

REFINITIV

# DELTA REPORT

## 10-Q

JANX - JANUX THERAPEUTICS, INC.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

**TOTAL DELTAS 747**

 CHANGES 215

 DELETIONS 250

 ADDITIONS 282

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended **June** **September** 30, 2023

**OR**

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

For the transition period from to

Commission File Number: 001-40475

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**Janux Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware** **82-2289112**

(State or other jurisdiction of  
incorporation or organization) **(I.R.S. Employer  
Identification No.)**

**10955 Vista Sorrento Parkway, Suite 200, San Diego,  
California** **92130**

(Address of principal executive offices) **(Zip Code)**

**Registrant's telephone number, including area code: (858) 751-4493**

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

<b>Title of each class</b>	<b>Trading</b>	<b>Name of each exchange on which registered</b>
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**Common Stock**

		<b>Symbol(s)</b>
Common Stock, \$0.001 par value per share	JANX	The Nasdaq Global Market
<p>Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes <input type="checkbox"/> No <input type="checkbox"/></p>		
<p>Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes <input type="checkbox"/> No <input type="checkbox"/></p>		
<p>Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.</p>		
Large accelerated filer <input type="checkbox"/>		Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>		Smaller reporting company <input type="checkbox"/>
Emerging growth company <input type="checkbox"/>		

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

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

As of **August 4, 2023** **November 3, 2023**, the Registrant had **46,138,810** **46,168,430** shares of common stock, \$0.001 par value per share, outstanding.

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### **JANUX THERAPEUTICS, INC.**

### **Quarterly Report on Form 10-Q**

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**PART I—FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**Janux Therapeutics, Inc.**  
**Condensed Balance Sheets**  
(in thousands, except share and par value data)

	December		September	December
	June 30, 2023	31, 2022	30, 2023	31, 2022
<b>Assets</b>				
Current assets:	(unaudited)		(unaudited)	

Cash and cash equivalents	\$ 33,703	\$ 51,426	\$ 17,152	\$ 51,426
Short-term investments	269,586	275,590	332,560	275,590
Prepaid expenses and other current assets	6,013	5,423	5,483	5,423
<b>Total current assets</b>	<b>309,302</b>	<b>332,439</b>	<b>355,195</b>	<b>332,439</b>
Restricted cash	816	816	816	816
Property and equipment, net	7,378	7,086	7,317	7,086
Operating lease right-of-use assets	21,571	22,279	21,208	22,279
Other long-term assets	2,433	1,390	2,314	1,390
<b>Total assets</b>	<b>\$ 341,500</b>	<b>\$ 364,010</b>	<b>\$ 386,850</b>	<b>\$ 364,010</b>
<b>Liabilities and Stockholders' Equity</b>				
Current liabilities:				
Accounts payable	\$ 1,910	\$ 2,159	\$ 2,505	\$ 2,159
Accrued liabilities	9,216	8,010	6,831	8,010
Current portion of deferred revenue	5,340	5,406	3,648	5,406
Unvested stock liabilities	30	169	25	169
Current portion of operating lease liabilities	1,408	763	1,462	763
<b>Total current liabilities</b>	<b>17,904</b>	<b>16,507</b>	<b>14,471</b>	<b>16,507</b>
Deferred revenue, net of current portion	307	2,221	—	2,221
Operating lease liabilities, net of current portion	23,820	24,542	23,431	24,542
<b>Total liabilities</b>	<b>42,031</b>	<b>43,270</b>	<b>37,902</b>	<b>43,270</b>
Commitments and contingencies (Note 3)				
Stockholders' equity:				
Preferred stock, \$0.001 par value; authorized shares – 10,000,000 at June 30, 2023 and December 31, 2022, respectively; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—	—	—

Common stock, \$0.001 par value; authorized shares – 200,000,000 at June 30, 2023 and December 31, 2022, respectively; issued shares – 41,891,226 and 41,684,666 at June 30, 2023 and December 31, 2022, respectively; outstanding shares – 41,867,536 and 41,616,260 at June 30, 2023 and December 31, 2022, respectively	42	42
Preferred stock, \$0.001 par value; authorized shares – 10,000,000 at September 30, 2023 and December 31, 2022, respectively; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; authorized shares – 200,000,000 at September 30, 2023 and December 31, 2022, respectively; issued shares – 46,168,430 and 41,684,666 at September 30, 2023 and December 31, 2022, respectively; outstanding shares – 46,151,427 and 41,616,260 at September 30, 2023 and December 31, 2022, respectively	46	42
Additional paid-in capital	445,924	432,703
Accumulated other comprehensive loss	(1,060)	(1,535)
Accumulated deficit	(145,43	7)
	299,469	(110,470)
Total stockholders' equity	299,469	320,740
Total liabilities and stockholders' equity	\$ 341,500	\$ 364,010
	<u>\$ 341,500</u>	<u>\$ 364,010</u>

*See accompanying notes.*

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### **Janux Therapeutics, Inc.** **Unaudited Condensed Statements of Operations and Comprehensive Loss** **(in thousands, except share and per share data)**

	Three Months				Three Months		Nine Months	
	Ended		Six Months Ended		Ended		Ended	
	June 30,		June 30,		September 30,		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Collaboration revenue	1,05	2,36	3,10	3,95	2,51	1,81	5,62	5,76
Operating expenses:								
Research and development	14,9	14,0	30,7	24,2	11,8	13,7	42,6	38,0
General and administrative	24	86	89	70	92	37	81	07
Total operating expenses	6,88	5,54	13,3	10,4	6,43	6,09	19,7	16,5
	1	0	45	87	8	8	83	85
	21,8	19,6	44,1	34,7	18,3	19,8	62,4	54,5
	05	26	34	57	30	35	64	92
Loss from operations	(20,	(17,	(41,	(30,	(15,	(18,	(56,	(48,
	748)	261)	029)	803)	813)	022)	842)	825)
Other income:								
Interest income	3,24		6,06		4,24	1,32	10,3	1,83
	0	373	2	505	5	6	07	1
Total other income	3,24		6,06		4,24	1,32	10,3	1,83
	0	373	2	505	5	6	07	1
Net loss	(17,	(16,	(34,	(30,	(11,	(16,	(46,	(46,
	\$ 508)	\$ 888)	\$ 967)	\$ 298)	\$ 568)	\$ 696)	\$ 535)	\$ 994)
Other comprehensive loss:								
Other comprehensive gain (loss):								
Unrealized gain (loss) on available-for-sale securities, net					(1,6			(2,0
	(321)	(340)	475	37)	(115)	(370)	360	07)
Comprehensive loss	(17,	(17,	(34,	(31,	(11,	(17,	(46,	(49,
	\$ 829)	\$ 228)	\$ 492)	\$ 935)	\$ 683)	\$ 066)	\$ 175)	\$ 001)

Net loss per common share, basic and diluted	(0.4 2)	(0.4 1)	(0.8 4)	(0.7 3)	(0.2 5)	(0.4 0)	(1.0 8)	(1.1 3)
Weighted-average shares of common stock outstanding, basic and diluted	41,8 36,2 38	41,4 48,7 43	41,8 00,3 04	41,3 82,4 81	45,7 08,6 49	41,5 26,5 24	43,1 17,4 03	41,4 31,0 23

See accompanying notes.

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**Janux Therapeutics, Inc.**  
**Unaudited Condensed Statements of Stockholders' Equity**  
**For the Six Nine Months Ended June 30, 2023 September 30, 2023 and 2022**  
(in thousands, except share data)

	Accumulated Contributed Capital Less Stock holders' Deficit Equity						Accumulated Contributed Capital Less Stock holders' Deficit Equity						
	Common Stock		Paid-in Capital	Common Stock	Less Stock holders' Deficit	Equity	Common Stock		Paid-in Capital	Common Stock	Less Stock holders' Deficit	Equity	
	Shares	Amount	Capital	Less Stock holders' Deficit	Equity		Shares	Amount	Capital	Less Stock holders' Deficit	Equity		
	es	unt	al	Loss	it	y	es	unt	al	Loss	it	y	
	Balance at	41,					41,						
	December 31, 2022	61	43	(1,	(11	32	61	43	(1,	(11	32		
		6,2	2,7	53	0,4	0,7	6,2	2,7	53	0,4	0,7		
		60	\$ 42	\$ 03	\$ 5)	\$ 70)	\$ 40	60	\$ 42	\$ 03	\$ 5)	\$ 70)	\$ 40

Issuance of common stock and pre-funded common stock warrants, net of issuance costs					4,1						
Exercise of pre- funded common stock warrants					80,						
Exercise of common stock options	14				1,5	1,5	1,8	1,6			1,6
Shares issued under employee stock purchase plan	8,6	—	80	—	—	80	79	—	59	—	59
Vesting of restricted shares	57,						57,				
Stock-based compensation	91	—	52	—	—	52	91	—	52	—	52
Unrealized gain on available- for-sale securities, net	1	—	8	—	—	8	1	—	8	—	8
Net loss	44,						51,				
Balance at June 30, 2023	71	—	13	—	—	13	40	—	14	—	14
	6	—	9	—	—	9	3	—	4	—	4
	—	—	10,	—	—	10,			15,		15,
			97	—	—	97			52		52
	—	—	4	—	—	4	—	—	2	—	2
	—	—	47	—	—	47			36	—	36
	—	—	5	—	—	5	—	—	0	—	0
	—	—	(34	—	—	(34			(46	—	(46
			,96	—	—	,96			,53	—	,53
	—	—	7)	—	—	7)	—	—	5)	—	5)
	41,	—	—	—	—	—	—	—	—	—	—
	86	—	44	(1,	(14	29					
	7,5	—	5,9	06	5,4	9,4					
	36	\$ 42	\$ 24	\$ 0)	\$ 37)	\$ 69					

Balance at		46,					
September 30,		15		50	(1,	(15	34
2023		1,4		7,0	17	7,0	8,9
		27	\$ 46	\$ 82	\$ 5)	\$ 05)	\$ 48

	Accumulated other comprehensive income						Accumulated other comprehensive income						Accumulated other comprehensive income				
	Addition			Other			Total			Addition			Other			Total	
	on	Comp	Accu	Stoc	on	Comp	Accu	Stoc	on	Comp	Accu	Stoc	on	Comp	Accu	Stoc	
	Paid-	rehe	mula	khol	Common	Paid-	rehe	mula	Common	Paid-	rehe	mula	khol	Common	Paid-	rehe	mula
Common Stock		in	sive	ted	ders'	Stock	in	nsive	ted	ders'	Stock	in	nsive	ted	ders'		
Shar	Amou	Capit	Defic	Equit	Shar	Amo	Capit	Defic	Equit	Shar	Amo	Capit	Defic	Equit			
es	nt	al	Loss	it	y	es	unt	al	Loss	it	y	es	nt	al	Loss	it	y
Balance at	41,					41,											
December	243		413		(47	36		24		41		(47	36				
31, 2021	,13		,96	(27	,41	6,3		3,1		3,9	(27	,41	6,3				
	7	\$ 41	\$ 7	\$ 0)	\$ 1)	\$ 27		37	\$ 41	\$ 67	\$ 0)	\$ 1)	\$ 27				
Exercise of																	
common																	
stock	7,4							7,4									
options	05	—	1	—	—	1		05	—	1	—	—	1				
Shares																	
issued																	
under																	
employee																	
stock																	
purchase	32,					30		66		30			30				
plan	662	—	307	—	—	7		2	—	7	—	—	7				
Vesting of	218							26									
restricted	,06					71		7,5		88			88				
shares	5	1	711	—	—	2		00	1	0	—	—	1				
Stock-based																	
compensation																	
	8,4					8,4											
	—	—	02	—	—	02		—	—	8	—	—	8				

Unrealized loss on available-for-sale securities, net	—	—	—	(1,63)	—	(1,63)	—	—	(2,07)	—	(2,07)
Net loss	—	—	—	(30,29)	—	(30,29)	—	—	—	—	(46,99)
Balance at June 30, 2022	41,26	423	—	(77,70)	34	—	—	—	—	—	44
	9	\$ 42	\$ 8	\$ 07)	\$ 9)	\$ 14					
Balance at September 30, 2022	41,55	—	—	55,07	42,81	(94,2,2)	33,40	—	—	1,5	
	04	\$ 42	\$ 53	\$ 77)	\$ 5)	\$ 13					

See accompanying notes.

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**Janux Therapeutics, Inc.**  
**Unaudited Condensed Statements of Stockholders' Equity**  
**For the Three Months Ended June 30, 2023 September 30, 2023 and 2022**  
(in thousands, except share data)

Accumulated Deficit					Accumulated Deficit				
Common Stock					Common Stock				
Shares	Amount	Capital	Loss	Equity	Shares	Amount	Capital	Loss	Equity

Balance at	41,								
March 31, 2023	80	43	(12	31					
	2,8	9,8	(73	7,9	1,2				
	07	\$ 42	\$ 90	\$ 9)	\$ 29)	\$ 64			
Shares issued under employee stock purchase plan	57, 91 1	—	8	—	—	8			
Balance at June 30, 2023				41,					
				86	44	(1,	(14	29	
				7,5	5,9	06	5,4	9,4	
				36	\$ 42	\$ 24	\$ 0)	\$ 37)	\$ 69
Issuance of common stock and pre-funded common stock warrants, net of issuance costs				4,1					
				53,	56,				56,
				71	52				53
				7	4	6	—	—	0
Exercise of pre- funded common stock warrants				80,					
				25					
				7	—	—	—	—	—
Exercise of common stock options				43,					
				23					
				0	—	79	—	—	79
Vesting of restricted shares	6,8 18	—	5	—	—	5	87	—	5
Stock-based compensation	—	—	01	—	—	01	—	—	48
Unrealized loss on available- for-sale securities, net	—	—	—	(32	—	(32	—	—	(11
Net loss	—	—	—	1)	—	1)	—	—	5)
				(17	(17				(11
				,50	,50				,56
	—	—	—	—	8)	8)	—	—	8)
	—	—	—	—	—	—	—	—	8)

Balance at June 30, 2023	41,86	44,7,5	(1,06)	(14,5,4)	29,9,4
	<u>36</u>	<u>\$ 42</u>	<u>\$ 24</u>	<u>\$ 0</u>	<u>\$ 37</u>
					<u>\$ 69</u>
Balance at September 30, 2023					46,15,1,4,27
					<u>\$ 46</u>
					<u>\$ 82</u>
					<u>\$ 5</u> )
					<u>\$ 05</u> )
					<u>\$ 48</u>

Accumulated Deficit						Accumulated Capital					
Stockholders' Equity						Stockholders' Equity					
Common Stock		Capital in Excess of Par Value		Deficit		Common Stock		Capital in Excess of Par Value		Deficit	
Shares	Amount	Capital	Loss	Deficit	Equity	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at March 31, 2022	41,393,660	418,42	(60,1,5)	,82	35,6,0						
Exercise of common stock options	1,000	—	—	—	—						
Shares issued under employee stock purchase plan	32,662	—	307	—	30,7						

Balance at					41,						
June 30,					50						
2022					1,2						
					69	\$ 42	\$ 88	\$ 07)	\$ 9)	\$ 9	\$ 14
Vesting of					49,						
restricted	73,				20	43					
shares	947	1	208	—	—	5	—	9	—	—	9
Stock-based											
compensation											
—	—	44	—	—	44	—	—	96	—	—	96
Unrealized											
loss on											
available-for-sale											
securities,					(34						
net	—	—	—	0)	—	0)	—	—	0)	—	0)
Net loss					(16	(16					
					,88	,88					
	—	—	—	—	8)	8)	—	—	—	—	6)
Balance at	41,				—	—	—	—	—	—	6)
June 30,	501		423		(77	34					
2022	,26		,38	(1,9	,70	3,8					
	9	\$ 42	\$ 8	\$ 07)	\$ 9)	\$ 14					
Balance at							41,				
September							55				
30, 2022							0,7				
							04	\$ 42	\$ 53	\$ 77)	\$ 5)
											\$ 13

See accompanying notes.

