

REFINITIV

DELTA REPORT

10-Q

XILIO THERAPEUTICS, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	7269

 CHANGES	196

 DELETIONS	1042

 ADDITIONS	6031

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2023** **March 31, 2024**
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: 001-40925

Xilio Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

85-1623397
(I.R.S. Employer
Identification Number)

828 Winter Street, Suite 300
Waltham, Massachusetts
(Address of principal executive offices)

02451
(Zip Code)

Registrant's telephone number, including area code: (857) 524-2466

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	XLO	Nasdaq Global Select Market

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

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

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

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

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

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

Number of shares of the registrant's common stock, \$0.0001 par value per share, outstanding on November 7, 2023 May 10, 2024:
27,542,000 36,912,373

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References to Xilio

Unless otherwise stated, all references to "us," "our," "we," "Xilio," "Xilio Therapeutics," "the Company" and similar references in this Quarterly Report on Form 10-Q refer to Xilio Therapeutics, Inc. and its consolidated subsidiaries. Xilio Therapeutics and its associated logos are registered trademarks of Xilio Therapeutics, Inc. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to secure sufficient additional capital in the near term or implement other strategies needed to alleviate our current doubt about our ability to continue as a going concern;
- our estimates regarding expenses, future revenue and capital requirements and our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and cash equivalents;
- the initiation, timing, progress and results of our research and development programs, and including preclinical studies and clinical trials;
- the potential advantages and benefits of our current and future product candidates, including our beliefs regarding the potential benefits of our current and future product candidates in combination with other agents;
- our strategic plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- the timing of and our ability to submit applications for, and obtain and, if approved, maintain regulatory approvals for our product candidates;
- the potential advantages and benefits of our current and future product candidates;
- the rate and degree of market acceptance of our product candidates, if approved;
- our estimates regarding the addressable patient population and potential market opportunity for our current and future product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our current or future competitors and any competing therapies that are or become available;
- developments relating to our competitors and our industry;

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- developments relating to our competitors and our industry;
- our ability to establish and maintain collaborations; collaborations and strategic partnerships and realize the expected benefits of such arrangements, including our partnership with Gilead Sciences, Inc., or Gilead, and our clinical collaboration with F. Hoffmann-La Roche Ltd;
- our expectations regarding milestones, equity investments and other contingent payments under our partnership with Gilead;
- our estimates regarding anticipated future cost savings associated with our strategic portfolio reprioritization and workforce reduction announced in March 2024;
- our expectations regarding the anticipated use of the proceeds from the private placement of our common stock and prefunded warrants that closed in April 2024;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- the impact of general economic conditions, including inflation; and
- the impact of public health crises, including epidemics and pandemics such as the COVID-19 pandemic, on our business, operations, strategy, goals and anticipated milestones, as well as our response to such epidemics or pandemics, inflation.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly those described in the “Risk Factor Summary” and “Risk Factors” section in Part II, Item 1A of this Quarterly Report on Form 10-Q, that could cause actual results or events to differ materially from the forward-looking statements that we make. Given these uncertainties, you should not place undue reliance on any these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Risk Factor Summary

Our business is subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations and future growth prospects. These risks are discussed more fully in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- Our recurring losses from operations and the early development stage of our lead product candidates raise substantial doubt regarding our ability to continue as a going concern. If we are unable to raise sufficient additional capital in the near term, we will may in the future need to implement additional cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs.
- Our business is highly dependent on the success of our current product candidates, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and commercially launch a product.
- Our approach to the discovery and development of product candidates based on our technological approaches is unproven, and we do not know whether we will be able to develop any products of commercial value.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

- Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time 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.

- We expect to develop certain of our product candidates in combination with third-party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such **third-party** drugs.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.
- We face risk related to our reliance on our current and any future third-party contract **manufacturers, development and manufacturing organizations, or CMOs, CDMOs**. For example, the **CMOs CDMO** on which we rely may not continue to meet regulatory requirements, may have limited capacity **or** **and** may experience interruptions in supply, any of which could adversely affect our development and commercialization plans for our product candidates.
- We expect to rely on third parties to conduct, supervise and monitor IND-enabling studies and clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations.
- **We have entered into, and may in the future seek to enter into, collaborations, licenses, or similar arrangements with third parties for the research, development and commercialization of certain of our current or future product candidates. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates.**

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- **Certain of our research and development and manufacturing activities take place in China through a third-party CDMO. A significant disruption in our ability to rely on this CDMO could materially adversely affect our business, financial condition and results of operations.**
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we are unable to obtain and maintain patent protection for any product candidates we develop or for other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.
- We rely on in-license agreements for patent rights with respect to our product candidates and may in the future acquire or in-license additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses or that we may be unable to acquire or in-license third-party intellectual property that may be necessary or important to our business operations.

- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.
- The price of our common stock has been and, in the future, could be subject to volatility related or unrelated to our operations, and purchasers of our common stock could suffer a decline in value.

Availability of Other Information About Xilio Therapeutics, Inc.

