), except where the failure to so comply would not, individually or in the aggregate, result in a Material Adverse Change. Neither the Company nor any of its subsidiaries has received any written notices, correspondence or other communications from, nor do they have knowledge that any of their collaboration partners has received, any written notices, correspondence or other communications from Regulatory Authorities alleging or asserting material non-compliance with any Applicable Regulatory Laws.
- (xx) Regulatory Filings. The Company has not failed to file with Regulatory Authorities any required material filing, declaration, listing, registration, report or submission with respect to the Company's products that are described in the Registration Statement and the Prospectus; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with Applicable Regulatory Laws when filed; and no material deficiencies regarding compliance with Applicable Regulatory Law have been asserted by any Regulatory Authority with respect to any such filings, declarations, listings, registrations, reports or submissions.

Any certificate signed by an officer of the Company and delivered to the Agents or to counsel for the Agents in connection with this Agreement shall be deemed to be a representation and warranty by the Company to the Agents as to the matters set forth therein.

The Company acknowledges that the Agents and, for purposes of the opinions to be delivered pursuant to <u>Section 7</u> hereof, counsel to the Company and counsel to the Agents, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

- 7. <u>Covenants of the Company</u>. The Company covenants and agrees with the Agents that:
  - (a) Registration Statement Amendments. After the date of execution of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by the Agents under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify the Agents promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information (in

each case, insofar as it relates to the transactions contemplated hereby), (ii) the Company will prepare and file with the Commission, promptly upon the Agents' reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agents' reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agents (provided, however, that the failure of the Agents to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agents' right to rely on the representations and warranties made by the Company in this Agreement); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into or exchangeable or exercisable for the Placement Shares unless a copy thereof has been submitted to the Agents within a reasonable period of time before the filing and the Agents have not reasonably objected thereto (provided, however, that (A) the failure of the Agents to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agents' right to rely on the representations and warranties made by the Company in this Agreement, and (B) the Company has no obligation to provide the Agents any advance copy of such filing or to provide the Agents an opportunity to object to such filing if the filing does not name the Agents and does not relate to the transaction herein provided) and the Company will furnish to the Agents at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act, or in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

- (b) Notice of Commission Stop Orders. The Company will advise the Agents promptly after it receives (i) notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, (ii) of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, (iii) of the initiation or threatening of any proceeding for any such purpose or (iv) of any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or for additional information related to the Registration Statement or the Prospectus; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.
- (c) <u>Delivery of Prospectus; Subsequent Changes</u>. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by the Agents under the Securities Act with respect to the offer and sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates (taking into account any extensions available) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If

during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Designated Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided*, *however*, that the Company may delay any such amendment or supplement if, as a result of a pending transaction or other development with respect to the Company in the reasonable judgment of the Company, it is in the best interest of the Company to do so, provided that no Placement Notice is in effect during such time. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B under the Securities Act, it will use its best efforts to comply with the provisions thereof and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agents promptly of all such filings if not available on EDGAR.

- (d) <u>Listing of Placement Shares</u>. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by the Agents under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as the Agents reasonably designate and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided*, *however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.
- (e) <u>Delivery of Registration Statement and Prospectus</u>. The Company will furnish to the Agents and their counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which the Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as the Agents may from time to time reasonably request and, at the Agents request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided*, *however*, that the Company shall not be required to furnish any document (other than the Prospectus) to the Agents or their counsel to the extent such document is available on EDGAR.
- (f) <u>Earnings Statement</u>. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.
- (g) <u>Expenses</u>. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of <u>Section</u>

11 hereunder, will pay all expenses incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for the Agents in connection therewith shall be paid by the Agents except as set forth in (vii) below), (iv) the printing and delivery to the Agents of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of the Agents' outside counsel for filings with the FINRA Corporate Financing Department, such legal expense reimbursement not to exceed \$10,000 (in addition to the fees and disbursements referred to in clause (viii) below) and, (viii) the reasonable fees and disbursements of the Agents' counsel (A) in an amount not to exceed \$50,000 arising out of executing this Agreement and the Company's delivery of the initial certificate pursuant to Section 7(m) and (B) in an amount not to exceed \$15,000 in connection with each Representation Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 7(m) (in addition to the fees and associated expenses referred to in clause (vii) above).