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### Janux Therapeutics, Inc. Unaudited Condensed Statements of Cash Flows (in thousands)

	Six Months Ended		Nine Months Ended	
	June 30,		September 30,	
	2023	2022	2023	2022
<b>Cash flows from operating activities</b>				
Net loss	(34,96 \$ 7)	(30,29 \$ 8)	(46,53 \$ 5)	(46,99 \$ 4)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	924	189	1,424	438
Stock-based compensation	10,97 4	8,402	15,52 2	12,99 8
Accretion of discounts on investments, net	(3,519)	(123)	(5,627)	(891)
Changes in operating assets and liabilities:				
Accounts receivable			—	(500)
Prepaid expenses and other current assets	(590)	(1,987)	(60)	(3,288)
Other long-term assets	(1,043)	185	(924)	(957)
Accounts payable	(278)	117	(50)	(517)
Accrued expenses	883	264	(1,104)	3,151
Deferred revenue	(1,980)	4,797	(3,979)	3,859
Operating lease right-of-use assets and liabilities, net	631	859	659	1,692
Net cash used in operating activities	(28,96 5)	(17,59 5)	(40,67 4)	(31,00 9)
<b>Cash flows from investing activities</b>				
Purchases of property and equipment	(865)	(1,869)	(1,335)	(4,389)
Purchases of short-term investments	(148,2 51)	(113,8 74)	(284,2 32)	(208,3 41)
Maturities of short-term investments	158,2 50	155,8 50	233,2 50	272,6 00
Net cash provided by investing activities		40,10		
	9,134	7		
Net cash provided by (used in) investing activities			(52,31 7)	59,87 0
<b>Cash flows from financing activities</b>				
Proceeds from exercise of vested and unvested common stock options and employee stock purchase plan	2,108	309		

*See accompanying notes.*

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**Janux Therapeutics, Inc.**  
**Notes to Unaudited Condensed Financial Statements**

## 1. Organization and Summary of Significant Accounting Policies

## Organization

Janux Therapeutics, Inc. (the "Company") was incorporated in the State of Delaware in June 2017 and is based in San Diego, California. The Company is a clinical stage clinical-stage biopharmaceutical company developing a broad pipeline of novel immunotherapies by applying its proprietary technology to its Tumor Activated T Cell Engager ("TRACTr" ("TRACTr")) and Tumor Activated Immunomodulator ("TRACIr" ("TRACIr")) platforms to better treat patients suffering from cancer.

## Liquidity and Capital Resources

From its inception through **June 30, 2023** **September 30, 2023**, the Company has devoted substantially all its efforts to organizing and staffing, business planning, raising capital and developing its TRACTr and TRACIr therapeutic platforms and assets. The Company has incurred net losses and negative cash flows from operations since inception and had an accumulated deficit of **\$145.4** **157.0** million as of **June 30, 2023** **September 30, 2023**. The Company has a limited operating history, has not generated any product revenue, and the sales and income potential of its business is unproven. To date the Company has funded its operations primarily with the net proceeds from the issuance of convertible promissory notes, the issuance of convertible preferred stock, the issuance of common stock in its initial public offering ("IPO"), **the issuance of common stock and pre-funded common stock warrants in an underwritten offering**, the exercise of common stock options, and amounts received under a collaboration agreement. The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to continue its research and development activities, initiate and complete clinical trials and launch and commercialize any product candidates for which it receives regulatory approval. The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity or debt financings or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects. There can be no assurance that such financing will be available or will be at terms acceptable to the Company, especially in light of COVID-19 and other public health crises, current financial conditions within the banking industry, including the effects of recent failures of financial institutions and liquidity levels, as well as recent or anticipated changes in interest rates and the inflationary macro environment. Management believes the Company has sufficient capital to fund its operation for at least 12 months from the issuance date of these unaudited condensed financial statements.

## Unaudited Interim Financial Information

The unaudited condensed financial statements as of **June 30, 2023** **September 30, 2023**, and for the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC"), and with accounting principles generally accepted in the United States ("GAAP") applicable to interim financial statements. These unaudited condensed financial statements have been prepared on the same basis as the Company's audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The condensed balance sheet data as of December 31, 2022 was derived from the Company's audited financial statements but does not include all disclosures required by GAAP. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2022.

## Use of Estimates

The Company's financial statements are prepared in accordance with GAAP. The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to estimates to complete the performance obligations and the estimated transaction price for collaboration revenue, accruals for research and development expenses, stock-based compensation and fair value measurements. These estimates and assumptions are based on current facts, historical experience and various other factors 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 and the recording of revenues and expenses that are not readily apparent from other sources. The Company continues to use the best information available to update its accounting estimates. Actual results may differ materially and adversely from these estimates.

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### **Janux Therapeutics, Inc. Notes to Unaudited Condensed Financial Statements-(Continued)**

#### **Fair Value Measurements**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to the short-term nature of those instruments. The fair value of assets classified within Level 1 is based on quoted prices in active markets as provided by the Company's investment managers. The fair value of short-term investments classified within Level 2 is based on standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers. The Company validates the quoted market prices provided by its investment managers by comparing the

investment managers' assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source. The Company has no financial liabilities recorded at fair value on a recurring basis. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis (in thousands):

Fair Value Measurements at Reporting Date Using				Fair Value Measurements at Reporting Date Using			
Quoted Prices in				Quoted Prices in			
Active Market for Identical Assets (Level	Significant Other Observations Able Inputs (Level	Significant Unobserved Inputs (Level	Active Market for Identical Assets (Level	Significant Other Observations Able Inputs (Level	Significant Unobserved Inputs (Level	Active Market for Identical Assets (Level	Significant Other Observations Able Inputs (Level
Total	1)	2)	3)	Total	1)	2)	3)
<b>As of June 30, 2023:</b>							
Assets:							
Cash equivalent \$:							
Money market funds	29,43				15,25		
\$ 1	\$ 1	\$ —	\$ —	\$ 8	\$ 8	\$ —	\$ —
Total cash equivalent	29,43				15,25		
	1	1	—	8	8	—	—

Short-term investment:								
U.S. Treasury securities	27,09	27,09	—	—	70,36	70,36	—	—
U.S. agency bonds	10,41	—	50	—	14,74	—	147,405	—
U.S. agency discount notes	4,424	—	—	—	4,480	—	4,480	—
Asset-backed securities	4,921	—	—	—	4,976	—	4,976	—
Corporate debt securities	1,978	—	—	—	1,989	—	1,989	—
Commercial paper	127,014	—	—	—	103,344	—	103,344	—
Total short-term investment	26,958	27,09	242,487	—	33,256	70,36	262,194	—
Restricted cash:								
Money market account	81,6	816	—	—	81,6	816	—	—
Total restricted cash	81,6	816	—	—	81,6	816	—	—

Total assets measured at fair value on a recurring basis	29 9,8 \$ 33	57,34 \$ 6	242,4 \$ 87	34 8,6 \$ 34	86,44 \$ 0	262,1 \$ 94	\$ —
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**Janux Therapeutics, Inc.**  
**Notes to Unaudited Condensed Financial Statements-(Continued)**

	Fair Value Measurements at Reporting Date Using					
	Quoted Prices in Active Markets for Identical Assets		Significant Other Observable Inputs		Significant Unobservable Inputs	
	Total	(Level 1)	(Level 2)	(Level 3)		
<b>As of December 31, 2022:</b>						
Assets:						
Cash equivalents:						
Money market funds	\$ 12,697	\$ 12,697	\$ —	\$ —		
Total cash equivalents	12,697	12,697	—	—		
Short-term investments:						
U.S. Treasury securities	63,016	63,016	—	—		
U.S. agency bonds	67,020	—	67,020	—		
U.S. agency discount notes	4,334	—	4,334	—		
Corporate debt securities	1,970	—	1,970	—		
Commercial paper	139,250	—	139,250	—		
Total short-term investments	275,590	63,016	212,574	—		
Restricted cash:						
Money market account	816	816	—	—		

Total restricted cash	816	816	—	—
Total assets measured at fair value on a recurring basis	\$ 289,103	\$ 76,529	\$ 212,574	\$ —

## Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, commercial paper and money market funds.

### Restricted Cash

Restricted cash consists of a money market account securing a standby letter of credit issued in connection with the Company's Torrey Plaza operating lease (as defined and described in Note 3).

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the accompanying balance sheets that sum to the amounts shown in the statements of cash flows (in thousands):

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 33,703	\$ 51,426	\$ 17,152	\$ 51,426
Restricted cash	816	816	816	816
Total cash and cash equivalents and restricted cash	\$ 34,519	\$ 52,242	\$ 17,968	\$ 52,242

### Short-Term Investments

Short-term investments consist of U.S. Treasury securities, U.S. agency bonds, U.S. agency discount notes, asset-backed securities, corporate debt securities and commercial paper, all of which are highly rated by Moody's, S&P, and Fitch. The Company has classified these investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investment securities as current assets. Those investments with maturity dates of three months or less at the date of purchase are presented as cash equivalents in the accompanying balance sheets. Short-term investments are carried at fair value with the unrealized gains and losses included in accumulated other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. The Company records an allowance for

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**Janux Therapeutics, Inc.**  
**Notes to Unaudited Condensed Financial Statements-(Continued)**

credit losses when unrealized losses are due to credit-related factors. Realized gains and losses are calculated using the specific identification method and recorded as interest income.

The following tables summarize short-term investments (in thousands):

	As of June 30, 2023				As of September 30, 2023			
	Amortized	Unrealized		Estimated Fair Value	Amortized	Unrealized		Estimated Fair Value
		Cost	Gains			Cost	Gains	
U.S. Treasury securities	\$ 27,172	\$ —	\$ (73)	\$ 27,099	\$ 70,561	\$ —	\$ (195)	\$ 70,366
U.S. agency bonds	104,875	—	(725)	104,150	148,222	—	(817)	147,405
U.S. agency discount notes	4,427	—	(3)	4,424	4,481	—	(1)	4,480
Asset-backed securities	4,974	—	(53)	4,921	5,026	—	(50)	4,976
Corporate debt securities	1,987	—	(9)	1,978	1,993	—	(4)	1,989
Commercial paper	127,211	—	—	127,014	103,451	—	—	103,344
Total	270,646	\$ 3	\$ (200)	\$ 269,586	333,734	\$ 2	\$ (1,1)	\$ 332,560
	<u>\$ 6</u>	<u>\$ 3</u>	<u>\$ 63)</u>	<u>\$ 6</u>	<u>\$ 4</u>	<u>\$ 2</u>	<u>\$ 76)</u>	<u>\$ 0</u>

	As of December 31, 2022			
	Amortized	Unrealized		Estimated Fair Value
		Cost	Gains	
U.S. Treasury securities	\$ 63,675	\$ —	\$ (659)	\$ 63,016
U.S. agency bonds	67,421	—	(401)	67,020
U.S. agency discount notes	4,321	13	—	4,334
Corporate debt securities	1,975	—	(5)	1,970
Commercial paper	139,733	26	(509)	139,250

Total	\$ <u>277,125</u>	\$ <u>39</u>	\$ <u>(1,574)</u>	\$ <u>275,590</u>
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The amortized cost and estimated fair value in the tables above exclude \$1.5 million and \$0.7 million of accrued interest receivable as of **June 30, 2023** **September 30, 2023** and December 31, 2022, respectively. Accrued interest receivable is included in prepaid expenses and other current assets in the accompanying balance sheets.

Contractual maturities of available-for-sale debt securities are as follows (in thousands):

	As of June 30, 2023		As of September 30, 2023	
	Due in 1 Year or Less	Due Between 1 and 2 Years	Due in 1 Year or Less	Due Between 1 and 2 Years
U.S. Treasury securities	\$ 5,736	\$ 21,363	\$ 15,489	\$ 54,877
U.S. agency bonds	58,647	45,503	66,206	81,199
U.S. agency discount notes	4,424	—	4,480	—
Asset-backed securities	—	4,921	4,976	—
Corporate debt securities	1,978	—	1,989	—
Commercial paper	127,014	—	103,344	—
Total	\$ <u>197,799</u>	\$ <u>71,787</u>	\$ <u>196,484</u>	\$ <u>136,076</u>

	As of December 31, 2022	
	Due in 1 Year or Less	Due Between 1 and 2 Years
U.S. Treasury securities	\$ 57,369	\$ 5,647
U.S. agency bonds	37,202	29,818
U.S. agency discount notes	4,334	—
Corporate debt securities	—	1,970
Commercial paper	139,250	—
Total	\$ <u>238,155</u>	\$ <u>37,435</u>

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### Janux Therapeutics, Inc. Notes to Unaudited Condensed Financial Statements-(Continued)

As of June 30, 2023 September 30, 2023, 40 46 out of 46 49 of our available-for-sale debt securities were in an aggregate gross unrealized loss position. The Company relies on both qualitative and quantitative factors to determine whether the unrealized loss for each available-for-sale debt security at any balance sheet date is due to a credit loss. Qualitative factors may include a credit downgrade, severity of the decline in fair value below amortized cost and other adverse conditions related specifically to the security, as well as the intent to sell the security, or whether the Company will "more likely than not" be required to sell the security before recovery of its amortized cost basis. The Company considers the decline in market value for the securities to be primarily attributable to current economic conditions and interest rate adjustments, rather than credit-related factors and does not intend to sell any securities prior to maturity. No allowance for credit losses has been recorded as of June 30, 2023 September 30, 2023 or December 31, 2022.