Investors and others should note that Xilio Therapeutics communicates we communicate with its our investors and the public using its our company website (www.xiliotx.com), including but not limited to investor presentations and scientific presentations, filings with the U.S. Securities and Exchange Commission, press releases, public conference calls and webcasts. You can also connect with Xilio Therapeutics us on Twitter X (@xiliotx) or LinkedIn. The information that Xilio Therapeutics posts we post on these channels and websites could be deemed to be material information. As a result, Xilio Therapeutics encourages we encourage investors, the media and others interested in Xilio Therapeutics our company to review the information that it posts we post on these channels, including Xilio Therapeutics' our investor relations website, on a regular basis. This list of channels may be updated from time to time on Xilio Therapeutics' our investor relations website (ir.xiliotx.com) and may include other social media channels than the ones described above. The contents of Xilio Therapeutics' our website or these channels, or any other website that may be accessed from its our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

XILIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets (In thousands, except share and per share data) (Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 59,772	\$ 120,385
Prepaid expenses and other current assets	4,708	4,111
Total current assets	64,480	124,496
Restricted cash	1,580	1,562
Property and equipment, net	6,366	7,255

Operating lease right-of-use asset	5,247	5,585
Other non-current assets	169	267
Total assets	<u>\$ 77,842</u>	<u>\$ 139,165</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,486	\$ 3,125
Accrued expenses	9,404	10,327
Operating lease liability, current portion	1,014	918
Note payable, current portion	4,957	6,667
Other current liabilities	68	82
Total current liabilities	<u>16,929</u>	<u>21,119</u>
Note payable, net of current portion	—	3,165
Operating lease liability, net of current portion	8,415	9,189
Other non-current liabilities	—	45
Total liabilities	<u>25,344</u>	<u>33,518</u>
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 27,542,000 shares issued and 27,528,926 shares outstanding at September 30, 2023; 27,471,607 shares issued and 27,425,447 shares outstanding at December 31, 2022	3	3
Additional paid-in capital	360,352	354,752
Accumulated deficit	(307,857)	(249,108)
Total stockholders' equity	<u>52,498</u>	<u>105,647</u>
Total liabilities and stockholders' equity	<u>\$ 77,842</u>	<u>\$ 139,165</u>
	March 31,	December 31,
	2024	2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 33,980	\$ 44,704
License agreement receivable	30,000	—
Prepaid expenses and other current assets	<u>5,205</u>	<u>3,423</u>
Total current assets	<u>69,185</u>	<u>48,127</u>
Restricted cash	2,763	1,587
Property and equipment, net	5,542	5,942
Operating lease right-of-use asset	4,998	5,125
Other non-current assets	<u>121</u>	<u>145</u>
Total assets	<u>\$ 82,609</u>	<u>\$ 60,926</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 746	\$ 1,050

Accrued expenses	8,002	10,497
Deferred revenue	21,725	—
Operating lease liability, current portion	1,081	1,047
Note payable, current portion	—	3,315
Other current liabilities	28	48
Total current liabilities	31,582	15,957
Deferred revenue, net of current portion	17,399	—
Operating lease liability, net of current portion	7,863	8,142
Total liabilities	56,844	24,099
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 34,473,486 shares issued and 34,472,646 shares outstanding at March 31, 2024; 27,613,263 shares issued and 27,607,646 shares outstanding at December 31, 2023	3	3
Additional paid-in capital	368,477	362,336
Accumulated deficit	(342,715)	(325,512)
Total stockholders' equity	25,765	36,827
Total liabilities and stockholders' equity	\$ 82,609	\$ 60,926

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

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XILIO THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Operating expenses						

Research and development	\$ 11,051	\$ 13,038	\$ 40,400	\$ 44,204	\$ 10,400	\$ 16,131
General and administrative	6,310	7,168	20,603	21,778	6,139	7,395
Restructuring					948	—
Total operating expenses	17,361	20,206	61,003	65,982	17,487	23,526
Loss from operations	(17,361)	(20,206)	(61,003)	(65,982)	(17,487)	(23,526)
Other income, net						
Other income, net	613	416	2,254	226	284	880
Total other income, net	613	416	2,254	226	284	880
Net loss and comprehensive loss	<u>\$ (16,748)</u>	<u>\$ (19,790)</u>	<u>\$ (58,749)</u>	<u>\$ (65,756)</u>	<u>\$ (17,203)</u>	<u>\$ (22,646)</u>
Net loss per share, basic and diluted	<u>\$ (0.61)</u>	<u>(0.72)</u>	<u>\$ (2.14)</u>	<u>\$ (2.40)</u>	<u>\$ (0.62)</u>	<u>\$ (0.83)</u>
Weighted average common shares outstanding, basic and diluted	<u>27,523,821</u>	<u>27,399,906</u>	<u>27,475,579</u>	<u>27,384,085</u>	<u>27,912,584</u>	<u>27,433,252</u>

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

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XILIO THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity (In thousands, except share data) (Unaudited)

Total				Total			
Common Stock	Additional	Accumulated	Stockholders'	Common Stock	Additional	Accumulated	Stockholder

	Shares	Amount	Paid-In Capital	Deficit	Equity	Shares	Amount	Paid-In Capital	Deficit	Equity
Balance at										
December										
31, 2022	27,425,447	\$ 3	\$ 354,752	\$ (249,108)	\$ 105,647					
Balance at										
December										
31, 2023	27,607,646	\$ 3	\$ 362,336	\$ (325,512)	\$ 36,827					
Issuance of common stock in connection with the Gilead stock purchase agreement, net of issuance costs						6,860,223	—	4,308	—	4,308
Vesting of restricted common stock	14,217	—	—	—	—	4,777	—	—	—	—
Exercise of stock options	156	—	—	—	—					
Stock-based compensation expense	—	—	1,791	—	1,791	—	—	1,833	—	1,833
Net loss	—	—	—	(22,646)	(22,646)	—	—	—	(17,203)	(17,203)
Balance at										
March 31, 2023	27,439,820	\$ 3	\$ 356,543	\$ (271,754)	\$ 84,792					
Issuance of common stock under employee stock purchase plan	68,929	—	140	—	140					
Vesting of restricted common stock	9,978	—	—	—	—					
Exercise of stock options	168	—	—	—	—					