- (h) <u>Use of Proceeds</u>. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."
- Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for five (5) Trading Days (i) following the termination of any Placement Notice given hereunder, the Company shall provide the Agents notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; provided, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options or warrants to purchase shares of Common Stock, restricted shares of Common Stock, restricted stock units or other equity awards, or Common Stock issuable upon the exercise of options or other equity awards pursuant to the any stock option, stock bonus or other stock plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets, (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to the Agents in advance, (iv) any shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding or (v) the issuance or sale of Common Stock, or securities convertible into or exercisable for Common Stock, in an amount greater than 2% of the Company's outstanding Common Stock at the time, offered and sold in a privately negotiated transaction to vendors, customers, strategic partners or potential strategic partners conducted in a manner so as not to be integrated with the offering of Common Stock hereby. Notwithstanding the foregoing provisions, nothing herein shall be construed to restrict the Company's ability, or require the Company to provide notice to the Agents, to file a registration statement under the Securities Act.

- (j) <u>Change of Circumstances</u>. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise the Agents promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided or required to be provided to the Agents pursuant to this Agreement.
- (k) <u>Due Diligence Cooperation</u>. During the term of this Agreement, the Company will cooperate with any reasonable due diligence review conducted by the Agents, their affiliates, agents and counsel from time to time in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as the Agents may reasonably request.
- (l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require with respect to the Placement Shares, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a "Filing Date"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through the Agents, the Net Proceeds to the Company and the compensation payable by the Company to the Agents with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.
- Representation Dates; Certificate. On or prior to the First Delivery Date and thereafter, during the term of this Agreement, (m) and each time the Company (i) files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(1) of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K); (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a report on Form 8-K containing amended financial information (other than an earnings release or other information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "Representation Date"); the Company shall furnish the Agents (but in the case of clause (iv) above only if (1) a Placement Notice is pending, (2) the Agents reasonably determine that the information contained in such Form 8-K is material to a holder of Common Stock and (3) the Agents request such certificate within two (2) Trading Days after the filing of such Form 8-K with the Commission) with a certificate, in the form attached hereto as Exhibit 7(m) (modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented), within two (2) Trading Days of any Representation Date. The requirement to provide a certificate under this Section 7(m) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of (i) the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and (ii) the next occurring Representation Date; provided, however, that such waiver shall not apply

for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide the Agents with a certificate under this <u>Section 7(m)</u>, then before the Company delivers the Placement Notice or the Agents sells any Placement Shares, the Company shall provide the Agents with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

- (n) <u>Legal Opinion</u>. On or prior to the First Delivery Date, the Company shall cause to be furnished to the Agents a written opinion and negative assurance letter of Cooley LLP ("<u>Company Counsel</u>"), or other counsel reasonably satisfactory to the Agents, in each case dated the date that the same is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented. Thereafter, during the term of this Agreement, within two (2) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as <u>Exhibit 7(m)</u> for which no waiver is applicable, the Company shall cause to be furnished to the Agents a written letter of Company Counsel, or other counsel reasonably satisfactory to the Agents, in form and substance reasonably satisfactory to the Agents, dated the date that the same is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented.
- Comfort Letter. On or prior to the First Delivery Date and thereafter, during the term of this Agreement, within two (2) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as <a href="Exhibit 7(m)">Exhibit 7(m)</a> for which no waiver is applicable, the Company shall cause its independent accountants to furnish the Agents letters (the "Comfort Letters"), dated the date the applicable Comfort Letter is delivered, in form and substance reasonably satisfactory to the Agents, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to the Agents in connection with registered public offerings (the first such letter delivered on the date hereof, the "Initial Comfort Letter") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.
- (p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agents; provided, however, that the Company may bid for and purchase shares of its Common Stock in accordance with Rule 10b-18 under the Exchange Act.
- (q) <u>Insurance</u>. The Company shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