The following table summarizes our available-for-sale debt securities in an unrealized loss position for which an allowance for credit losses has not been recorded at December 31, 2022, aggregated by major security type and length of time in a continuous unrealized loss position (in thousands):

	As of June 30, 2023						As of December 31, 2022					
	Less Than 12 Months		12 Months or Longer		Total		Less Than 12 Months		12 Months or Longer		Total	
	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized	Unrealized
	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
	ed	es	ed	es	ed	es	ed	es	ed	es	ed	es
	ue	ue	ue	ue	ue	ue	ue	ue	ue	ue	ue	ue
U.S.												
Treasury												
asus	2				2		1				6	
ry	7,				7,		5,				3,	
sec	0				0		5		47,		0	
uriti	9	(7			9	(7	6	(8	45	(57	1	(6
es	\$ 9	\$ 3)	\$ —	\$ —	\$ 9	\$ 3)	\$ 6	\$ 2)	\$ 0	\$ 7)	\$ 6	\$ 59)

U.S.			1									
age	9		0		6					6		
ncy	9,		4,		7,					7,		
bon	1		1		0					0		
ds	5	(7	4,9	5	(7	2	(4			2	(4	
	5	20)	95	(5)	0	25)	0	01)	—	—	0	01)
U.S.												
age												
ncy												
disc												
oun	4,			4,								
t	4			4								
not	2			2								
es	4	(3)	—	—	4	(3)						
Ass												
et-												
bac												
ked	4,			4,								
sec	9			9						9		
uriti	2	(5		2	(5							
es	1	3)	—	—	1	3)						
Cor												
por												
ate												
deb												
t	1,			1,		1,				1,		
sec	9			9		9				9		
uriti	7			7		7				7		
es	8	(9)	—	—	8	(9)	0	(5)	—	—	0	(5)
Co						1				1		
mm	9			9		1				1		
erci	9,			9,		8,				8,		
al	6			6		8				8		
pap	3	(2		3	(2	4	(5			4	(5	
er	3	00)	—	—	3	00)	0	09)	—	—	0	09)

Tot	2	2	2	2	2	2
al	3	4	0	3	0,	5
	7,	2,	3,			0,
	2 (1,	2 (1,	3	47,	8 (1,	
	1 05	0 06	9 (9	45	(57 4	57
	\$ 0	\$ 8)	\$ 95	\$ (5)	\$ 5	\$ 3)
	<u>\$ 0</u>	<u>\$ 8)</u>	<u>\$ 95</u>	<u>\$ (5)</u>	<u>\$ 5</u>	<u>\$ 3)</u>
	<u><u>\$ 0</u></u>	<u><u>\$ 8)</u></u>	<u><u>\$ 95</u></u>	<u><u>\$ (5)</u></u>	<u><u>\$ 5</u></u>	<u><u>\$ 3)</u></u>

There were no available-for-sale debt securities in a continuous unrealized loss position for 12 months or longer at September 30, 2023.

As of December 31, 2022						
	Less Than 12 Months		12 Months or Longer		Total	
	Unrealized		Unrealized		Unrealized	
	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
U.S. Treasury securities	\$ 15,566	\$ (82)	\$ 47,450	\$ (577)	\$ 63,016	\$ (659)
U.S. agency bonds	67,020	(401)	—	—	67,020	(401)
Corporate debt securities	1,970	(5)	—	—	1,970	(5)
Commercial paper	118,840	(509)	—	—	118,840	(509)
Total	<u>\$ 203,396</u>	<u>\$ (997)</u>	<u>\$ 47,450</u>	<u>\$ (577)</u>	<u>\$ 250,846</u>	<u>\$ (1,574)</u>

## Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company invests its cash reserves in money market funds or available-for-sale debt securities in accordance with its investment policy. The Company's investment policy includes guidelines on acceptable investment securities, limits interest-bearing security investments to certain types of debt and money market instruments issued by the U.S. government and institutions with investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer in order to maintain appropriate diversification. In accordance with the Company's policies, the Company monitors exposure with its counterparties. The Company also maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such account and management believes that the Company is not exposed to significant credit risk.

The Company is also subject to credit risk from its accounts receivable. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral. As of June 30, 2023 September 30, 2023, and December 31, 2022, all of the Company's accounts receivable, if any, relate to a single customer. For the three

and **six** months ended **June 30, 2023** **September 30, 2023** and 2022, all of the Company's revenue related to a single customer.

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### **Janux Therapeutics, Inc.**

### **Notes to Unaudited Condensed Financial Statements-(Continued)**

#### **Leases**

The Company determines if a contract contains a lease at the inception of the contract and evaluates each lease agreement to determine whether the lease is an operating or finance lease. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Liabilities from operating leases are included in current portion of operating lease liabilities, and operating lease liabilities, net of current portion on the accompanying balance sheets. The Company does not have any financing leases. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company does not have material short-term lease costs.

Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable.

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### **Janux Therapeutics, Inc.**

### **Notes to Unaudited Condensed Financial Statements-(Continued)**

For those leases where the implicit rate is not provided, the Company determines an incremental borrowing rate ("IBR") based on the information available at the lease commencement date in determining the present value of lease payments. The IBR is the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company's operating leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. The Company has elected the practical expedient to account for the lease and non-lease components, such as common area maintenance charges, as a single lease component for the Company's facilities leases. The Company has elected to recognize lease incentives, such as tenant improvement allowances, at the lease commencement date as a reduction to the ROU asset and lease liabilities balance until paid to it by

the lessor to the extent that the lease provides a specified fixed or maximum level of reimbursement and the Company is reasonably certain to incur reimbursable costs at least equaling such amounts.

## **Revenue Recognition**

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the

## Notes to Unaudited Condensed Financial Statements-(Continued)

product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those

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## Janux Therapeutics, Inc.

### Notes to Unaudited Condensed Financial Statements-(Continued)

instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

### Research and Development Expenses

All research and development costs are expensed in the period incurred. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

### Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for stock options

and over the respective offering period for employee stock purchase plan rights. The Company estimates the fair value of equity awards using the Black-Scholes option pricing model and recognizes forfeitures as they occur.

### Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive loss is unrealized gain (loss) on available-for-sale securities. Comprehensive losses have been reflected in the statements of operations and comprehensive loss and as a separate component in the statements of stockholders' equity.

### Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, including pre-funded common stock warrants that were issued in an underwritten offering in July 2023 (Note 5), without consideration for potentially dilutive securities. The pre-funded common stock warrants are included in the calculation of basic and diluted net loss per share as the exercise price of \$0.001 per share is non-substantive and the shares are issuable for little or no consideration. The Company has excluded weighted-average unvested shares of 26,987 20,274 shares, 197,515 136,505 shares, 38,160 32,132 shares and 252,335 213,301 shares from the weighted-average number of shares of common stock outstanding for the three months ended June 30, 2023 September 30, 2023 and 2022 and six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be anti-dilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	September 30,	
	2023	2022
Common stock options	8,495,581	7,591,570
Unvested common stock	17,003	112,325
Employee stock purchase plan shares	23,172	12,965
Total potentially dilutive shares	8,535,756	7,716,860

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### Janux Therapeutics, Inc. Notes to Unaudited Condensed Financial Statements-(Continued)

June 30,

	<b>2023</b>	<b>2022</b>
Common stock options	9,076,276	7,548,970
Unvested common stock	23,690	161,760
Employee stock purchase plan shares	8,276	5,936
<b>Total potentially dilutive shares</b>	<b>9,108,242</b>	<b>7,716,666</b>

## 2. Balance Sheet Details

Property and equipment, net consist of the following (in thousands):

	<b>June 30,</b>	<b>December 31,</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Laboratory equipment	\$ 7,503	\$ 6,838	\$ 8,075	\$ 6,838
Furniture and fixtures	792	752	792	752
Computer equipment and software	496	323	496	323
Assets not placed in service	470	145	337	145
<b>Total property and equipment</b>	<b>9,261</b>	<b>8,058</b>	<b>9,700</b>	<b>8,058</b>
Less: accumulated depreciation	(1,883)	(972)	(2,383)	(972)
<b>Property and equipment, net</b>	<b>\$ 7,378</b>	<b>\$ 7,086</b>	<b>\$ 7,317</b>	<b>\$ 7,086</b>

Accrued liabilities consist of the following (in thousands):

	<b>June 30,</b>	<b>December 31,</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Accrued compensation	\$ 1,665	\$ 2,671	\$ 2,391	\$ 2,671
Accrued research and development	6,529	4,716	3,831	4,716
Other accrued liabilities	1,022	623	609	623
<b>Accrued liabilities</b>	<b>\$ 9,216</b>	<b>\$ 8,010</b>	<b>\$ 6,831</b>	<b>\$ 8,010</b>

## 3. Commitments and Contingencies

### License Agreement with WuXi Biologics (Hong Kong) Limited

In April 2021, the Company entered into a cell line license agreement ("Cell Line License Agreement") with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), pursuant to which the Company received a non-exclusive, worldwide, sublicensable license under certain of WuXi Biologics' patent rights, know-how and biological materials ("WuXi Biologics Licensed Technology"), to use the WuXi Biologics Licensed Technology to make, use, sell, offer for sale and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement ("WuXi Biologics Licensed Product").

In consideration for the license, the Company paid WuXi Biologics a non-refundable, one-time license fee of \$0.2 million upon WuXi Biologics' achievement of a certain technical milestone. This one-time license fee was recognized as research and development expense when incurred since the WuXi Biologics Licensed Technology had no alternative future use. If the Company does not engage WuXi Biologics or its affiliates to manufacture the WuXi Biologics Licensed Products for its commercial supplies, the Company is required to make royalty payments to WuXi Biologics in an amount equal to a low single-digit percentage of specified portions of net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. The Company has the right (but not the obligation) to buy out its remaining royalty obligations with respect to each WuXi Biologics Licensed Product by paying WuXi Biologics a one-time payment in an amount ranging from low single digit million dollars to a maximum of \$15.0 million depending on the development and commercialization stage of the WuXi Biologics Licensed Product (the "Buyout Option"), and upon such payment, the Company's license with respect to such WuXi Biologics Licensed Product will become fully paid-up, irrevocable, and perpetual. The royalty obligations will remain in effect during the term of the Cell Line License Agreement so long as the Company has not exercised the Buyout Option.

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### **Janux Therapeutics, Inc.**

#### **Notes to Unaudited Condensed Financial Statements-(Continued)**

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon three months' prior written notice and the Company's payment of all amounts due to WuXi Biologics through the effective date of termination, (ii) by either party for the other party's material breach that remains uncured for 30 days after written notice, and (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure.

## **Operating Leases**

In October 2021, the Company entered into a lease agreement (the "Torrey Plaza Lease") to lease office and laboratory space in San Diego, California. The Company determined this facilities lease was an operating lease at the inception of the lease contract.

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**Janux Therapeutics, Inc.**  
**Notes to Unaudited Condensed Financial Statements-(Continued)**

According to accounting standards, the Torrey Plaza Lease commenced on April 1, 2022 and has a term of 130 months from the commencement date. The lease Torrey Plaza Lease provides an option to extend the term of the lease for a period of 5 years beyond the initial term, which the Company is not reasonably certain to exercise and therefore was not considered in determining the ROU assets and lease liabilities balance.

As required under the terms of the Torrey Plaza Lease, in October 2021 the Company entered into a standby letter of credit, which is secured by a money market account in the amount of \$0.8 million. The letter of credit is subject to draw down by the landlord upon certain events of breach or default by the Company. The letter of credit amount is subject to a 50% reduction subject to certain conditions on or following the date that is 54 months following the contractual lease commencement date.

Future minimum noncancelable operating lease payments as of **June 30, 2023** **September 30, 2023** are as follows (in thousands):

2023 (remaining)	\$ 1,673	\$ 841
2024	3,403	3,403
2025	3,505	3,505
2026	3,611	3,611
2027	3,719	3,719
Thereafter	20,702	20,702
<b>Total minimum lease payments</b>	<b>36,613</b>	<b>35,781</b>
Less: Imputed interest	(11,385)	(10,888)
<b>Total operating lease liabilities</b>	<b>25,228</b>	<b>24,893</b>
Less: Current portion of operating lease liabilities	(1,408)	(1,462)
<b>Operating lease liabilities, net of current portion</b>	<b>\$ 23,820</b>	<b>\$ 23,431</b>

The Torrey Plaza lease had a remaining lease term of **9.6** **9.3** years and a discount rate of 8% as of **June 30, 2023** **September 30, 2023**. Operating lease expense included in the measurement of lease liabilities for the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023** was \$0.9 million and \$1.7 million. Cash paid for amounts included in the measurement of lease liabilities for the three and six months ended June 30, 2023 was \$0.8 million and \$1.1 million. Operating lease expense included in the measurement of lease liabilities for the three and six months ended June 30, 2022 was \$0.9 million and \$1.0 **2.6** million, respectively. Cash paid for amounts included in the measurement of lease liabilities for the three and **six** **nine** months ended **June 30, 2022** **September 30, 2023** was \$0.8 million and \$1.9 million, respectively. Operating lease expense included in the measurement of lease liabilities for the three and nine months ended September

30, 2022 was \$0.9 million and \$1.9 million, respectively. Cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2022 was immaterial.

## Contingencies

From time to time, the Company may be subject to claims or lawsuits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of **June 30, 2023** **September 30, 2023**, the Company is not currently party to any material legal proceedings.

## 4. Related Party Transactions

In January 2021, the Company entered into a Support Services Agreement (the "2021" "2021 Support Services Agreement" "Agreement") with **COI Pharmaceuticals, Avalon BioVentures, Inc.** ("COI" ("Avalon")) that outlines the terms of services provided by **COI** **Avalon** to the Company, as well as the fees charged for such services. **COI** **Avalon** is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio companies of Avalon Ventures, an entity that beneficially owns greater than 5% of our outstanding capital stock. The 2021 Support Services Agreement was most recently renewed in January 2023 and will continue to renew for additional one-year renewal periods until terminated by the parties. Either party may terminate the 2021 Support Services Agreement with 30 days written notice.

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### **Janux Therapeutics, Inc.** **Notes to Unaudited Condensed Financial Statements-(Continued)**

Operating expense recognized by the Company under the 2021 Support Services Agreement for the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023** was immaterial. Operating expense recognized by the Company under the 2021 Support Services Agreement for the three and **six** **nine** months ended **June 30, 2022** **September 30, 2022** was as follows (in thousands):

	<b>Three Months</b>		<b>Six Months Ended</b>	
	<b>Ended</b>	<b>June 30, 2022</b>	<b>June 30, 2022</b>	<b>June 30, 2022</b>
Research and development		\$ 197	\$ 405	
General and administrative		22	64	
Total		\$ 219	\$ 469	

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### Janux Therapeutics, Inc.