Stock-based compensation expense	—	—	1,800	—	1,800
Net loss	—	—	—	(19,355)	(19,355)
Balance at June 30, 2023	27,518,895	\$ 3	\$ 358,483	\$ (291,109)	\$ 67,377
Vesting of restricted common stock	7,598	—	—	—	—
Exercise of stock options	2,433	—	8	—	8
Stock-based compensation expense	—	—	1,861	—	1,861
Net loss	—	—	—	(16,748)	(16,748)
Balance at September 30, 2023	27,528,926	\$ 3	\$ 360,352	\$ (307,857)	\$ 52,498
Balance at March 31, 2024					
				34,472,646	\$ 3 \$ 368,477 \$ (342,715) \$ 25,765

	Total					Total				
	Common Stock		Additional	Accumulated	Stockholders'	Common Stock		Additional	Accumulated	Stockholder
	Shares	Amount	Paid-In Capital	Deficit	Equity	Shares	Amount	Paid-In Capital	Deficit	Equity
Balance at December 31, 2021	27,358,375	\$ 3	\$ 346,312	\$ (160,886)	\$ 185,429					
Balance at December 31, 2022						27,425,447	\$ 3	\$ 354,752	\$ (249,108)	\$ 105,641
Vesting of restricted common stock	15,441	—	—	—	—	14,217	—	—	—	—
Exercise of stock options	2,657	—	16	—	16	156	—	—	—	—
Stock-based compensation expense	—	—	2,029	—	2,029	—	—	1,791	—	1,791
Net loss	—	—	—	(21,353)	(21,353)	—	—	—	(22,646)	(22,646)

Balance at						
March 31,						
2022	27,376,473	\$ 3	\$ 348,357	\$ (182,239)	\$ 166,121	
Vesting of						
restricted						
common						
stock	15,361	—	—	—	—	
Stock-based						
compensation						
expense	—	—	2,709	—	2,709	
Net loss	—	—	—	(24,613)	(24,613)	
Balance at						
June 30,						
2022	27,391,834	\$ 3	\$ 351,066	\$ (206,852)	\$ 144,217	
Vesting of						
restricted						
common						
stock	15,315	—	—	—	—	
Stock-based						
compensation						
expense	—	—	1,871	—	1,871	
Net loss	—	—	—	(19,790)	(19,790)	
Balance at						
September						
30, 2022	27,407,149	\$ 3	\$ 352,937	\$ (226,642)	\$ 126,298	
Balance at						
March 31,						
2023						
	27,439,820	\$ 3	\$ 356,543	\$ (271,754)	\$ 84,790	

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

XILIO THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows (In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (58,749)	\$ (65,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,451	1,358
Non-cash interest expense	141	164
Stock-based compensation expense	5,452	6,609
Loss on disposal of property and equipment	3	1
Changes in operating assets and liabilities:		
Prepaid and other assets	(597)	1,283
Operating lease right-of-use asset	338	288
Accounts payable	(1,625)	(972)
Accrued expenses and other liabilities	(928)	116
Operating lease liability	(679)	(591)
Net cash used in operating activities	(55,193)	(57,500)
Cash flows from investing activities:		
Purchases of property and equipment	(486)	(1,358)
Net cash used in investing activities	(486)	(1,358)
Cash flows from financing activities:		
Repayments of debt principal	(5,000)	—
Payments of finance lease	(64)	(64)
Proceeds from issuance of common stock under employee stock purchase plan	140	—
Proceeds from exercise of stock options	8	16
Net cash used in financing activities	(4,916)	(48)
Decrease in cash, cash equivalents and restricted cash	(60,595)	(58,906)
Cash, cash equivalents and restricted cash, beginning of period	121,947	199,606
Cash, cash equivalents and restricted cash, end of period	\$ 61,352	\$ 140,700
Supplemental cash flow disclosure:		
Cash paid for interest	\$ 474	\$ 380
Supplemental disclosure of non-cash activities:		
Capital expenditures included in accounts payable or accrued expenses	\$ —	\$ 371
Reconciliation to amounts within the condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 59,772	\$ 139,143
Restricted cash	1,580	1,557
Cash, cash equivalents and restricted cash, end of period	\$ 61,352	\$ 140,700
	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (17,203)	\$ (22,646)

Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	443	499
Non-cash interest (income) expense	(1)	31
Stock-based compensation expense	1,833	1,791
Changes in operating assets and liabilities:		
License agreement receivable	(30,000)	—
Prepaid and other assets	(1,782)	406
Operating lease right-of-use asset	127	108
Accounts payable	(304)	(1,358)
Accrued expenses and other liabilities	(2,495)	(3,868)
Deferred revenue	39,124	—
Operating lease liability	(244)	(213)
Net cash used in operating activities	(10,502)	(25,250)
Cash flows from investing activities:		
Purchases of property and equipment	—	(170)
Net cash used in investing activities	—	(170)
Cash flows from financing activities:		
Repayments of debt principal	(3,333)	(1,667)
Payments of finance lease	(21)	(21)
Proceeds from issuance of common stock under the Gilead stock purchase agreement, net of issuance costs	4,308	—
Net cash provided by (used in) financing activities	954	(1,688)
Decrease in cash, cash equivalents and restricted cash	(9,548)	(27,108)
Cash, cash equivalents and restricted cash, beginning of period	46,291	121,947
Cash, cash equivalents and restricted cash, end of period	\$ 36,743	\$ 94,839
Supplemental cash flow disclosure:		
Cash paid for interest	\$ 62	\$ 209
Supplemental disclosure of non-cash activities:		
Capital expenditures included in accounts payable or accrued expenses	\$ 21	\$ 310
Reconciliation to amounts within the consolidated balance sheets:		
Cash and cash equivalents	\$ 33,980	\$ 93,271
Restricted cash	2,763	1,568
Cash, cash equivalents and restricted cash, end of period	\$ 36,743	\$ 94,839

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

XILIO THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements (Dollars in thousands, unless otherwise stated) (Unaudited)

1. Description of Business, and Liquidity and Going Concern

Description of Business

Xilio Therapeutics, Inc. ("Xilio" or the "Company") is a clinical-stage biotechnology company dedicated to discovering and developing tumor-activated immuno-oncology ("I-O") therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. The Company was incorporated in Delaware in June 2020, and its headquarters are located in Waltham, Massachusetts.

Liquidity and Going Concern

Since its inception, the Company has devoted substantially all of its financial resources and efforts to research and development activities. As of September 30, 2023 March 31, 2024, the Company had an accumulated deficit of \$307.9 million \$342.7 million and has incurred significant operating losses, including net losses of \$58.7 million \$17.2 million and \$65.8 million \$22.6 million for the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. The Company expects its operating losses and negative operating cash flows to continue for the foreseeable future as it continues to advance its product candidates through clinical trials, maintains the infrastructure necessary to support these activities and continues to incur costs associated with operating as a public company. The As of March 31, 2024, the Company had cash and cash equivalents of \$34.0 million. Based on its current operating plans, the Company anticipates that its existing cash and cash equivalents of \$59.8 million as of September 30, 2023 March 31, 2024, together with the \$30.0 million upfront payment received in April 2024 under the exclusive license agreement with Gilead Sciences, Inc. ("Gilead") and approximately \$14.6 million in aggregate gross proceeds received in April 2024 from private placements with certain existing investors and Gilead, will be sufficient to fund the Company's operating expenses and capital expenditure requirements into the second quarter of 2025. However, the Company has based this estimate on assumptions that may prove to be wrong, and the Company could exhaust its available capital resources sooner than it anticipates. In addition, since these amounts may not be sufficient to enable the Company to fund its current operating plan and capital expenditure requirements operations for at least twelve months from the date of issuance of these the condensed consolidated financial statements. These factors raise statements, there is substantial doubt about the Company's ability to continue as a going concern.

To continue to fund the operations of the Company, management has developed plans, which in the near term primarily consist of raising additional capital through one or more of the following: additional equity or debt financings; additional collaborations, partnerships or licensing transactions; or other sources. However, there can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise, and the Company may be unable to obtain sufficient additional capital. If the Company is not able to secure sufficient additional capital in the near term, the Company will may in the future need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external

costs related to its operations and research and development programs. In addition, if the Company's efforts to secure sufficient additional capital in the near term are unsuccessful, the Company may in the future need to seek to engage in one or more other strategic alternatives, including without limitation, the sale or divestiture of some or all of its assets or proprietary technologies.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been

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condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2022 December 31, 2023 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 2, 2023 April 1, 2024. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the

unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to present fairly the Company's financial position as of September 30, 2023 March 31, 2024 and the results of its operations for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 and cash flows for the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2023 March 31, 2024 are not necessarily indicative of the results for the year ending December 31, 2023 December 31, 2024 or for any future period.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Xilio Development, Inc., a Delaware corporation and Xilio Securities Corporation, a Massachusetts security corporation. All intercompany accounts and transactions have been eliminated in consolidation.

Significant Accounting Policies

The significant accounting policies used in preparation of the unaudited condensed consolidated financial statements are described in Note 2, "Summary of Significant Accounting Policies" of the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023. There Except as described below, there have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, except as noted below. December 31, 2023.

Collaboration Agreements Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of expenses during the reporting period. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Factors that may affect estimates include expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Significant estimates of accounting reflected in these consolidated financial statements include, but are not limited to, estimates related to revenue recognition, accrued expenses, the valuation of stock-based compensation, including stock options and restricted common stock, useful life of long-lived assets and income taxes. Actual results could differ from those estimates.

Revenue Recognition

The Company analyzes its collaboration agreements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). The Company has entered into, and may in the activities future enter into, collaboration and exposed to significant risks and rewards dependent on the commercial

success of such activities and therefore licensing agreements that are within the scope of ASC Topic 808, 606, under which the Company has granted licenses to certain of the Company's product

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candidates and performs research, development and other services in connection with such arrangements. The terms of these arrangements may include payment of one or more of the following: non-refundable upfront fees; reimbursement of research and development costs; development, regulatory and sales-based milestone payments; and royalties on annual net sales of licensed products.