- (r) Compliance with Laws. The Company and each of its subsidiaries shall use commercially reasonable efforts to maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Change.
- (s) <u>Investment Company Act</u>. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.
- (t) <u>Securities Act and Exchange Act</u>. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.
- (u) No Offer to Sell. Other than a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and the Agents, each Agent in its capacity as principal or agent hereunder, neither the Agents nor the Company (including its agents and representatives, other than the Agents in their capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.
- (v) <u>Sarbanes-Oxley Act</u>. The Company and its subsidiaries will use commercially reasonable efforts to comply in all material respects with all effective applicable provisions of the Sarbanes-Oxley Act.
- (w) <u>Sales Through Agents</u>. With respect to the offering and sale of Placement Shares pursuant to this Agreement, the Company agrees that any offer to sell Placement Shares, any solicitation of an offer to buy Placement Shares, and any sales of Placement Shares shall only be effected by or through a single Designated Agent on any single given day, and the Company shall in no event request that more than one Agent offer or sell Placement Shares pursuant to this Agreement on the same day.
- 8. <u>Conditions to the Agents' Obligations</u>. The Agents agree that their obligations under this Agreement are several and not joint. The obligations of the Agents hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by the Agents of a due diligence review satisfactory to the Agents in their reasonable judgment, and to the continuing satisfaction (or waiver by the Agents in their sole discretion) of the following additional conditions:
  - (a) <u>Registration Statement Effective</u>. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued by any Placement Notice.

- (b) <u>Prospectus Supplement</u>. The Company shall have filed with the Commission the Prospectus Supplement pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second Business Day following the date of this Agreement.
- (c) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (d) <u>No Misstatement or Material Omission</u>. The Agents shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agents' reasonable opinion is material, or omits to state a fact that in the Agents' reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (e) <u>Material Changes</u>. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Change or any development that could reasonably be expected to result in a Material Adverse Change, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset-backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset-backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of the Agents (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.
- (f) <u>Company Counsel Legal Opinion</u>. The Agents shall have received the opinions and negative assurance letters, as applicable, of Company Counsel required to be delivered pursuant to <u>Section 7(n)</u> on or before the date on which such delivery of such opinion is required pursuant to <u>Section 7(n)</u>.

- (g) <u>The Agents Counsel Legal Opinion</u>. The Agents shall have received from White & Case LLP, counsel for the Agents, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to <u>Section 7(n)</u>, with respect to such matters as the Agents may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.
- (h) <u>Comfort Letter</u>. The Agents shall have received the Comfort Letter required to be delivered pursuant to <u>Section 7(o)</u> on or before the date on which such delivery of such Comfort Letter is required pursuant to <u>Section 7(o)</u>.
- (i) Representation Certificate. The Agents shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).
- (j) <u>Secretary's Certificate</u>. On or prior to the First Delivery Date, the Agents shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to the Agents and their counsel.
- (k) <u>No Suspension</u>. The Common Stock shall be duly listed, and admitted and authorized for trading, subject to official notice of issuance, on Nasdaq. Trading in the Common Stock shall not have been suspended on Nasdaq.
- (l) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to the Agents such appropriate further information, certificates and documents as the Agents may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish the Agents with such conformed copies of such opinions, certificates, letters and other documents as the Agents shall have reasonably requested.
- (m) <u>Securities Act Filings Made</u>. All filings with the Commission required by Rule 424 under the Securities Act with respect to the Placement Shares to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.
- (n) <u>Approval for Listing</u>. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice and Nasdaq shall not have provided any objections thereto.
- (o) <u>No Termination Event</u>. There shall not have occurred any event that would permit the Agents to terminate this Agreement pursuant to <u>Section 11(a)</u>.
- (p) <u>FINRA</u>. FINRA shall have raised no objection to the terms of this offering and the amount of compensation allowable or payable to the Agents as described in the Prospectus.

### 9. <u>Indemnification and Contribution</u>.

(a) <u>Company Indemnification</u>. The Company agrees to indemnify and hold harmless the Agents, their affiliates and their respective members, directors, officers, partners, employees and agents, and each person, if any, who (i) controls the Agents within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with the Agents, in each case from and against

any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all investigative, legal and other expenses reasonably incurred in connection with, and any and all amounts paid in settlement (in accordance with this Section 9) of, any action, suit, investigation or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party (including, without limitation, any governmental or self-regulatory authority, or otherwise, or any claim asserted or threatened), as and when incurred, to which the Agents, or any such other person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus (or any amendment or supplement to the Registration Statement or the Prospectus) or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated therein or necessary to make the statements therein (solely with respect to the Prospectus, in the light of the circumstances under which they were made) not misleading or (z) any breach by any of the indemnifying parties of any of their respective representations, warranties or agreements contained in this Agreement; provided, however, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with the Agents' Information (as defined in Section 20(a)). This indemnity agreement will be in addition to any liability that the Company might otherwise have.