#### Notes to Unaudited Condensed Financial Statements-(Continued)

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Research and development	\$ 134	\$ 539
General and administrative	21	85
Total	\$ 155	\$ 624

## 5. Stockholders' Equity

### Shelf Registration Statement

In August 2022, the Company filed a shelf registration statement (File No. 333-266720), which was declared effective in September 2022. The shelf registration statement provides the Company with the ability to offer up to \$400.0 million of certain securities, including shares of its common stock, from time to time. The specific terms of any offering under the shelf registration statement are established at the time of such offering.

In August 2022, the Company entered into an Open Market Sale Agreement<sup>SM</sup> ("Sale Agreement") with Jefferies LLC ("Jefferies") to sell shares of common stock, from time to time, through an "at the market offering" program having an aggregate offering price of up to \$100.0 million through which Jefferies would act as sales agent. In May 2023, the Company terminated the Sale Agreement.

In May 2023, the Company entered into an ATM Equity Offering<sup>SM</sup> Sales Agreement ("New Sale Agreement") with BofA Securities, Inc. ("BofA") to sell shares of common stock, from time to time, through an "at the market offering" program having an aggregate offering price of up to \$150.0 million through which BofA would act as sales agent. There was no activity from the New Sale Agreement during the **six** **nine** months ended **June 30, 2023** **September 30, 2023**. As of **June 30, 2023** **September 30, 2023**, \$150.0 million of common stock remained available for sale under the New Sale Agreement.

In July 2023, the Company closed an underwritten offering of 4,153,717 shares of its common stock and pre-funded warrants to purchase 583,483 shares of common stock. The shares of common stock were sold at a price of \$12.46 per share and the pre-funded common stock warrants were sold at a price of \$12.459 per pre-funded common stock warrant, resulting in gross proceeds of \$59.0 million. Fees related to the offering included underwriting discounts, commissions, and offering expenses in the aggregate amount of \$2.5 million, resulting in net proceeds of \$56.5 million. The pre-funded common stock warrants will not expire until exercised in full and are exercisable in cash or by means of a cashless exercise.

The Company has assessed the pre-funded common stock warrants for appropriate equity or liability classification. The pre-funded common stock warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria.

In addition, such pre-funded common stock warrants do not provide any guarantee of value or return and do not provide the warrant holders with the option to settle any unexercised warrants for cash outside of the Company's control. The pre-funded common stock warrants also include a separate provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 19.9% of the Company's outstanding common stock. The Company valued the pre-funded common stock warrants at issuance, concluding that their sale price approximated their fair value. Accordingly, the pre-funded common stock warrants are accounted for as a component of additional paid-in capital at the time of issuance.

## 2017 Equity Incentive Plan

In August 2017, the Company adopted the Janux Therapeutics, Inc. 2017 Equity Incentive Plan (the "2017 Plan"), which provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and other stock awards to its employees, members of its board of directors and consultants. The maximum term of options granted under the 2017 Plan is ten years and, in general, the options issued under the 2017 Plan vest over a four-year period from the vesting commencement date. The 2017 Plan allows for the early exercise of stock options, which may be subject to repurchase by the Company at the original exercise price.

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### Janux Therapeutics, Inc.

### Notes to Unaudited Condensed Financial Statements-(Continued)

Upon the effectiveness of the 2021 Plan defined and described below, no further grants will be made under the 2017 Plan. Any outstanding awards granted under the 2017 Plan will remain subject to the terms of the 2017 Plan and applicable award agreements.

## 2021 Equity Incentive Plan

In June 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan," and together with the 2017 Plan the "Plans"). Under the 2021 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock awards, performance cash awards and other forms of stock awards to employees, directors and consultants. The maximum term of options granted under the 2021 Plan is ten years and, in general, the options issued under the 2021 Plan vest over a four-year period from the vesting commencement date. The

2021 Plan does not permit early exercises. A total of 2,775,890 new shares of common stock were initially reserved for issuance under the 2021 Plan. The number of shares reserved that were remaining under the 2017 Plan as of the effective date of the 2021 Plan, or 1,424,110 shares, were added to the shares initially reserved under the 2021 Plan upon its effectiveness and any future cancellations under the 2017 Plan will become available for future issuance under the 2021 Plan. In addition, the number of shares of common stock available for issuance under the 2021 Plan automatically increases on January 1 of each calendar year through January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares

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**Janux Therapeutics, Inc.**

**Notes to Unaudited Condensed Financial Statements-(Continued)**

determined by the Company's board of directors. As of **June 30, 2023** **September 30, 2023**, there were **8,759,876** **8,991,993** shares authorized for issuance under the 2021 Plan, inclusive of shares added from 2017 Plan cancellations.

A summary of the Company's stock option activity under its Plans is as follows (in thousands, except share, per share data and years):

	Weigh ted- Averag e Remai ning Contra ctual Term Aggreg ate Intrinsi c Value				Weigh ted- Averag e Remai ning Contra ctual Term Aggreg ate Intrinsi c Value			
	Numb er of Outsta nding Option s	Weight ed- Averag e Exercis e Price	Weight ed- Averag e Years)	Numb er of Outsta nding Option s	Weight ed- Averag e Exercis e Price	Weight ed- Averag e Years)	Numb er of Outsta nding Option s	
Balance at December 31, 2022	7,34 5,44 4	11.6 \$ 7	29,8 8.31 \$ 06	7,34 5,44 4	11.6 \$ 7	29,8 8.31 \$ 06	7,34 5,44 4	
Granted	1,97 4,25 0	13.9 \$ 1		1,98 4,65 0	13.9 \$ 0			

Exercised	(148, 649)	10.6 \$ 3		(191, 879)	\$ 8.65
Forfeited or cancelled	(94,7 69)	16.1 \$ 1		(642, 634)	13.7 \$ 1
Balance at June 30, 2023	9,07 6,27 6	12.1 \$ 3 7.66 \$ 88	22,9		
Vested and expected to vest at June 30, 2023	9,07 6,27 6	12.1 \$ 3 7.66 \$ 88	22,9		
Exercisable at June 30, 2023	5,53 1,37 8	9.41 \$ 13 \$ 9.41 7.02 \$ 13	22,5		
Balance at September 30, 2023			8,49 5,58 1	12.1 \$ 0 \$ 0	15,0 7.60 \$ 76
Vested and expected to vest at September 30, 2023			8,49 5,58 1	12.1 \$ 0 \$ 0	15,0 7.60 \$ 76
Exercisable at September 30, 2023			5,41 3,68 8		14,9 7.09 \$ 99

The weighted-average grant date fair value per share of option grants for the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022 was \$10.09, and \$12.65 **12.52**, respectively. The total intrinsic value of stock options exercised for the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022 was \$1.5 **1.9** million and \$0.1 million, respectively. As of **June 30, 2023** **September 30, 2023**, total unrecognized stock-based compensation cost associated with option grants was \$49.3 **40.0** million, which is expected to be recognized over a remaining weighted-average period of approximately **2.5** **2.3** years.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants under the Plans were as follows:

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	3.5% – 4.2%	1.5% – 3.6%	3.5% – 4.2%	1.5% – 3.7%
Expected volatility	83% – 87%	81% – 85%	83% – 87%	81% – 85%
Expected term (in years)	5.3 – 6.1	5.3 – 6.1	5.3 – 6.1	5.3 – 6.1
Expected dividend yield	—	—	—	—

*Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.

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### **Janux Therapeutics, Inc.** **Notes to Unaudited Condensed Financial Statements-(Continued)**

*Expected volatility.* Given the Company's limited historical stock price volatility data, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Expected term.* The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is generally the contractual term.

*Expected dividend yield.* The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

## **2021 Employee Stock Purchase Plan**

In June 2021, the Company adopted the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 10, 2021. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common

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### **Janux Therapeutics, Inc.** **Notes to Unaudited Condensed Financial Statements-(Continued)**

stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. A total of 466,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP automatically increases on January 1 of each calendar year through January 1, 2031, in an amount equal to the lesser of (i) 1% of the total number of shares of the Company's common stock on the last day of the calendar month before the date of each automatic increase and (ii) 932,000 shares; provided that before the date of any such increase, the Company's board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). In June 2021, employees began to enroll in the ESPP and the Company's first offering period commenced. For the three and ~~six~~ nine months ended ~~June 30, 2023~~ ~~September 30, 2023~~, stock-based compensation expense related to the ESPP was \$0.40 million and \$0.60 million, respectively. Stock-based compensation expense related to the ESPP for the three and ~~six~~ nine months ended ~~June 30, 2022~~ ~~September 30, 2022~~ was \$0.2 million and \$0.30 million, respectively. As of ~~June 30, 2023~~ ~~September 30, 2023~~, total unrecognized stock-based compensation expense related to the ESPP was \$0.60 million, which is expected to be recognized over a remaining weighted-average period of approximately 1.51 years.

### Stock-Based Compensation Expense

Stock-based compensation expense has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months				Three Months			
	Ended		Six Months Ended		Ended		Nine Months Ended	
	June 30,	2023	June 30,	2023	September 30,	2023	September 30,	2023
Research and development	\$ 2,449	\$ 2,023	\$ 7	4,80	\$ 1,572	\$ 2,019	\$ 6,379	\$ 5,702
General and administrative	3,052	2,421	7	6,16	2,976	2,577	9,143	7,296
Total	\$ 5,501	\$ 4,444	\$ 74	10,9	8,40	\$ 4,548	\$ 4,596	\$ 15,52
	<u><u>\$ 5,501</u></u>	<u><u>\$ 4,444</u></u>	<u><u>\$ 74</u></u>	<u><u>10,9</u></u>	<u><u>8,40</u></u>	<u><u>\$ 4,548</u></u>	<u><u>\$ 4,596</u></u>	<u><u>\$ 12,99</u></u>

### Unvested Stock Liabilities

A summary of the Company's unvested shares and unvested stock liabilities is as follows (in thousands, except share data):

	Number of Unvested Shares	Unvested Stock Liabilities	Number of Unvested Shares	Unvested Stock Liabilities
Balance at December 31, 2022	68,406	\$ 169	68,406	\$ 169
Vested shares	(44,716)	(139)	(51,403)	(144)
Balance at June 30, 2023	<u>23,690</u>	<u>\$ 30</u>		
Balance at September 30, 2023			<u>17,003</u>	<u>\$ 25</u>

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### **Janux Therapeutics, Inc.** **Notes to Unaudited Condensed Financial Statements-(Continued)**

#### **Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following:

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Common stock options outstanding	9,076,276	7,345,444	8,495,581	7,345,444
Shares available for issuance under the Plans	4,216,753	4,012,001	4,754,218	4,012,001
Shares available for issuance under the ESPP	<u>1,175,413</u>	<u>816,478</u>	<u>1,175,413</u>	<u>816,478</u>
Pre-funded common stock warrants			503,226	—
Total	<u>14,468,44</u>	<u>12,173,923</u>	<u>14,928,438</u>	<u>12,173,923</u>
	<u>2</u>			

#### **6. Research Collaboration and Exclusive License Agreement**

In December 2020, the Company entered into a research collaboration and exclusive license agreement (the “Merck Agreement”), pursuant to which the Company granted Merck Sharp & Dohme Corp. (“Merck”) an exclusive, worldwide, royalty-bearing, sublicensable license to certain of its patent rights and know-how for up to two collaboration targets

("First Collaboration Target" and "Second Collaboration Target", together the "Collaboration Targets") related to next generation T cell engager immunotherapies for the treatment of cancer. In each case, once the Collaboration Targets are designated by Merck, they have the right to research, develop, make, have made, use, import, offer to sell, and sell compounds and any licensed products related thereto. Merck selected the

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**Table of Contents****Janux Therapeutics, Inc.****Notes to Unaudited Condensed Financial Statements-(Continued)**

First Collaboration Target upon execution of the Merck Agreement and selected the Second Collaboration Target in May 2022. Following the research term, Merck will have the sole right to research, develop, manufacture, and commercialize the licensed compounds and products directed against the Collaboration Targets. Consideration in the Merck Agreement consists of (i) an \$8.0 million non-refundable and non-creditable upfront fee, (ii) \$8.0 million paid upon the selection of the Second Collaboration Target, (iii) research program funding (iv) development and regulatory milestones, (v) commercial milestones, and (vi) royalty payments. Under the Merck Agreement, the Company is eligible to receive up to an aggregate of \$142.5 million per Collaboration Target in milestone payments (\$285.0 million collectively for both Collaboration Targets), contingent on the achievement of certain regulatory and development milestones. Merck is also required to make milestone payments to the Company upon the successful completion of certain commercial milestones, in an aggregate amount not to exceed \$350.0 million for each licensed product under either of the Collaboration Targets. The Merck Agreement provides that Merck is obligated to pay to the Company tiered royalty payments on a product-by-product and country-by-country basis, ranging from low single-digit to low teens percentage royalty rates on specified portions of annual net sales for licensed products under either of the Collaboration Targets that are commercialized. Such royalties are subject to reduction, on a product-by-product and country-by-country basis, for licensed products not covered by patent claims, or that require Merck to obtain a license to obtain a license to third-party intellectual property in order to commercialize the licensed products, or that are subject to compulsory licensing.

The Merck Agreement will terminate at the end of the calendar year in which the expiration of all royalty obligations occurs for all licensed products under the agreement. Merck has the unilateral right to terminate the Merck Agreement in its entirety or on a Collaboration Target by Collaboration Target basis at any time and for any reason upon prior written notice to the Company. Both parties have the right to terminate the agreement for an uncured material breach, certain illegal or unethical activities, and insolvency of the other party. Upon expiration of the agreement but not early termination thereof, and provided all payments due under the agreement have been made, Merck's exclusive licenses under the agreement will become fully paid-up and perpetual.

The Company recognized \$1.1 million, \$2.4 million, \$3.1 million, and \$4.0 million of revenue under the Merck Agreement for the three months ended June 30, 2023 September 30, 2023 and 2022 and six months ended June 30, 2023 September 30, 2023 and 2022, respectively. As of June 30, 2023 September 30, 2023, aggregate deferred revenue related to the Merck Agreement was \$5.6 million, \$5.3 million all of which was classified as current. The Company did not

have an accounts receivable balance outstanding as of **June 30, 2023** **September 30, 2023** and December 31, 2022. The remaining performance obligations under the Merck Agreement relate to the Company's conduct of research services and the Company's participation in a joint research committee for the Second Collaboration Target. The performance obligations related to the First Collaboration Target were completed as of **June 30, 2023** **September 30, 2023**. As it relates to the Second Collaboration Target, the Company estimates the remaining term of the research services, over which revenue will be recognized, to be **1.2** **0.9** years as of **June 30, 2023** **September 30, 2023**.