Under ASC 808”). For 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 808 that contain multiple elements, 606, the Company first determines which elements performs the following five steps: (i) identification of the collaboration contract with the customer; (ii) determination of whether the promised goods or services are deemed to be within performance obligations, including whether they are distinct in the scope of ASC 808 and which elements context of the collaboration are more reflective contract; (iii) measurement of a vendor-customer relationship the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and therefore within the scope (v) recognition of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. For collaboration agreements where revenue when (or as) the Company is reimbursed satisfies each performance obligation.

- **Performance Obligations.** The promised goods or services in the Company's arrangements typically consist of a license, or option to license, rights to the Company's intellectual property or research and development services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

- **Customer Options.** If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or the option expires.
- **Transaction Price.** The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all variable consideration subject to constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues in the period of adjustment.

The Company allocates the transaction price to the identified performance obligations based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for a portion of its research and development expenses or participates each performance obligation identified in the cost-sharing contract. The Company utilizes key

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assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and development expenses, such reimbursements the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and cost-sharing arrangements the resulting amounts allocated are reflected as a reduction consistent with the amounts the Company would expect to receive for the satisfaction of research and development expenses each performance obligation.

- **Milestone Payments.** At the inception of each arrangement that includes development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur.
- **Royalties.** For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration or licensing arrangements.
- **Recognition.** The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations that consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its customers based on billing schedules established in each contract. Non-refundable upfront payments are included in the estimation of the transaction price, allocated to the performance obligation(s) based upon relative standalone selling price and recognized for each performance obligation based upon the measure of progress (point in time or over time) for each performance obligation. Payments received for goods and services not yet provided are recorded as deferred revenue. Amounts are recorded as accounts receivable when the Company's condensed consolidated statements right to consideration is unconditional.

For a discussion of operations accounting for collaboration and comprehensive loss, as the Company does not consider performing research license revenues, see Note 6, *Collaboration and development services for reimbursement to be a part of its ongoing major or central operations. License Agreements.*

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company holds all cash and cash equivalents at accredited financial institutions. Bank accounts in the United States are generally insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. Substantially all of the Company's cash and cash equivalents are FDIC insured, including funds held through an insured cash sweep program. The Company has not experienced any losses in its cash and cash equivalents and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses that are regularly provided to the chief operating decision maker. The guidance is effective for fiscal years beginning after December 15, 2023 and interim periods

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within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is to be applied retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company is currently evaluating the potential impact of adopting this new guidance on its condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), which modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. This Company is currently evaluating the potential impact of adopting this new guidance on its condensed consolidated financial statements and related disclosures.

3. Property and Equipment, Net

Property and equipment, net consists of the following as of September 30, 2023, March 31, 2024 and December 31, 2022:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Laboratory equipment	\$ 6,091	\$ 5,587	\$ 5,815	\$ 5,815
Computers and software	183	228	183	183
Furniture and fixtures	681	636	681	681
Leasehold improvements	5,124	5,124	5,124	5,124
Construction in process	—	98	21	—
Total property and equipment	12,079	11,673	11,824	11,803

Less: accumulated depreciation	(5,713)	(4,418)	(6,282)	(5,861)
Property and equipment, net	\$ 6,366	\$ 7,255	\$ 5,542	\$ 5,942

The Company recognized depreciation and amortization expense related to property and equipment of \$1.4 \$0.4 million and \$1.3 million \$0.5 million for the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively.

4. Accrued Expenses and Restructuring

Accrued expenses consist of the following as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
External research and development	\$ 4,553	\$ 3,178	\$ 4,715	\$ 4,867
Personnel-related	4,051	5,413	1,356	4,690
Restructuring			948	—
Professional and consulting fees	627	1,536	874	845
Other	173	200	109	95
Total accrued expenses	\$ 9,404	\$ 10,327	\$ 8,002	\$ 10,497

In March 2024, the Company's board of directors approved a strategic portfolio reprioritization and workforce reduction. As part of the workforce reduction, the Company recognized restructuring charges of \$0.9 million during the three months ended March 31, 2024, primarily related to employee severance and benefits continuation. The workforce reduction was completed in April 2024. The Company did not make any payments related to the restructuring during the three months ended March 31, 2024. All employee severance and benefits continuation payments are expected to be completed by the end of the third quarter of 2024.

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The following table summarizes the accrued restructuring liability activity for the Company's workforce reduction for the three months ended March 31, 2024:

Severance and Related Benefits

Accrued restructuring liability as of December 31, 2023	\$	—
Restructuring charges		948
Accrued restructuring liability as of March 31, 2024	\$	948

5. Loan and Security Agreement

In November 2019, the Company's wholly owned subsidiary, Xilio Development, Inc. ("Borrower" Xilio Development"), entered into a loan and security agreement (as amended and restated in May 2023, the "Loan Agreement") with Pacific Western Bank ("PacWest"), with the Company as a guarantor. Under the Loan Agreement, in November 2019, the Borrower Xilio Development borrowed \$10.0 million under a term loan. Interest on amounts outstanding under the Loan Agreement accrues accrued at a variable annual rate equal to the greater of (i) the prime rate plus 0.25% or (ii) 4.75%. As In the first quarter of September 30, 2023, the interest rate on the term loan was 8.75%. The Borrower was required to make interest-only payments on any 2024, Xilio Development repaid all amounts outstanding balances through December 31, 2022. The Borrower commenced making equal monthly payments of principal plus interest in January 2023, and it will be required to make such payments until the term loan matures on June 30, 2024.