- (b) The Agents Indemnification. The Agents agree, severally and not jointly, to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto) or in any free writing prospectus in reliance upon and in conformity with the Agents' Information.
- (c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the

indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any other legal expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm (plus one local counsel) admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to such fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party, in form and substance reasonably satisfactory to such indemnified party, from all liability arising out of such claim, action or proceeding and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) <u>Contribution</u>. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable or insufficient from the Company or the Agents, the Company and the Agents will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit, investigation or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Agents, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Agents may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the

Company on the one hand and the Agents on the other hand. The relative benefits received by the Company on the one hand and the Agents on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agents from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agents, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action, suit, investigation or proceeding in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agents, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agents agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action, suit, investigation or proceeding in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action, suit, investigation, proceeding or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), the Agents shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, any affiliates of the Agents, any members, directors, partners, officers, employees or agents of the Agents and each person that is controlled by or under common control with either Agent, will have the same rights to contribution as that party, and each director and officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to <u>Section 9(c)</u> hereof or pursuant to <u>Section 9(e)</u> hereof.

(e) <u>Settlement Without Consent if Failure to Reimburse</u>. If an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel for which it is entitled to be reimbursed under this Section 9, such

indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by <u>Section 9(a)</u> effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agents, any controlling persons, or the Company (or any of their respective officers, directors, employees or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

#### 11. Termination.

- Each Agent has the right by giving notice as hereinafter specified at any time to terminate this Agreement if (i) any (a) Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of the Agents, may materially impair the ability of the Agents to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; provided, however, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under <u>Sections 7(m)</u>, 7(n), or 7(0), the Agents' right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than fifteen (15) calendar days from the date such delivery was required; (iii) any other condition of the Agents' obligations hereunder is not fulfilled; (iv) any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred; (v) a general banking moratorium shall have been declared by any of United States federal or New York authorities; or (vi) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States or international political, financial or economic conditions that, in the judgment of the Agents, may materially impair the ability of the Agents to sell the Placement Shares hereunder or to enforce contracts for the sale of securities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If an Agent elects to terminate this Agreement as provided in this <u>Section 11(a)</u>, such Agent shall provide the required notice as specified in Section 12 (Notices). Such Agent's termination of this Agreement applies solely to such Agent and not to the other Agents who are party to this Agreement.
- (b) The Company shall have the right, by giving ten (10) days' prior notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16

- and <u>Section 17</u> hereof shall remain in full force and effect notwithstanding such termination.
- (c) The Agents shall have the right, by giving ten (10) days' prior notice as hereinafter specified to terminate this Agreement in their sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.
- (d) Unless earlier terminated pursuant to this <u>Section 11</u>, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through the Agents on the terms and subject to the conditions set forth herein; *provided* that the provisions of <u>Section 7(g)</u>, <u>Section 9</u>, <u>Section 10</u>, <u>Section 11(f)</u>, <u>Section 16</u> and <u>Section 17</u> hereof shall remain in full force and effect notwithstanding such termination.
- (e) This Agreement shall remain in full force and effect unless terminated pursuant to <u>Sections 11(a)</u>, <u>(b)</u>, <u>(c)</u>, or <u>(d)</u> above or otherwise by mutual agreement of the parties; *provided*, *however*, that any such termination by mutual agreement shall in all cases be deemed to provide that <u>Section 7(g)</u>, <u>Section 9</u>, <u>Section 10</u>, <u>Section 11(f)</u>, <u>Section 16</u> and <u>Section 17</u> shall remain in full force and effect.
- (f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided*, *however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agents or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.
- (g) Subject to the additional limitations set forth in <u>Section 7</u> of this Agreement and notwithstanding anything herein to the contrary, in the event of termination of this Agreement prior to the sale of any Placement Shares, the Agents will only be entitled to reimbursement of its out of pocket expenses actually incurred.
- Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms 12. of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to the Agents, shall be delivered to the Agents at Leerink Partners LLC, 1301 Avenue of the Americas, 12th Floor, New York, NY 10019, fax no. (212) 499-7051, Attention: Peter M. Fry, e-mail: peter.fry@leerink.com, with a copy (which shall not constitute notice) to 1301 Avenue of the Americas, 12th Floor, New York, NY 10019, fax no. (212) 499-7051, Attention: General Counsel, e-mail: LegalNotice@leerink.com, and Cantor Fitzgerald & Co., 110 E. 59th Street, New York, New York 10022, fax no. (212) 307-3730, Attention: General Counsel, with a copy to White & Case, LLP, 1221 Avenue of the Americas, New York, NY 10020, Attention: Jessica Y. Chen; or if sent to the Company, shall be delivered to Kura Oncology, Inc., 12730 High Bluff Drive, Suite 400, San Diego, CA 92130 Tel no. (858) 500-8800, attention: Chief Legal Officer, with a copy to Cooley LLP, 10265 Science Center Drive, San Diego, CA 92121, Tel no. (858) 550-6000, attention: Charles Bair. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a