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### **7. Subsequent Events**

In July 2023, the Company closed an underwritten offering of 4,153,717 shares of its common stock and pre-funded warrants to purchase 583,483 shares of common stock. The shares of common stock were sold at a price of \$12.46 per share and the pre-funded warrants were sold at a price of \$12.459 per pre-funded warrant, resulting in gross proceeds of \$59.0 million. Fees related to the offering included underwriting discounts, commissions, and estimated offering expenses in the aggregate amount of \$2.5 million, resulting in estimated net proceeds of \$56.5 million.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q (Quarterly Report) and the audited financial statements and related notes thereto as of and for the year ended December 31, 2022 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC), on March 10, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Furthermore, past operating results are not necessarily indicative of results that may occur in future periods.*

### **Overview**

We are an innovative clinical-stage biopharmaceutical company developing tumor-activated immunotherapies for cancer. Our proprietary technology has enabled the development of two distinct bispecific platforms: Tumor Activated T Cell Engagers (TRACTr) and Tumor Activated Immunomodulators (TRACIr). The TRACTr platform produces T cell engagers (TCEs) with a tumor antigen-binding domain and a CD3 T cell binding domain, while the TRACIr platform produces bispecifics with a tumor antigen-binding domain and a costimulatory CD28 binding domain. The goal of both platforms is to provide cancer patients with safe and effective therapeutics that direct and guide their immune system to eradicate tumors while minimizing safety concerns. Our initial focus is on developing a novel class of TRACTr therapeutics designed to target clinically validated TCE drug targets, but overcome liabilities associated with prior generations TCEs. While TCE therapeutics have displayed potent anti-tumor activity in hematological cancers, developing TCEs to treat solid tumors has faced challenges due to the limitations of prior TCE technologies, namely (i) on-target healthy tissue immune activation that contributes to cytokine release syndrome (CRS) and healthy tissue toxicity and (ii) poor pharmacokinetics (PK) leading to short half-life. Our first clinical candidate, JANX007, is a prostate-specific membrane antigen or PSMA-TRACTr and is being investigated in a Phase 1 clinical trial in adult subjects with metastatic castration-resistant prostate cancer (mCRPC). In July 2023 we announced interim clinical data for JANX007 which displayed meaningful PSA drops in-line with what has been achieved by un-masked T cell engagers, and we believe displayed a differentiated profile with regards to CRS, healthy tissue toxicities and PK, consistent with the TRACTr mechanism-of-action. Our second clinical candidate, JANX008, is an epidermal growth factor receptor or EGFR-TRACTr and is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including colorectal cancer, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma. The first patient for this trial was dosed in April 2023. We are anticipate providing an update on our clinical programs in 2024. Our TRACTr pipeline also developing includes a trophoblast cell surface antigen 2 or TROP2-TRACTr, which is a clinically validated anti-tumor target that is overexpressed in various cancer types, such as breast, lung, urothelial, endometrial, ovarian, prostate, pancreatic, gastric, colon, head and neck, and glioma. We expect to select a have completed TROP2-TRACTr development candidate in 2023. Our TRACIr drug candidate, pipeline includes JANX009, which is a programmed death-ligand 1 or PD-L1-TRACIr and is being investigated in preclinical studies designed for the treatment of solid tumors. We expect to be ready to submit an have completed Investigational New Drug application (IND) enabling studies and manufacturing for this product candidate in 2023. In addition to named programs, we are generating a number of unnamed TRACTr and TRACIr programs for potential future development. With the additional capital raised from our underwritten offering in July 2023, we are well-positioned to advance another program into clinical trials and advance additional preclinical programs. We are currently assessing priorities in our preclinical pipeline.

We were incorporated in June 2017. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, business development, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and development for our lead programs, establishing and enhancing our intellectual property portfolio and providing general and administrative support for these operations. All of our product candidates and research programs other than JANX007 and JANX008 are in preclinical development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. We have funded our operations primarily with the net proceeds from the issuance of convertible promissory notes, the issuance of convertible preferred stock, the

exercise of common stock options, proceeds from our initial public offering (IPO), the issuance of common stock and pre-funded common stock warrants in public and/or underwritten offerings and amounts received under a collaboration agreement with Merck Sharp & Dohme Corp. (Merck).

We have incurred operating losses since our inception and have not yet generated any product revenue. Our net losses were \$35.0 million \$46.5 million and \$30.3 million \$47.0 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. As of June 30, 2023 September 30, 2023, we had an accumulated deficit of \$145.4 million \$157.0 million.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our clinical and preclinical studies and our expenditures on other research and development activities and the

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timing of any revenue recognition under our collaboration agreement with Merck. We expect our expenses and operating losses will increase substantially and that we will continue to incur significant losses for the foreseeable future as we conduct our ongoing and planned research and development activities and conduct preclinical studies and clinical trials, hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates, which will not be for many years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates or to our platform technologies that we would otherwise prefer to develop and market ourselves. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, will be sufficient to meet our anticipated cash operating expenses and capital expenditure requirements through at least the next 12 months, following the date of this Quarterly Report. Report and through 2027.

## **Our Research Collaboration with Merck**

In December 2020, we entered into a research collaboration and exclusive license agreement with Merck to develop TRACTr product candidates that are distinct from those in our internally developed pipeline (the Merck Agreement). Merck has the right to select up to two collaboration targets (each a Collaboration Target) related to next generation T cell

engages immunotherapies for the treatment of cancer. Merck selected the first Collaboration Target upon execution of the agreement and selected the second Collaboration Target in May 2022. Merck received an exclusive worldwide license for each selected target and intellectual property from the collaboration. In return, we are eligible to receive up to \$500.5 million per target in upfront and milestone payments, plus royalties on sales of the products derived from the collaboration. Merck provides research funding under the collaboration.

## Risks and Uncertainties

Global economic and business activities continue to face widespread macroeconomic uncertainties, including those associated with COVID-19 and other public health crises, bank failures, inflation and monetary supply shifts, recession risks and potential disruptions from the ongoing Russia-Ukraine conflict, the war in the Middle East and related sanctions. For example, in 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of certain financial institutions. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. Inflation generally affects us by increasing our salaries and fees paid to third-party contract service providers. We have considered potential impacts arising from the risks and uncertainties as described above and have not experienced any material disruption to our operations to date.

## Support Services Agreement with Avalon BioVentures, Inc. (formerly COI Pharmaceuticals, Inc.)

In January 2021, we entered into a Support Services Agreement (the 2021 Support Services Agreement) with COI Pharmaceuticals Avalon BioVentures, Inc. (COI) (Avalon) that outlines the terms of services provided by COI Avalon to the Company, as well as the fees charged for such services. COI Avalon is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio companies of Avalon Ventures, an entity that beneficially owns greater than 5% of our outstanding capital stock. The amounts paid to COI Avalon include support service fees or mark-ups of up to 5%. The 2021 Support Services Agreement was most recently renewed in January 2023 and will continue to renew for additional one-year renewal periods until terminated by the parties. Either party may terminate the 2021 Support Services Agreement with 30 days written notice.

## Financial Operations Overview

### Revenues

To date, we have not generated any revenues from the commercial sale of any products, and we do not expect to generate revenues from the commercial sale of any products for the foreseeable future, if ever. We recognized \$3.1 million \$5.6 million and \$4.0 million \$5.8 million of revenue under the Merck Agreement for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively.

### Research and Development

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To date, our research and development expenses have related primarily to direct and indirect expenses in connection with the development of our TRACTr and TRACIr platforms, discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Our direct research and development expenses include:

- external research and development expenses incurred under agreements with CROs and consultants to conduct our preclinical and clinical studies;
- license fees; and
- laboratory equipment, materials and supplies.

Our indirect research and development expenses include:

- salaries and employee-related costs, including recruiting fees and stock-based compensation for those individuals involved in research and development efforts;
- maintenance of facilities and equipment, software license fees, depreciation; and
- allocated facilities and equipment-related expenses, which include rent, utilities, insurance, and office supplies.

Certain research and development expenses as listed above include amounts paid to COI Avalon pursuant to the 2021 Support Services Agreement.

We anticipate that our research and development expenses will substantially increase for the foreseeable future as we continue the development of our TRACTr and TRACIr platforms and the discovery and development of product candidates under our TRACTr and TRACIr platforms.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of clinical trials and preclinical studies of product candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. 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.

## General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant general and administrative expenses include facility-related costs, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities; legal fees relating to intellectual property and corporate matters; professional fees for accounting, tax and consulting services; insurance costs; and other operating costs. Our general and administrative expenses include amounts paid to **COI** **Avalon** pursuant to the **2021 Support Services Agreement** for certain back-office and administrative support services, including facilities support. We anticipate that our general and administrative expenses will increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses associated with operating as a public company, including expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

## Other Income

Other income consists of interest income on our cash and cash equivalents and short-term investments.

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### Results of Operations

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

	Three Months Ended June 30,			Three Months Ended September 30,		
	2023		2022	Change	2023	
			(in thousands)			
Collaboration revenue	\$ 1,057	\$ 2,365	\$ 8)	(1,30	\$ 2,517	\$ 1,813
Operating expenses:						
Research and development	14,924	14,086	838		11,892	13,737
General and administrative	6,881	5,540	1,341		6,438	6,098

Total operating expenses	21,805	19,626	2,179	18,330	19,835	(1,505)
Loss from operations	(20,748)	(17,261)	7)	(15,813)	(18,022)	2,209
Other income	3,240	373	2,867	4,245	1,326	2,919
Net loss	<u>\$ (17,508)</u>	<u>\$ (16,888)</u>	<u>\$ (620)</u>	<u>\$ (11,568)</u>	<u>\$ (16,696)</u>	<u>\$ 5,128</u>

#### Collaboration Revenue

Collaboration revenues were \$1.1 million \$2.5 million and \$2.4 million \$1.8 million for the three months ended June 30, 2023 September 30, 2023 and 2022, respectively. The decrease increase of \$1.3 million \$0.7 million was due to a decrease an increase in full-time equivalent hours incurred in the performance of research services required under the Merck Agreement.

#### Research and Development Expense

The following table summarizes our direct and indirect research and development expenses for the three months ended June 30, 2023 September 30, 2023 and 2022:

	Three Months Ended			Three Months Ended		
	June 30,		Chang e	September 30,		Chang e
	2023	2022		2023	2022	
Direct costs:						
JANX007	\$ 2,091	\$ 1,257	\$ 834	\$ 1,704	\$ 1,351	\$ 353
JANX008	1,786	3,043	(1,257)	1,088	1,510	(422)
Preclinical stage programs and other direct unallocated costs	3,669	4,075	(406)	2,586	4,628	(2,042)
Total direct costs	7,546	8,375	(829)	5,378	7,489	(2,111)
Indirect costs						
			1,66			
	7,378	5,711	7	6,514	6,248	266
Total research and development expenses	<u>\$ 14,924</u>	<u>\$ 14,086</u>	<u>\$ 838</u>	<u>\$ 11,892</u>	<u>\$ 13,737</u>	<u>\$ 45</u>

IND applications for JANX007 and JANX008 were cleared by the U.S. Food and Drug Administration (FDA) in May 2022 and January 2023, respectively. As a result, we have separated direct costs for the development of JANX007 and JANX008 from preclinical stage programs and other direct unallocated costs for the three months ended **June 30, 2023** **September 30, 2023** and 2022. We will further separate direct costs related to our other programs as future IND applications are cleared by the FDA. These changes in presentation had no effect on net loss, total research and development expenses, stockholders' equity, or cash flows as previously reported.

Research and development expenses were **\$14.9 million** **\$11.9 million** and **\$14.1 million** **\$13.7 million** for the three months ended **June 30, 2023** **September 30, 2023** and 2022, respectively. The increase decrease of **\$0.8 million** **\$1.8 million** was primarily due to increases decreases in indirect preclinical stage programs and other direct unallocated costs of **\$1.7 million** **\$2.0 million** and direct costs related to the development of JANX008 of **\$0.4 million**, offset by increases in direct costs related to the development of JANX007 of **\$0.8 million**, offset by decreases in direct costs related to the development of JANX008 of **\$1.3 million** **\$0.4 million** and preclinical stage programs and other unallocated direct indirect costs of **\$0.4 million** **\$0.3 million**. The increase in indirect costs was primarily due to personnel costs of **\$0.8 million**, stock-based compensation expense of **\$0.4 million**, and increases in facilities and other costs of **\$0.4 million** and personnel costs of **\$0.3 million**, offset by a decrease in stock-based compensation expense of **\$0.5 million**.

#### *General and Administrative Expense*

General and administrative expenses were **\$6.9 million** **\$6.4 million** and **\$5.5 million** **\$6.1 million** for the three months ended **June 30, 2023** **September 30, 2023** and 2022, respectively. The increase of **\$1.4 million** **\$0.3 million** was primarily due to increases in stock-based compensation of **\$0.6 million** **\$0.4 million**, personnel and facilities related costs of **\$0.6 million** and **\$0.3 million**, offset by a decrease in consulting and professional fees of **\$0.2 million** **\$0.4 million**.

#### Other Income

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#### *Other Income*

Other income was **\$3.2 million** **\$4.2 million** and **\$0.4 million** **\$1.3 million** for the three months ended **June 30, 2023** **September 30, 2023** and 2022, respectively. The increase of **\$2.8 million** **\$2.9 million** was due to the impact of increases in interest rates on our debt securities, resulting in increased interest income.

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

Six Months Ended June 30,			Nine Months Ended September 30,		
2023	2022	Change	2023	2022	Change
(in thousands)			(in thousands)		

Collaboration revenue	\$ 3,105	\$ 3,954	\$ (849)	\$ 5,622	\$ 5,767	\$ (145)
Operating expenses:						
Research and development	30,789	24,270	6,519	42,681	38,007	4,674
General and administrative	13,345	10,487	2,858	19,783	16,585	3,198
Total operating expenses	44,134	34,757	9,377	62,464	54,592	7,872
Loss from operations	(41,029)	(30,803)	26)	(56,842)	(48,825)	7)
Other income	6,062	505	5,557	10,307	1,831	8,476
Net loss			(4,66			
	\$ (34,967)	\$ (30,298)	\$ 9)	\$ (46,535)	\$ (46,994)	\$ 459

#### Collaboration Revenue

Collaboration revenues were \$3.1 million \$5.6 million and \$4.0 million \$5.8 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. The decrease of \$0.9 million \$0.2 million was due to a decrease in full-time equivalent hours incurred in the performance of research services required under the Merck Agreement.