The Loan Agreement contains customary representations, warranties and covenants and also includes customary terms covering events of default, including payment defaults, breaches of covenants, a change of control provision and occurrence of a material adverse effect. As security for its obligations under the Loan Agreement, the Borrower granted and PacWest a first priority released all security interest on substantially all of the Borrower's assets, excluding intellectual property, subject to certain exceptions.

Upon the occurrence interests in Xilio Development's and continuation of an event of default, a default interest rate of an additional 5% per annum may be applied to the outstanding loan balance, and the administrative agent, collateral agent, and lender may declare all outstanding obligations immediately due and payable and exercise all of their rights and remedies as set forth in the Loan Agreement and under applicable law. As of September 30, 2023, the Company and Borrower were in compliance with all covenants under the Loan Agreement. its affiliates' assets.

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The Borrower has the following minimum aggregate future loan principal payments under the Loan Agreement as of September 30, 2023:

Minimum Loan Payments

2023 (remaining three months)	\$ 1,667
2024	3,333
Total future principal payments	5,000
Less: unamortized discount	(43)
Total note payable	\$ 4,957

The Company recognized \$0.6 million, \$0.1 million and \$0.5 million, \$0.2 million of interest expense related to the Loan Agreement for the nine, three months ended September 30, 2023, March 31, 2024 and 2022, 2023, respectively, which is reflected in other income, net on the condensed consolidated statements of operations and comprehensive loss.

6. Collaboration and License Agreements

License Agreement with Gilead Sciences, Inc.

In March 2024, Xilio Development entered into a license agreement with Gilead, pursuant to which it granted Gilead an exclusive global license to develop and commercialize XTX301, the Company's tumor-activated IL-12 product candidate, and specified other molecules directed to IL-12.

Xilio Development is responsible for conducting clinical development for XTX301 in the ongoing Phase 1 clinical trial through an initial planned Phase 2 dose expansion clinical trial. Following the delivery by Xilio Development of a specified clinical data package for XTX301 related to the Phase 1 clinical trial and planned Phase 2 clinical trial, Gilead can elect to transition responsibilities for the development and commercialization of XTX301 to Gilead, subject to the terms of the license agreement and payment by Gilead of a \$75.0 million transition fee.

In connection with the execution of the license agreement, in March 2024, the Company also entered into a stock purchase agreement with Gilead. Under the stock purchase agreement, Gilead agreed to purchase up to an aggregate of \$25.0 million in the Company's common stock (or at Gilead's election, prefunded warrants in lieu of shares of common stock) in an initial private placement in connection with the execution of the license agreement and in up to three additional private placements through March 2025 at a predetermined mechanism for the purchase price per share, at all times subject to Gilead not being deemed the beneficial owner of greater than 19.9% of the Company's common stock upon the closing of the applicable private placement. In March 2024, the Company initially issued and sold 6,860,223 shares of common stock to Gilead at a purchase price of \$1.97 per share and received approximately \$13.5 million in aggregate gross proceeds.

Upon execution of the agreements, the Company was entitled to receive approximately \$43.5 million in upfront payments, including an upfront cash payment of \$30.0 million under the license agreement and an initial equity investment by Gilead of approximately \$13.5 million under the stock purchase agreement. Upon execution of the agreements, the Company was also eligible to receive up to \$604.0 million in additional contingent payments, which include (i) approximately \$11.5 million in proceeds from up to three additional private placements, (ii) the \$75.0 million transition fee and (iii) up to \$517.5 million in specified development, regulatory and sales-based milestones. Prior to the potential transition fee, up to \$29.0 million of the total additional contingent payments are related to the potential additional private placements and a near-

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term development milestone. In addition, the Company is eligible to receive tiered royalties ranging from high single digits to mid-teens on annual global net product sales.

The Company considered the ASC 606 criteria for combining contracts and determined the license agreement and the stock purchase agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The Company concluded the initial private placement and the additional private placements do not represent freestanding financial instruments as such instruments are not legally detachable due to contractual transfer restrictions. The Company accounted for the common stock issued to Gilead in the initial private placement based on the fair market value of the common stock on the date of issuance. The fair market value of the common stock issued to Gilead in the initial private placement was \$4.4 million, based on the closing price of the Company's common stock on the date of issuance, resulting in a \$9.1 million premium. The Company determined that the premium paid by Gilead for the common stock purchased in the initial private placement should be attributed to the transaction price of the license agreement.

The Company determined that the license agreement represents a contract with a customer within the scope of ASC 606 and identified two promises under the license agreement: (i) the exclusive licenses granted to Gilead related to the Company's IL-12 program and (ii) the provision by Xilio Development and its affiliates of development services related to ongoing and planned clinical trials for XTX301 through an initial planned Phase 2 clinical trial. The Company determined that the exclusive license and development services were not capable of being distinct on the basis that the development services to be provided by Xilio Development are specialized in nature, specifically with respect to its specialized expertise related to XTX301, the IL-12 program and the Company's proprietary platform for tumor-activated biologics. Accordingly, the Company concluded that there is a single identified combined performance obligation consisting of the exclusive license and the development services.