nationally-recognized overnight courier, (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid) and (iv) when delivered by electronic communication ("<u>Electronic Notice</u>"), at the time the party sending Electronic Notice receives verification of receipt by the receiving party, other than via autoreply. For purposes of this Agreement, "<u>Business Day</u>" shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

An Electronic Notice shall be deemed written notice for purposes of this Section 12 if sent to the electronic mail address specified by the receiving party in Section 12. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives actual acknowledgment of receipt from the person whom the notice is sent, other than via auto-reply. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("Nonelectronic Notice"), which shall be sent to the requesting party within 10 days of receipt of the written request for Nonelectronic Notice.

- 13. <u>Successors and Assigns</u>. This Agreement shall inure to the benefit of and be binding upon the Company and the Agents and their respective successors and the affiliates, controlling persons, officers and directors referred to in <u>Section 9</u> hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that each Agent may assign its rights and obligations hereunder to an affiliate of each Agent without obtaining the Company's consent so long as such affiliate is a registered broker dealer.
- 14. <u>Adjustments for Share Splits</u>. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.
- Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules and exhibits attached hereto and 15. Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agents; provided, however, that Schedule 2 of this Agreement may be amended by either party from time to time by sending a notice containing a revised <u>Schedule 2</u> to the other party in the manner provided in <u>Section 12</u> and, upon such amendment, all references herein to **Schedule 2** shall automatically be deemed to refer to such amended **Schedule 2**. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

- 16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.
- 17. <u>Waiver of Jury Trial</u>. The Company and each of the Agents each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.
- 18. <u>Absence of Fiduciary Relationship</u>. The Company acknowledges and agrees that:
  - (a) the Agents have been retained solely to act as sales agent in connection with the sale of the Common Stock and that no fiduciary, advisory or agency relationship between the Company and the Agents have been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Agents have advised or is advising the Company on other matters;
  - (b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;
  - (c) the Company has been advised that the Agents and their affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Agents have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and
  - (d) the Company waives, to the fullest extent permitted by law, any claims it may have against the Agents, for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of the Placement Shares under this Agreement and agrees that the Agents shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.
- 19. <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or other electronic transmission.
- 20. <u>Definitions</u>. As used in this Agreement, the following term has the meaning set forth below:
  - (a) "<u>Agents' Information</u>" means, solely the following information: in the prospectus supplement, dated November 2, 2023, the seventh paragraph under the caption "Plan of Distribution."

21. <u>Recognition of the U.S. Special Resolution Regimes</u>. In the event that an Agent is a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from an Agent of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

In the event that an Agent is a Covered Entity and an Agent or a BHC Act Affiliate of an Agent becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against an Agent are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Agreement, (A) "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); (B) "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); (C) "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and (D) "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding among the Company, Leerink Partners and Cantor, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company, Leerink Partners and Cantor.