#### Research and Development Expense

The following table summarizes our direct and indirect research and development expenses for the six nine months ended June 30, 2023 September 30, 2023 and 2022:

	Six Months Ended June 30,			Nine Months Ended September 30,		
			Chang e			Chang e
	2023	2022		(in thousands)	2023	2022
<b>Direct costs:</b>						
JANX007			1,41			1,77
	\$ 3,807	\$ 2,389	\$ 8	\$ 5,511	\$ 3,739	\$ 2
JANX008			(2,17			(2,5
	3,128	5,306	8)	4,217	6,816	99)

Preclinical stage programs and other direct unallocated costs	9,276	6,740	6	2,53	11,862	11,369	493
Total direct costs	16,21			1,77			
	1	14,435		6	21,590	21,924	(334)
Indirect costs	14,57			4,74			5,00
	8	9,835		3	21,091	16,083	8
Total research and development expenses	30,78			6,51			4,67
	\$ 9	\$ 24,270	\$ 9	\$ 42,681	\$ 38,007	\$ 4	

IND applications for JANX007 and JANX008 were cleared by the FDA in May 2022 and January 2023, respectively. As a result, we have separated direct costs for the development of JANX007 and JANX008 from preclinical stage programs and other direct unallocated costs for the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022. We will further separate direct costs related to our other programs as future IND applications are cleared by the FDA. These changes in presentation had no effect on net loss, total research and development expenses, **stockholders'** **stockholders'** equity, or cash flows as previously reported.

Research and development expenses were **\$30.8 million** **\$42.7 million** and **\$24.3 million** **\$38.0 million** for the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, respectively. The increase of **\$6.5 million** **\$4.7 million** was primarily due to increases in indirect costs **\$4.8 million**, preclinical stage programs and other unallocated direct costs of **\$2.5 million** **\$5.0 million**, direct costs related to the development of JANX007 of **\$1.4 million** **\$1.8 million** and preclinical stage programs and other direct unallocated costs of **\$0.5 million**, offset by decreases in direct costs related to the development of JANX008 of **\$2.2 million** **\$2.6 million**. The increase in indirect costs was primarily due to personnel costs of **\$2.0 million** **\$2.3 million**, facilities and other costs of **\$1.7 million** **\$2.0 million** and stock-based compensation expense of **\$1.1 million** **\$0.7 million**.

#### General and Administrative Expense

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General and administrative expenses were **\$13.3 million** **\$19.8 million** and **\$10.5 million** **\$16.6 million** for the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, respectively. The increase of **\$2.8 million** **\$3.2 million** was primarily due to increases in stock-based compensation of **\$1.4 million** **\$1.8 million** and personnel and facilities related costs of **\$1.4 million**.

#### Other Income

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Other income was \$6.1 million \$10.3 million and \$0.5 million \$1.8 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively. The increase of \$5.6 million \$8.5 million was due to the impact of increases in interest rates on our debt securities, resulting in increased interest income.

## Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses and negative cash flows for the foreseeable future. As of June 30, 2023 September 30, 2023, we had cash, cash equivalents, restricted cash and short-term investments of \$304.1 million \$350.5 million. Inclusive in this amount is \$0.8 million of restricted cash that is not available for current use.

In August 2022, we filed a shelf registration statement (File No. 333-266720), which was declared effective in September 2022. The shelf registration statement provides us with the ability to offer up to \$400.0 million of certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the shelf registration statement are established at the time of such offering.

In August 2022, we entered into an Open Market Sale Agreement<sup>SM</sup> (Sale Agreement) with Jefferies LLC (Jefferies) to sell shares of our common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to \$100.0 million through which Jefferies would act as sales agent. In May 2023, we terminated the Sale Agreement.

Additionally, in May 2023, we entered into an ATM Equity Offering<sup>SM</sup> Sales Agreement (New Sale Agreement) with BofA Securities, Inc. (BofA) to sell shares of our common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to \$150.0 million through which BofA would act as sales agent. As of June 30, 2023 September 30, 2023, \$150.0 million of common stock remained available for sale under the New Sale Agreement.

In July 2023, we closed an underwritten offering of 4,153,717 shares of our common stock and pre-funded warrants to purchase 583,483 shares of common stock. The shares of common stock were sold at a price of \$12.46 per share and the pre-funded common stock warrants were sold at a price of \$12.459 per pre-funded common stock warrant, resulting in gross proceeds of \$59.0 million. Fees related to the offering included underwriting discounts, commissions, and estimated offering expenses in the aggregate amount of \$2.5 million, resulting in estimated net proceeds of \$56.5 million.

The following summarizes our cash flows for the periods indicated:

Six Months Ended June 30,		Nine Months Ended September 30,	
2023	2022	2023	2022

	(in thousands)		(in thousands)	
Net cash provided by (used in):				
Operating activities	\$ (28,965)	\$ (17,595)	\$ (40,674)	\$ (31,009)
Investing activities	9,134	40,107	(52,317)	59,870
Financing activities	2,108	309	58,717	309
Net increase in cash, cash equivalents and restricted cash	<u>\$ (17,723)</u>	<u>\$ 22,821</u>		
Net increase (decrease) in cash, cash equivalents and restricted cash			\$ (34,274)	\$ 29,170

### ***Operating Activities***

Net cash used in operating activities of \$29.0 million \$40.7 million for the six nine months ended June 30, 2023 September 30, 2023 was primarily due to our net loss of \$35.0 million \$46.5 million and a change in operating assets and liabilities and other non-cash charges of \$5.0 million \$9.7 million, adjusted for \$11.0 million \$15.5 million of stock-based compensation expense. Net cash used in operating activities of \$17.6 million \$31.0 million for the six nine months ended June 30, 2022 September 30, 2022 was primarily due to our net loss of \$30.3 million \$47.0 million, adjusted for \$8.4 million \$13.0 million of stock-based compensation expense and a change in operating assets and liabilities and other non-cash charges of \$4.3 million \$3.0 million.

### ***Investing Activities***

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Net cash used in investing activities of \$52.3 million for the nine months ended September 30, 2023 was primarily due to \$51.0 million of net purchases of short-term investments and by our purchase of property and equipment, primarily consisting of laboratory equipment of \$1.3 million. Net cash provided by investing activities of \$9.1 million \$59.9 million for the six nine months ended June 30, 2023 September 30, 2022 was primarily due to \$10.0 million \$64.3 million of net maturities of short-term investments offset by our purchase of property and equipment, primarily consisting of laboratory equipment of \$0.9 million. Net cash provided by investing activities of \$40.1 million for the six months ended June 30, 2022 was primarily due to \$42.0 million of net maturities of short-term investments offset by our purchase of property and equipment, primarily consisting of laboratory equipment of \$1.9 million \$4.4 million.

### ***Financing Activities***

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Net cash provided by financing activities of \$2.1 million \$58.7 million for the six nine months ended June 30, 2023 September 30, 2023 was primarily due to proceeds from the issuance of common stock option and pre-funded common stock warrants, net of issuance costs, of \$56.5 million, and exercises of common stock options and proceeds from shares issued under our the employee stock purchase plan, plan (ESPP) of \$2.2 million. Net cash provided by financing activities of \$0.3 million for the six nine months ended June 30, 2022 September 30, 2022 was primarily due to proceeds from shares issued under our employee stock purchase plan. ESPP.

### **Funding Requirements**

Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, will be sufficient to meet our anticipated cash operating expenses and capital expenditure requirements through at least the next 12 months, following the date of this Quarterly Report, Report and through 2027. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for JANX007 and JANX008 and the IND-enabling studies and planned future clinical trials for TROP2-TRACTr and TRACIr costimulatory bispecific; JANX008;
- the number and characteristics of clinical programs that we pursue;
- the outcome, timing and costs of seeking FDA, European Commission and any other comparable regulatory approvals for any future drug candidates;
- the costs of manufacturing our product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinic activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims including litigation costs and the outcome of such litigation;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;

- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the disruptions to and volatility in the credit and financial markets in the United States and worldwide from COVID-19 or other epidemics; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or

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convertible debt securities, the ownership interest of our stockholders will be or could 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 and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

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

In April 2021, we entered into a cell line license agreement (Cell Line License Agreement) with WuXi Biologics (Hong Kong) Limited (WuXi Biologics). According to the terms of the Cell Line License Agreement, if we do not engage WuXi Biologics or its affiliates to manufacture the therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (WuXi Biologics Licensed Products) for our commercial supplies, we are required to make royalty payments to WuXi Biologics in an amount equal to a low single-digit percentage of specified portions of net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. We have the right (but not the obligation) to buy out our remaining royalty obligations with respect to each WuXi Biologics Licensed Product by paying WuXi Biologics a one-time payment in an amount ranging from low single digit million dollars to a maximum of \$15.0 million (Buyout Option). The royalty obligations will remain in effect during the term of the Cell Line License Agreement so long as we have not exercised the Buyout Option. See the section within Item 1 of Part I, "Notes to

Condensed Financial Statements — Note 3 — Commitments and Contingencies" of this Quarterly Report for additional information.

In October 2021, we entered into a noncancelable agreement to lease office and laboratory space in San Diego, California (Torrey Plaza Lease) with aggregate payments of approximately \$38.0 million over the 126-month term of the lease. The Torrey Plaza Lease commenced in July 2022. See the section within Item 1 of Part I, "Notes to Condensed Financial Statements — Note 3 — Commitments and Contingencies" of this Quarterly Report for additional information.

We enter into contracts in the normal course of business with various third parties for preclinical and clinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

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

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to estimates to complete the performance obligations and the estimated transaction price for collaboration revenues, accruals for research and development expenses and estimates used in valuing our equity awards for stock-based compensation expense. 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.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, see Item 1 of Part I, "Notes to Condensed Financial Statements — Note 1 — Organization and Summary of Significant Accounting Policies" of this Quarterly Report and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" contained in our Annual Report on Form 10-K, filed with the SEC on March 10, 2023. There have not been any material changes to the critical accounting policies discussed therein during the three months ended **June 30, 2023** **September 30, 2023**.

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

Not applicable to a smaller reporting company.

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**Item 4. Controls and Procedures.**
**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation and supervision of our Chief Executive Officer and our Acting Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Acting Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable

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assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Acting Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during our most recent quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II—OTHER INFORMATION**
**Item 1. Legal Proceedings.**

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

## Item 1A. Risk Factors.

*Investing in our common stock is speculative and involves a high degree of risk. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (\*) those risk factors that reflect changes from the similarly titled risk factors included in our Annual Report on Form 10-K, filed with the SEC on March 10, 2023.*

### Summary of Risks Associated with Our Business

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report and our other filings with the SEC before making investment decisions regarding our common stock.*

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate certain product development programs or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are early in our development efforts and all of our product candidates and research programs other than JANX007 and JANX008 are in the preclinical development or discovery stage. We have a very limited history of conducting clinical trials to test our product candidates in humans.
- Preclinical and clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. JANX007, JANX008 and any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- We may rely on third parties to conduct, supervise, and monitor our ongoing and planned clinical trials or perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- The market opportunity for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining

highly qualified personnel, we may not be able to successfully implement our business strategy.

- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours and our ability to successfully commercialize our products may be adversely affected.

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- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with current or future federal, state and foreign laws, regulations, contracts, self-regulatory schemes, industry standards and other obligations relating to privacy and security could lead to regulatory investigations or actions (which could include civil or criminal penalties), private litigation (including class claims) and mass arbitration demands, adverse publicity, disruptions of our business operations and other adverse business consequences.

## Risk Factors

### Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

***We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.\****

We are an early-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, business development, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and preclinical studies for our lead programs, establishing and enhancing our intellectual property portfolio and providing general and administrative support for these operations. All of our product candidates and research programs other than JANX007 and JANX008 are in preclinical development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, our net losses were **\$35.0 million** **\$46.5 million** and **\$30.3 million** **\$47.0 million**, respectively. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

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

preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company 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 the loss of all or part of investments.

***If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.\****

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and potential clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of **June 30, 2023** **September 30, 2023**, we had **\$303.3 million** **\$349.7 million** in cash and cash equivalents and short-term investments. Based upon our current operating plan, we estimate that our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 **months**. **months following the date of this Quarterly Report and through 2027**. However, we believe that our existing cash and cash equivalents and short-term investments will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for JANX007 and JANX008 and the IND-enabling studies and planned future clinical trials for TROP2-TRACTr and TRACI<sup>r</sup> costimulatory bispecific; JANX008;
- the number and characteristics of clinical programs that we pursue;

- the outcome, timing and costs of seeking FDA, European Commission and any other comparable regulatory approvals for any future drug candidates;
- the costs of manufacturing our product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinic activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claim including litigation costs and the outcome of such litigation;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;
- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical and macroeconomic conditions, including COVID-19, the military conflict in Ukraine and Russia, the war in the Middle East and bank failures; and
- the costs of operating as a public company.

Because we do not expect to generate revenue from product sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.\****

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements

that include covenants limiting or restricting our ability to take specific actions, such as limitations on our ability to incur additional debt, make capital expenditures or declare dividends.

To the extent we raise funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. For example, we have entered into a collaboration with Merck to develop certain specified product candidates, which contains exclusive license rights in favor of Merck. If Merck decides not to pursue the collaboration, we will not receive the benefit of the milestone and royalty payments that we would otherwise potentially receive pursuant to our collaboration with Merck and accordingly may need to raise capital from other sources. 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 or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product

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development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

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### **Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates**

***We are early in our development efforts and all of our product candidates and research programs other than JANX007 and JANX008 are in the preclinical development or discovery stage. We have a very limited of conducting clinical trials to test our product candidates in humans.\****

We are early in our development efforts and most of our operations to date have been limited to developing our platform technologies and conducting drug discovery and preclinical studies. Other than JANX007 and JANX008, our platform technologies and product candidates remain in the preclinical or discovery stage and our product candidates are based on novel technologies. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our clinical trials will be completed on time, if at all, that our planned development programs would be acceptable to the FDA, the EMA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates could be successfully commercialized.