For the purposes of ASC 606, the transaction price of the license agreement at the outset of the arrangement was determined to be \$39.1 million, which consisted of the upfront cash payment of \$30.0 million under the license agreement and the \$9.1 million premium on the sale of common stock to Gilead in the initial private placement, which was allocated to the single combined performance obligation. The Company used the most likely amount method to estimate variable consideration. All contingent payments have been fully constrained at contract inception, as the achievement of the milestones underlying such contingent payments is uncertain and highly susceptible to factors outside of the Company's control. Accordingly, all such contingent payments were excluded from the transaction price. The Company anticipates that it will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and may adjust the transaction price as necessary. Sales-based royalties, including milestone payments based on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the royalties relate. The Company plans to recognize such revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Revenue associated with the combined performance obligation will be recognized as services are provided as control is transferred over time. The Company measures progress based on the amount of costs incurred relative to the total costs expected to fulfill the combined performance obligation. In management's judgment, this input method is the best measure of progress towards satisfying the combined performance obligation and reflects a faithful depiction of the transfer of goods and services.

Under the terms of the license agreement, the \$30.0 million upfront payment was paid by Gilead in April 2024. Accordingly, as of March 31, 2024, the Company recorded a receivable from Gilead for such amount.

As of March 31, 2024, no revenue has been recognized under the license agreement or the stock purchase agreement. The Company recorded deferred revenue of \$39.1 million for the transaction price as of March 31, 2024, of which \$21.7 million was recorded as a current liability on the Company's condensed consolidated balance sheets as of March 31, 2024.

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Clinical Trial Collaboration with F. Hoffmann-La Roche Ltd.

In July 2023, the Company and F. Hoffmann-La Roche Ltd. ("Roche") entered into a clinical trial collaboration (the "Roche Clinical Collaboration") pursuant to a clinical supply agreement to evaluate XTX101 in combination with atezolizumab (Tecentriq®) in a Phase 1/2 clinical trial consisting of a Phase 1 dose escalation portion assessing the combination in patients with advanced solid tumors and a planned Phase 2 portion assessing the combination in patients with microsatellite stable colorectal cancer.

Under the clinical supply agreement, the Company is eligible to receive specified cost-sharing payments from Roche, and each company will supply its respective anti-cancer agent to support the Phase 1/2 clinical trial. The Company will sponsor is responsible for sponsoring and conduct conducting the Phase 1/2 clinical trial and retains global development and commercialization rights to XTX101.

The Company concluded that the cost-sharing payments from the Roche Clinical Collaboration are not in the scope of ASC 606 because the Company does not consider performing research and development services for reimbursement to be part of its ongoing major or central operations. Therefore, the Company applied a reasonable, rational, and consistently applied accounting policy election to record the cost-sharing payments from the Roche Clinical Collaboration as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive loss for the period in which a study development event is achieved. During the three and nine months ended September 30, 2023 March 31, 2024, the Company recognized a reduction of research and development expenses of \$2.0 million. As of September 30, 2023 March 31, 2024, \$2.0

million of earned but unpaid cost-sharing payments were included in prepaid expenses and other current assets of the Company's condensed consolidated balance sheets.

7. Commitments and Contingencies

The Company has an operating lease for its headquarters and a finance lease for certain lab equipment. In August 2019, the Company entered into a facility lease agreement with a landlord providing funding for tenant improvements and occupancy of approximately 27,830 square feet of office and laboratory space (the "premises") at 828 Winter Street, Waltham, Massachusetts. The initial term of the lease expires in March 2030, unless terminated earlier in accordance with the terms of the lease. The Company has an option to extend the lease for an additional term of five years at then-market rates. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement, and management of the leased premises, which it began paying simultaneous with the rent commencement date in March 2020. As of September 30, 2023, March 31, 2024 and December 31, 2022, December 31, 2023, the Company had a letter of credit for the benefit of its landlord in the amount of \$1.6 million, collateralized by a money market account, which is recorded as restricted cash on the condensed consolidated balance sheets.

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8. Preferred Stock and Common Stock

Undesignated Preferred Stock

As of September 30, 2023, March 31, 2024 and December 31, 2022, December 31, 2023, the Company's certificate of incorporation, as amended, authorized the Company to issue up to 5,000,000 shares of undesignated preferred stock at \$0.0001 par value per share. As of September 30, 2023, March 31, 2024 and December 31, 2022, December 31, 2023, there were no shares of preferred stock issued or outstanding.

Common Stock

As of September 30, 2023, March 31, 2024 and December 31, 2022, December 31, 2023, the Company is authorized to issue up to 200,000,000 shares of common stock, \$0.0001 par value per share under its certificate of incorporation, as amended.

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Shares Reserved for Future Issuance

As of September 30, 2023 and December 31, 2022, The Company has reserved for future issuances the Company had reserved following shares of common stock for future issuance under the 2020 Stock Incentive Plan (as amended, the "2020 Plan"), the 2021 Stock Incentive Plan (the "2021 Plan"), the 2022 Inducement Stock Incentive Plan (the "2022 Inducement Plan") as of March 31, 2024 and the 2021 Employee Stock Purchase Plan (the "2021 ESPP") as follows: December 31, 2023:

	September 30, 2023	December 31, 2022
Shares of common stock reserved for exercise of a warrant	2,631	2,631
Shares of common stock reserved for exercise of outstanding stock options under the 2020 Plan, 2021 Plan and 2022 Inducement Plan	7,823,478	4,960,553
Shares of common stock reserved for future awards under the 2021 Plan	1,412,759	2,848,568
Shares of common stock reserved for future awards under the 2022 Inducement Plan	220,000	275,000
Shares of common stock reserved for purchase under the 2021 ESPP	772,507	566,720
Total shares reserved for future issuance	10,231,375	8,653,472

	March 31, 2024	December 31, 2023
Stock options	10,355,400	9,456,237
Employee stock purchase plan	977,376	701,244
Warrants	2,631	2,631
Total shares reserved for future issuance	11,335,407	10,160,112

9. Stock-Based Compensation

Equity Incentive Plans

2020 Stock Incentive Plan

Under the 2020 Stock Incentive Plan (as amended, the "2020 Plan"), the Company was authorized to issue shares of common stock to the Company's employees, officers, directors, consultants and advisors in the form of options, restricted stock awards or other stock-based awards.