Very truly yours,

### LEERINK PARTNERS LLC

By: /s/ Peter M. Fry

Name: Peter M. Fry

Title: Head of Alt. Equities

## **CANTOR FITZGERALD & CO.**

By: /s/ Sage Kelly

Name: Sage Kelly

Title: Senior Managing Director and Global Head of Investment

Banking

ACCEPTED as of the date first-above written:

## KURA ONCOLOGY, INC.

By: /s/ Troy Wilson

Name: Troy E. Wilson, Ph.D., J.D.

Title: President and Chief Executive Officer

[Signature Page to Sales Agreement]

## **FORM OF PLACEMENT NOTICE**

From: [●] Cc: [●] To: [●]

Date: [●], 202[3]

Subject: Leerink Partners and Cantor At the Market Offering—Placement Notice

#### Ladies and Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement among Kura Oncology, Inc. (the "<u>Company</u>"), Leerink Partners LLC ("<u>Leerink Partners</u>") and Cantor Fitzgerald & Co. ("<u>Cantor</u>", and together with Leerink Partners, the "<u>Agents</u>") dated November 2, 2023 (the "<u>Agreement</u>"), I hereby request on behalf of the Company that the Designated Agent sell up to [●] shares of the Company's common stock, par value \$0.0001 per share, at a minimum market price of \$[●] per share[; *provided* that no more than [●] Shares shall be sold in any one Trading Day (as such term is defined in Section 3 of the Agreement]. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold].

# **The Company**

Troy Wilson, Ph.D., J.D., Chairman, President and Chief Executive Officer

Teresa Bair, J.D., Chief Legal Officer and Secretary

Thomas Doyle, Senior Vice President, Finance and Accounting

# **Leerink Partners LLC**

Dan Dubin, M.D.

Sean Pitt

atm@leerink.com

# Cantor Fitzgerald & Co.

Sameer Vasudev

CFC ontrolled Equity Offering @cantor.com

# Compensation

The Designated Agent shall be paid compensation equal	to up to a total of	f 3.0% of the gross	proceeds from the sale	es of Common Stock
pursuant to the terms of this Agreement.				

### **OFFICER CERTIFICATE**

The undersigned, the duly qualified and elected [ ], **Koira Oncology, Inc.** ("<u>Company</u>"), a Delaware corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to <u>Section 7(m)</u> of the Sales Agreement dated November 2, 2023 (the "<u>Sales Agreement</u>") among the Company and Leerink Partners LLC and Cantor Fitzgerald & Co., that to the best of the knowledge of the undersigned:

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and
- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.
- (iii) As of the date hereof, (A) the Registration Statement complies in all material respects with the requirements of the Securities Act and does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading, (B) the Prospectus complies in all material respects with the requirements of the Securities Act does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (C) no event has occurred as a result of which it is necessary to amend or supplement the Registration Statement or the Prospectus in order to make the statements therein not untrue or misleading or for clauses (A) and (B) above, to be true and correct.
- (iv) There has been no Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change on the business, properties, management, financial position, stockholders' equity, results of operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity, since the date as of which information is given in the Prospectus, as amended or supplemented to the date hereof.
- (v) The Company does not possess any material non-public information.
- (vi) The maximum amount of Placement Shares that may be sold pursuant to the Sales Agreement has been duly authorized by the Company's board of directors or a duly authorized committee thereof pursuant to a resolution or unanimous written consent in accordance with the Company's amended and restated articles of incorporation, amended and restated bylaws and applicable law.

Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Sales Agreement.

	By:	
		Name: Title:
		Date:
2		

IN WITNESS WHEREOF, each of the undersigned, in such individual's respective capacity as Chief Executive Officer or Chief Legal Officer of the Company, has executed this Officers' Certificate on behalf of the Company.

### 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, Troy E. Wilson, Ph.D., J.D., certify that:

- 1. I have reviewed this Form 10-Q of Kura Oncology, 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(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.

Date: November 2, 2023 /s/ Troy E. Wilson, Ph.D., J.D.

Troy E. Wilson, Ph.D., J.D.
President and Chief Executive Officer
(Principal Executive and Financial Officer)

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

In connection with the Quarterly Report of Kura Oncology, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, Ph.D., J.D., as President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- 1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Date: November 2, 2023	By:	/s/ Troy E. Wilson, Ph.D., J.D.
		Troy E. Wilson, Ph.D., J.D.
		President and Chief Executive Officer
		(Principal Executive and Financial Officer)