Because of the early stage of development of our products candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- completion of additional preclinical studies with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing with comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- successful enrollment in, and completion of, clinical trials and achieving positive results from the trials;
- demonstrating a risk-benefit profile acceptable to regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including biologics license applications (BLAs), from the FDA and equivalent approvals from comparable foreign regulatory authorities and maintaining such approvals;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities for clinical supply and, if and when approved, for commercial supply;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and
- maintaining a continued acceptable safety profile of any product following approval, if any.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our JANX007 JANX008, TROP2-TRACTr and TRACIr costimulatory bispecific candidates, JANX008, as well as our other product candidates, which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire; however, given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

**Preclinical and clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. JANX007, JANX008 and any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.\***

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Preclinical and clinical development is expensive and can take many years to complete, and their outcome is inherently uncertain. Failure or delay can occur at any time during the drug development process including due to factors outside of our control. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in conducting our current clinical trials and initiating our future clinical trials for our product candidates and we cannot be certain that the trials or any other future clinical trials for our product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure related to:

- the FDA, the EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials, or the sufficiency of preclinical data to initiate clinical trials;
- the size of the study population for further analysis of the study's primary endpoints;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval or ethics committee **positive** opinions;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- addressing patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Our product candidates may be used in combination with other cancer drugs, such as other immuno-oncology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agents such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

Of the large number of products in development, only a small percentage successfully complete the FDA, the European Commission's or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for our product candidates, the FDA, the European Commission or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA, the European Commission or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA, the European Commission or comparable foreign regulatory authorities may not approve the

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labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

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In addition, the FDA, the EMA and the European Commission or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

***Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.***

We have concentrated our research and development efforts on product candidates using our proprietary technology, and our future success depends on the successful development of this approach. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. As we have not tested any of our product candidates in humans, and our current data is limited to animal models and preclinical cell lines, the results of our preclinical studies may not translate into humans and may not accurately predict the safety and efficacy of our product candidates in humans. Our approach may be unsuccessful in identifying product candidates for our development programs. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our ongoing and planned clinical trials or commercializing any products on a timely or profitable basis, if at all. Further, because all of our product candidates and development programs are based on the same platform technologies, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

The clinical trial requirements of the FDA, EMA and other comparable foreign regulatory agencies and authorities, and the criteria regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

The immuno-oncology industry is also rapidly developing, and our competitors may introduce new technologies that render our technologies obsolete or less attractive, or limit the commercial value of our product candidates. New technology could emerge at any point in the development cycle of our product candidates. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

***If we experience delays in or difficulties enrolling our ongoing and planned clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.***

We may not be able to initiate or continue our ongoing and planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA, or comparable foreign regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is

affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;

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- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

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- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our ongoing and planned clinical trials may compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Further, because our ongoing and planned clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development***

***programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.***

As we continue developing and conducting clinical trials of our product candidates, serious adverse events (SAEs), undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Should we observe any SAEs in our ongoing or planned clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely, such as imposition of a clinical hold by the FDA or comparable actions of foreign regulatory authorities and institutional review boards and ethics committees. The class of TCEs has been associated with overactivation of the immune system leading to cytokine release syndrome (CRS) and on-target healthy tissue toxicities, and while we have designed our TRACTr and TRACIr platform technologies and product candidates to mitigate these safety risks, until such time as we complete large-scale human trials there can be no assurances that our product candidates will not experience similar effects.

Even if our product candidates initially show positive results in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) or equivalent foreign procedure to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, vary, withdraw, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

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- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;

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- we may be obliged to, need to, or decide to recall or remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

***Interim, topline and preliminary data from our preclinical studies or clinical trials may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies or clinical trials, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

***The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.\****

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally the FDA, and by foreign regulatory authorities, which regulations may differ from country to country. Neither we nor any current or future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA. Equivalent limitations are imposed by comparable foreign regulatory authorities within their territories.

Obtaining regulatory approval of a BLA, or in an equivalent foreign process, can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, the EMA and the European Commission, or other foreign regulatory **agencies, authorities**, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA, European Commission or comparable foreign regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are positive, such data may not be sufficient to support approval by the FDA, the European Commission or other comparable foreign regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA, the European Commission or other comparable foreign regulatory authorities denying approval of a product candidate for any or all indications. The FDA, the EMA, the European Commission or other comparable foreign regulatory authorities, may also require us to conduct additional studies or trials

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for our product candidates either prior to or post-approval, or may object to elements of our clinical development program such as the number of subjects in our clinical trials from the United States or abroad.

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The FDA, the EMA, the European Commission or other comparable foreign regulatory authorities can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a

program for many reasons, including:

- the FDA, the EMA or comparable foreign regulatory authorities' authorities' disagreement with the design or implementation of our ongoing or planned clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, the EMA, the European Commission or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individual using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA, the EMA and the European Commission or comparable foreign regulatory authorities that our product candidates are safe and effective for the proposed indication;
- the FDA's, the EMA's, EMA's, or comparable foreign regulatory authorities' authorities' disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, the EMA's, EMA's or a comparable foreign regulatory authorities' requirement for additional nonclinical studies or clinical trials;
- the FDA's, the EMA's, EMA's, the European Commission's or comparable foreign regulatory authorities' disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA's or comparable foreign regulatory authorities' failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, the European Commission or comparable foreign regulatory authorities' to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, the European Commission, or other regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing authorization application for our product candidates, the FDA, the European Commission, or the applicable foreign regulatory agency authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or in the case of the FDA, the implementation of a REMS, and in the case of comparable foreign regulatory authorities equivalent actions, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency authority also may approve a product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA, European Commission, or applicable foreign regulatory agency authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

***Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current cGMP regulations, as well as GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS and the European Commission, or comparable foreign regulatory authorities may require equivalent actions as a

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condition of approval of our product candidates, which could include requirements for a medication guide, physician communication

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plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

The FDA's, EMA's, European Commission, and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;

- mandating modifications to promotional materials or require us to provide corrective information to healthcare professionals, or require other restrictions on the labeling or marketing of such products;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension, modification or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us;
- refusal to permit the import or export of products; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

Moreover, the FDA and other regulatory authorities strictly regulate the promotional claims that may be made about biologic products. In particular, while physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, a product may not be promoted for uses that are not approved by the FDA, the European Commission or other comparable foreign regulatory authorities as reflected in the product's approved labeling. The FDA and other comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

***Disruptions at the FDA and other comparable foreign regulatory authorities and bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.\****

The ability of the FDA, EMA, European Commission, and other foreign regulatory authorities to review applications for approval and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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Disruptions at the FDA and other foreign regulatory authorities may also slow the time necessary for new biologics to be reviewed and/or approved by necessary foreign regulatory authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, the FDA and regulatory authorities outside the United States have and may adopt restrictions or other policy measures in response to public health crises that divert resources and delay their attention from any submissions we may make. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. 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 research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

### **Risks Related to Manufacturing, Commercialization and Reliance on Third Parties**

***We may rely on third parties to conduct, supervise, and monitor our ongoing and planned clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.\****

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our preclinical studies, ongoing clinical trials and any future clinical trials of our product candidates. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the European Economic Area, or EEA, countries, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical

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trials may be deemed unreliable, and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing authorization applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third

parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA, the EMA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing authorization application we submit by the FDA, the EMA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

***We contract with third parties for the manufacturing and supply of certain of our product candidates for use in preclinical testing and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.\****

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that the BDS for each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA, or equivalent

foreign application, on a timely basis and must adhere to the relevant Good Laboratory Practice regulations and cGMP regulations enforced by the FDA, and competent authorities of EEA countries, through their facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third-party contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would

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increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and timelines and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- an inability to initiate or continue preclinical studies or clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and

- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

***Manufacturing our product candidates is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.***

Manufacturing our product candidates is complex and requires the use of technologies directed to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or expiry. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency, significant lead times and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Due to the early nature of our product candidates, the drug product may not be stable over time causing changes to be made to the manufacturing, formulation or storage process, which may result in delays or stopping the development of the product candidate.

***Changes in methods of product candidate manufacturing may result in additional costs or delays.***

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize yield, manufacturing batch size, change drug product dosage form, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical

trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more

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clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

***Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue 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:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- 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 availability of coverage and adequate reimbursement from third-party payors, and the willingness of patient to pay out of pocket in the absence of coverage or limited third-party payor reimbursement;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

***We may not be able to successfully commercialize our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.\****

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA, the European Commission, or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for

in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. The approach to pricing and reimbursement also varies widely between third countries, including between EEA countries.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications

for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, in the US the Centers for Medicare & Medicaid Services (CMS) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

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 medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, including in some EEA countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In the EU, this Health Technology Assessment (HTA) process, which is currently governed by the national laws of the individual EU Member States, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. Moreover, EU Member States may choose to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit. If we are unable to

maintain favorable pricing and reimbursement status in EU Member States for our products, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In some other foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the Affordable Care Act) signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a

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biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Equivalent laws and procedures apply in foreign countries.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action, court decisions or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

**Relevant regulatory exclusivities may not be granted or, if granted, may be limited.**

The EU provides opportunities for data and market exclusivity related to Marketing Authorizations (MAs). Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess an application for authorization of a generic product or of a biosimilar for eight years from the date of authorization of the innovative product, after which an application for authorization of a generic or biosimilar may be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful applicant for authorization of a generic or biosimilar from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

***The market opportunity for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.\****

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of the number of people who have PSMA, EGFR or TROP2 other specific anti-tumor target expression are based on our assumptions and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients who may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet

conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

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***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable,

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material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.***

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product portfolios; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country

may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be

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obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

### **Risks Related to Our Collaborations and Other Strategic Agreements**

***Our existing collaboration with Merck is important to our business. If Merck ceases development efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

We have entered into collaboration with Merck to develop certain specified product candidates. All of our revenue to date has been derived from our existing collaboration agreement with Merck, and a significant portion of our near-term future revenue is expected to be derived from this agreement or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreement will be substantially less than expected.

We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Our collaborators may have other marketed products and product

candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not realize the benefits of any acquisitions, collaborations, in-license or strategic alliances that we enter into.\****

We have entered into a research collaboration and exclusive license agreement with Merck and in the future may seek and form strategic alliances, create joint ventures or additional collaborations, or enter into acquisitions or licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations

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and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we

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will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

***We may wish to form additional collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.***

We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

## Risks Related to Our Industry and Business Operations

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and foreign regulatory authorities, provide accurate information to the FDA and foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits

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stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional

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reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

***We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.***

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by

consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We may not be able to maintain product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims, or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

***We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.\****

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our

management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

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We conduct substantially all of our operations remotely and at our facilities in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. There also may be shortages of skilled labor due to public health crises, macroeconomic conditions, or other factors that may make it more difficult for us to attract and retain qualified personnel and lead to increased labor costs. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.\****

As of **June 30, 2023** **September 30, 2023**, we had **67** **64** employees. As we advance our research and development programs, we will be required to further increase the number of our employees and the scope of our operations, particularly in the areas of research and clinical development, medical affairs, general and administrative matters relating to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as monotherapy and in combination with other therapeutics; and

- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.***

The development and commercialization of new products is highly competitive. We largely compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA, European Commission, or other regulatory approval for their products more rapidly than we may obtain approval for ours, if ever, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. Moreover, with the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products that are similar to our product candidates have already been approved and other products in the same class are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory

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authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If

the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are

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not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies pursuing a variety of approaches to immuno-oncology treatments, including large pharmaceutical and biotechnology companies, such as AbbVie, Amgen, AstraZeneca/MedImmune, Bristol-Myers Squibb, Johnson & Johnson, Merck, Novartis, Pfizer and Roche/Genentech. Other companies using PSMA-targeting therapeutics for the treatment of cancer include Amgen, Aptevo, Calibr/Abbvie Crescendo Biologics, Harpoon Therapeutics, Lava Therapeutics, Poseida Therapeutics, Regeneron Pharmaceuticals, Sorrento Therapeutics, TeneoBio, Tmunity Therapeutic, Novartis and Bayer. We also face competition from biologic prodrug developers such as Akrevia Therapeutics, Sanofi, Bayer, BioAtla, Chugai Pharmaceutical, CytomX Therapeutics, Genentech, Harpoon Therapeutics, Maverick/Takeda, Nektar Therapeutics, Pandion Therapeutics, Revitope Oncology, Roche Holding and Seagen.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

### ***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under current law, U.S. federal net operating losses (NOLs) incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely to offset future taxable income, but the deductibility of such U.S. federal NOLs is limited to 80% of taxable income.

As of December 31, 2022, we had \$50.0 million \$49.6 million of U.S. federal NOLs and \$82.0 million \$80.1 million of state NOLs. Of the total federal NOLs, \$49.5 million \$49.1 million have an indefinite carryforward period. The remaining federal

and total state NOLs have a 20-year carryforward period, and will begin to expire in 2037 unless previously utilized. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation’s ability to use its pre-change NOL carryforwards and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs and other applicable tax attributes carried forward may further affect the limitation in future years. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

***Epidemic diseases could adversely impact our business, including our ongoing and planned clinical trials, supply chain and business development activities.\****

COVID-19 has caused, and a resurgence of COVID-19 or another A health epidemic or pandemic may cause, significant disruptions that could severely impact our business and clinical trials, including:

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- interruption or delays in our operations, which may impact our ability to conduct and produce preclinical results required for submission of an IND in the United States or equivalent marketing authorization applications in foreign jurisdictions;

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- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our ongoing and planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our ongoing and planned clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations which may require us to change the ways in which our ongoing and planned clinical

- trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA, the EMA or the European Commission, or other comparable foreign regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 or other an epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA, the EMA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

A resurgence of COVID-19 or another health epidemic or pandemic may also materially affect us economically. While the potential economic impact brought by, and the duration of, a resurgence of COVID-19 or other health crises may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position.

The extent to which a resurgence of COVID-19 a health epidemic or pandemic or other health crises may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence and may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

## Risks Related to Government Regulation

***Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers are subject, directly or indirectly, to U.S. federal and state, EU, or foreign jurisdictions' jurisdictions' healthcare fraud and abuse laws, transparency laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business

operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or

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the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity

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does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, a claim for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare

professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European Union and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, 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 and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

***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 charge for such product candidates.\****

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The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting 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 for which we obtain marketing approval.

In March 2010, the Affordable Care Act was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act 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 Affordable Care Act 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 Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is also unclear how any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year until 2032. 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.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, 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. HHS has 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. 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 costs pharmaceutical and biological products. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

In the European Union, many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies through HTA processes. The HTA process is currently governed by national laws in each EU Member State. In December 2021 the European Union Parliament adopted the HTA regulation which, when it enters into application in 2025, will be intended to harmonize the clinical benefit assessment of HTA across the European Union. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other

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countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU.

We expect that the healthcare reform measures that have been adopted, and that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other comparable 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.

***The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common stock.\****

Following the result of a referendum in 2016, the United Kingdom (UK) left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the European Union, the UK was subject to a transition period until December 31, 2020 (the Transition Period) during which European Union rules continued to apply. The UK and the European Union have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and European Union's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the European Union and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extend to procedures such as batch release certification. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Under the terms of the Northern Ireland Protocol, Northern Ireland will continue to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods. As part of the TCA, the European Union and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept European Union batch testing and batch release. However, the European Union continues to apply European Union laws that require batch testing and batch release to take place in the European Union territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the European Union market for commercial use. As it relates to marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities will be required to place medicinal products on the market in Great Britain. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework" which is intended to revise the Northern Ireland Protocol in order to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK-only

regulatory environment under the authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in various stages, with new arrangements relating to the supply of medicines into Northern Ireland anticipated to take effect in 2025.

Since a significant proportion of the regulatory framework in the UK applicable to medicinal products is derived from European Union Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the European Union, now that UK legislation has the potential to diverge from European Union legislation. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill which received Royal Assent on June 29, 2023 and is intended to remove all EU-derived legislation

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from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK. On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for

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clinical trials. The consultation closed on March 14, 2022. On October 12, 2023, the MHRA introduced a new Notification Scheme to enable a more streamlined and aims risk-proportionate approach to streamline the processing of initial clinical trial applications for Phase 3 and Phase 4 clinical trials. This new scheme forms part of the review of the regulatory framework governing clinical trials approvals, enable innovation, enhance in the UK. Further initiatives adopted by the UK Government with respect to the regulation of clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The following outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the European Union and restrict our ability to generate revenue and achieve and sustain

profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the European Union for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with current or future federal, state and foreign laws, regulations, contracts, self-regulatory schemes, industry standards and other obligations relating to privacy and security could lead to regulatory investigations or actions (which could include civil or criminal fines and penalties), private litigation (including class claims) and mass arbitration demands, adverse publicity, disruptions of our business operations and other adverse business consequences.\****

In the ordinary course of business, we process personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including health information privacy laws, data breach notification laws, personal information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations. HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act (CCPA) of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA), (collectively, CCPA), applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and affording honor request of California residents to exercise certain privacy rights with respect to their personal information, such as those noted below. The CCPA provides for civil penalties for violations (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 increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the California Privacy Rights Act of 2020 (CPRA) expanded the CCPA's requirements, including by adding a new right for individuals

to correct their personal information and establishing a new California Privacy Protection Agency (CPPA) to implement and enforce the **CPRA**, **law**, which could result in increased enforcement. Other states have also enacted data privacy laws. For example, Virginia, Colorado, Utah, and Connecticut, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These state laws and the CCPA provide individuals with certain rights concerning their personal information, including the right to access, correct, or delete certain personal information, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. While these states, like the CCPA, exempt some data processed in the context of clinical trials, these laws further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, under various privacy laws and other obligations, we

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may be required to obtain certain consents to process personal information. Our inability or failure to do so could result in material adverse consequences, including interrupting our clinical trial activities. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In

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the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies, state attorneys general, legislatures and consumer protection agencies.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) and Australia's Privacy Act impose strict requirements for processing personal data and violators of these laws face significant penalties. For example, under the EU GDPR and UK GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros (£17.5 million for the UK GDPR) or 4% of annual global revenue, whichever is greater. Further, the EU GDPR provides for private litigation related to the processing of personal information, which can be brought by classes of data subjects or consumer protection organizations authorized by law to represent the interests of such classes. Similarly, consumer associations may bring proceedings to defend collective interests of data subjects under the EU GDPR, independently of the absence of a mandate to that effect.

We are bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require us to impose specific contractual restrictions on our service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. We also publish privacy policies, marketing materials and other statements

regarding data privacy and security. If these policies, materials 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. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards with which we are legally or contractually bound to comply, or may become subject to in the future. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Our obligations related to data privacy and security (and consumers' data privacy expectations) 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, which may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information 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.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including private lawsuits and class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through imposition of significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices. 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 information or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or revisioning or restructuring of our operations.

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 operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or revisioning or restructuring of our

operations. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information.

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***In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.\****

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. In particular, the EEA and the 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 (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 personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

## Risks Related to Our Intellectual Property

***If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and***

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***commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.\****

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, product candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that any

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claims that issue from our patent applications will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does

not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. No earlier than October 1, 2022, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). This will be 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.

**Geo-political** **Geopolitical** 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 the military conflict in Ukraine** and **Russia** 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. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly 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.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses,

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and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly

uncertain. 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 were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, or *inter partes* review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity 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. In addition, 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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product.

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Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may

encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

***We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.***

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. Patent Cooperation Treaty, and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and

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content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize

our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or may exclusively license;
- we or licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;

- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

### ***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

### ***We are currently party to an in-license agreement under which we were granted rights to manufacture certain components of our product candidates. If we breach our obligations under this and future license agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.\****

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including payment obligations for achievement of certain milestones on product sales. For example, we have licensed a cell line to manufacture these products under an agreement with WuXi Biologics. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to

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terminate the license. If our license agreements are terminated, we may experience significant delays, difficulties, and costs in developing new cell lines and identifying an alternative source to manufacture components of our candidate products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

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 or prospects.

In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing intellectual property involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of licensed intellectual property by us alone or with our licensors and partners;
- the right to control prosecution, maintenance, enforcement, and defense of the licensed patents and improvements thereof;
- the scope and duration of our payment obligations; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described herein. If we or our licensor fail to adequately protect this intellectual property, our ability to develop, manufacture, or commercialize products could suffer.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

***In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.***

We currently own intellectual property directed to our product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary.

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These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

Moreover, some of our owned patent applications and patents may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned patents may be subject to a reservation of rights by one or more third parties. Any of the

foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. We cannot be certain that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We are currently aware of a third-party European patent that may cover our products. However, we do not plan to launch any product in the European Union before the expiration of such patent. Third parties may assert infringement claims against us based on existing or future intellectual property rights. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the

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presumption of validity enjoyed by issued patents. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing candidate product or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing candidate product or product. 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. 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 investigational products or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do

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this. Proving invalidity may be difficult and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. 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 during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. 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. 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, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. 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 become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors or other third parties may infringe our patents, trademarks 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 and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties

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practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the

invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 during litigation. There could also be public announcements of the results of hearings, motions or other

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interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our preclinical studies, initiate and continue clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

As is common in the pharmaceutical industry, in addition to our employees, in the future we may engage the services of consultants to assist us in the development of our product candidates. Many of these potential consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary

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damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.\****

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents that issue in the future. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the

prosecution of our patent applications and the enforcement or defense of our issued patents. 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, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide

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evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Thus, 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, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. 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, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain

situations. We cannot predict how decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the Supreme Court of the United States held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obvious-type double patenting. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or that we may license in the future, if any, licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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.***

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Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

***We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our

employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or

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misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

***We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome

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could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date excluding U.S. provisional patent applications. Given the amount of time

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required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (PTE) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it

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may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

## **Risks Related to the Securities Market and Ownership of Our Common Stock**

***An active trading market for our common stock may not continue to be developed or be sustained, which may make it more difficult for you to sell your shares.***

Prior to our IPO in June 2021, there had been no public market for our common stock. The trading market for our common stock on the Nasdaq Global Market has been limited and an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at a price that is attractive to you, or at all.

***The price of our common stock could be subject to volatility related or unrelated to our operations.\****

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Our stock price may be volatile. The stock market in general and the market for biotechnology and pharmaceutical companies, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares at a price that is attractive to you, or at all. The market price for our common stock may be influenced by numerous factors, many of which are beyond our control, including:

- adverse results or delays in preclinical studies or clinical trials;
- results from our future clinical trials with our future product candidates or of our competitors;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- developments with respect to our intellectual property rights;
- overall performance of the equity markets;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the published opinions and third-party valuations by banking and market analysts;
- political uncertainty and/or instability in the United States;
- the future impact of a resurgence of COVID-19 or other health epidemic or pandemic; and
- any other factors discussed in this Quarterly Report.

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In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As a result of their share ownership, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our

organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

***If there are substantial sales of shares of our common stock, the market price of our common stock could decline.\****

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of **June 30, 2023** **September 30, 2023**, we had **41,891,226** **46,168,430** outstanding shares of common stock.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

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Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. 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, investors may be materially diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2021 Equity Incentive Plan (2021 Plan), we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under our 2021 Plan automatically increases on January 1 of each calendar year, through January 1, 2031, in an amount equal to the lesser of (i) 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase; or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1st. In addition, pursuant to our 2021 Employee Stock Purchase Plan, the number of shares of our common stock reserved for issuance automatically increases on January 1 of each calendar year, through January 1, 2031, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, and (ii) 932,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;

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- the ability of our board of directors to issue shares of preferred stock and to determine the price and other term of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from

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with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

***Our amended and restated certificate of incorporation and our amended and restated bylaws 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 and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. 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. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws provide that the federal district courts of the United States of America will be the exclusive forum for

resolving any complaint asserting a cause of action arising under the Securities Act, including any complaint against the underwriters of any offering giving rise to such claim. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the

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exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

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 and may discourage these types of lawsuits and result in increased costs for investors to bring a claim. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

## **General Risk Factors**

***We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to public company reporting and compliance initiatives.***

As a public company listed on the Nasdaq Global Market, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation

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related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from

certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The increased costs decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.\****

As a public company, we are subject to requirements of the Sarbanes-Oxley Act, the regulations of the Nasdaq Global Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources. Company responsibilities required by the Sarbanes-Oxley Act include, among other things, that we maintain corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to develop, maintain, and improve the effectiveness of our internal controls and procedures, and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

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Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be

discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Market. We are not currently required to make a formal assessment of the effectiveness of our internal control over financial reporting under the SEC rules that implement Section 404 of the Sarbanes-Oxley Act. We are also required to provide an annual management report on the effectiveness of our disclosure controls and procedures over financial reporting.

If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our common stock.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and

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forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements."

***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 adversely affect our business operations 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 (Tax Act), the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the U.S. tax laws. Effective January 1, 2022, the Tax 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. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue

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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.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.\****

As a result of disruptions and changes in the macro environment, including those resulting from COVID-19 and actions taken to slow its spread, bank failures, and geo-political geopolitical actions such as the United States and foreign government actions related to Russia's invasion of the military conflict in Ukraine and Russia and the war in the Middle

East, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms or failure to access to our liquidity within the U.S. banking system could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

***Inflation may adversely affect us by increasing our costs.***

Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, administration and other costs of doing business. We may experience

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increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

***If our internal information technology systems or sensitive information, or those of our third-party CROs or other contractors or consultants, are or were compromised, we could experience adverse consequences from such compromise, including but not limited to, a material disruption of our product candidates' development programs, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, and other adverse consequences.\****

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we process proprietary, confidential, and sensitive information, including personal information (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such sensitive information.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including, but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and 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), stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, earthquakes, fires, floods, and other similar threats. Severe ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent 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. Future or past business transactions (such as acquisitions or integrations)

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

We rely on third-party service providers and technologies to operate critical business systems and have outsourced elements of our operations to third parties in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or

security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or 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 or disruption to our information technology systems or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business operations. For example, a security incident could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of preclinical study data or clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable

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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 take steps to detect and remediate vulnerabilities, but we may not be able in the future to detect and remediate all vulnerabilities in our information technology systems because such threats and techniques change frequently and are often sophisticated in nature. Therefore, such vulnerabilities may not be detected until after a security incident has occurred. **Unremedied high risk or critical vulnerabilities post material risk to our business.** 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, including individuals and data protection authorities. 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, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); 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 interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates

could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

***We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters and main research facility are located in the county of San Diego, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are

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operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws) prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-

U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

We, and the third parties with whom we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and

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biological materials. Each of 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous 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 research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Patent protection is available on a national or regional level. Filing, prosecuting and defending patents throughout the world and on all of our product candidates would be prohibitively expensive. As such, our intellectual property rights outside the United States may not extend to all other possible countries outside the United States and we may not be able to prevent third parties from practicing our inventions in countries outside the United States where we do not have patent protection, or from selling in and importing products into other jurisdictions made using our inventions in such countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These

products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Further, the legal systems of certain countries particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any such lawsuits that we initiate and the damages and other remedies awarded, if any, may not be commercially meaningful.

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Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. We plan to enter into contract research and manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties at nominal or no consideration. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. 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.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

***We could be subject to securities class action litigation.***

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 pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.***

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder

approval of any golden parachute payments not previously approved.

In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth

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company. We will remain an emerging growth company until the earlier of (i) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our IPO), (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the date upon which we are deemed to be a “large accelerated filer”, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company, which would allow us to take advantage of many of the same exemptions available to emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On June 10, 2021, the SEC declared effective our registration statement on Form S-1 (File No. 333-256297), as amended, filed in connection with our initial public offering (IPO). At the closing of the offering on June 15, 2021, we issued and sold 13,110,000 shares of our common stock at the IPO price to the public of \$17.00 per share, which included the

exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of \$222.9 million, before deducting underwriting discounts and commissions of approximately \$15.6 million and offering costs of approximately \$3.1 million. BofA, Cowen and Company, LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering. H.C. Wainwright & Co., LLC acted as lead manager for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

Upon receipt, the net proceeds from our IPO were held in cash and cash equivalents, primarily in money market funds invested in U.S. government agency securities. As of June 30, 2023 September 30, 2023, we have not used any of the proceeds from our IPO and there has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on June 11, 2021. Pursuant to our investment policy we have invested these funds in high-quality marketable security types with contractual maturity dates of less than two years until needed to fund our operations.

## **Item 5. Other Information.**

During the three months ended June 30, 2023 September 30, 2023, no director or officer adopted or terminated any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement (as such terms are defined pursuant to Item 408(a) of Regulation S-K).

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## **Item 6. Exhibits.**

Exhibit Number	Description
3.1	<a href="#">Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed June 15, 2021).</a>
3.2	<a href="#">Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed June 15, 2021).</a>
4.1	<a href="#">Reference is made to Exhibit 3.1 and Exhibit 3.2.</a>
4.2	<a href="#">Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed June 7, 2021).</a>
4.3	<a href="#">Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated April 15, 2021, as amended (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, filed June 7, 2021).</a>

10.1 4.4	<a href="#">ATM Equity Offerings™ Sales Agreement, dated May 9, 2023, by and between the Registrant and BofA Securities, Inc. Form of Pre-Funded Warrant (incorporated by reference to Exhibit 1.1 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 9, 2023 [July 18, 2023]),</a>
10.1	<a href="#">Underwriting Agreement, between the Company and BofA Securities, Inc., dated as of July 17, 2023 (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 18, 2023).</a>
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1#	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

# The information in Exhibit 32.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

### JANUX THERAPEUTICS, INC.

Date: August 8, 2023 November 7, 2023

By: \_\_\_\_\_ /s/ David Campbell, Ph.D.

David Campbell, Ph.D.

President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 8, 2023 November 7, 2023

By: \_\_\_\_\_ /s/ Tighe Reardon  
Tighe Reardon  
Acting Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Campbell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Janux Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, 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 all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting for the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023 November 7, 2023

By: \_\_\_\_\_ /s/ David Campbell, Ph.D.

David Campbell, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

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**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Tighe Reardon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Janux Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and

procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: **August 8, 2023** November 7, 2023

By: \_\_\_\_\_ /s/ Tighe Reardon  
Tighe Reardon  
Acting Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of Janux Therapeutics Inc. (the "Company") for the period ending **June 30, 2023** **September 30, 2023** as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, that to 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.

Date: **August 8, 2023** **November 7, 2023**

By: **/s/ David Campbell, Ph.D.**

**David Campbell, Ph.D.**

**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: **August 8, 2023** **November 7, 2023**

By: **/s/ Tighe Reardon**

**Tighe Reardon**

**Acting Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

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