2021 Stock Incentive Plan

In September 2021, the Company's board of directors and stockholders adopted the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the IPO in October 2021. Upon effectiveness of the 2021 Plan, the Company ceased granting awards under the 2020 Plan. The 2021 Plan provides for the grant of

incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The Company initially reserved 6,579,016 shares of common stock under the 2021 Plan. The 2021 Plan provides that the number of shares of the Company's common stock initially reserved and available for issuance under the 2021 Plan was the sum of (1) 2,654,828; plus (2) the number of shares (up to 3,967,038 shares) as is equal to the sum of (x) the number of shares of the Company's common stock reserved for issuance under the 2020 Plan that remained available for grant under the 2020 Plan immediately prior to the effectiveness of the 2021 Plan and (y) the number of shares of the Company's common stock subject to outstanding awards whether granted under the 2020 Plan or outside of the 2020 Plan which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right and that, prior to the effectiveness of the 2021 Plan, would have become available for issuance under the 2020 Plan; plus (3) an annual increase, to will be added cumulatively increased on the first day January 1 of each fiscal calendar year beginning with the fiscal year,

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commencing on January 1, 2022 and continuing until, and including, January 1, 2031, equal to the lesser of (i) by 5% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) the number of shares of common stock date or such lesser amount determined by the Company's board of directors. On January 1, 2023 January 1, 2024, the number of shares reserved for issuance under the 2021 Plan automatically increased by 1,373,580 1,380,663 shares.

As of September 30, 2023 March 31, 2024, there were 1,412,759 2,550,749 shares available for future issuance under the 2021 Plan.

2022 Inducement Plan

In 2022, the Company's board of directors adopted the 2022 Inducement Stock Incentive Plan pursuant to Nasdaq Rule 5635(c)(4) (the "2022 Inducement Plan"). In accordance with Rule 5635(c)(4), stock-based incentive awards under the 2022 Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's board of directors, or an employee who is being rehired following a bona fide period of non-employment by the Company as a material inducement to the employee's entering into employment with the Company. An aggregate of 275,000 shares of the Company's common stock has been reserved for issuance under the 2022 Inducement Plan.

The exercise price of stock options granted under the 2022 Inducement Plan will not be less than the fair market value of a share of the Company's common stock on the grant date. Other terms of awards, including vesting requirements, are determined by the Company's board of directors and are subject to the provisions of the 2022 Inducement Plan.

As of September 30, 2023 March 31, 2024, there were 220,000 shares available for future issuance under the 2022 Inducement Plan.

2021 Employee Stock Purchase Plan

In 2021, the Company's board of directors and stockholders adopted the 2021 ESPP, Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to the IPO in October 2021. The Company initially reserved 292,031 shares of common stock for issuance under the 2021 ESPP. In addition, the The 2021 ESPP provides that the number of shares of common stock reserved for issuance under the 2021 ESPP will be cumulatively increased on January 1 of each calendar year by the lesser of (i) 584,062 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on such date and (iii) a number of shares of common stock as or such lesser amount determined by the Company's board of directors. On January 1, 2023, the number directors (up to a maximum increase of 584,062 shares reserved for issuance under the 2021 ESPP was increased by 274,716 shares. Offering periods under the 2021 ESPP commence on each June 1 and December 1, and end on the following November 30 and May 31, respectively. During the nine months ended September 30, 2023, 68,929 shares were purchased under the 2021 ESPP. During the nine months ended September 30, 2022, no shares were purchased under the 2021 ESPP.

As of September 30, 2023, there were 772,507 shares available for future issuance under the 2021 ESPP.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2023 and 2022, the Company recorded compensation expense related to stock options, restricted common stock and ESPP share purchases for employees and non-employees, which was allocated as follows in the condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expense	\$ 548	\$ 594	\$ 1,670	\$ 1,827
General and administrative expense	1,313	1,277	3,782	4,782
Total stock-based compensation expense	\$ 1,861	\$ 1,871	\$ 5,452	\$ 6,609

per year). On January

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1, 2024, the number of shares reserved for issuance under the 2021 ESPP was increased by 276,132 shares. The Company did not issue shares under the 2021 ESPP during the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, there were 977,376 shares available for future issuance under the 2021 ESPP.

Stock-Based Compensation Expense

During the three months ended March 31, 2024 and 2023, the Company recorded compensation expense related to stock options, restricted stock units and restricted common stock for employees and non-employees and share purchases under the 2021 ESPP for employees, which was allocated as follows in the condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended March 31,	
	2024	2023
Research and development expense	\$ 506	\$ 573
General and administrative expense	1,327	1,218
Total stock-based compensation expense	<u>\$ 1,833</u>	<u>\$ 1,791</u>

Stock Options

A summary of stock option activity under the Company's 2020 Plan, 2021 Plan and 2022 Inducement Plan is as follows:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term		Aggregate Intrinsic Value (1)	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term		Aggregate Intrinsic Value (1)
			(In years)	(In thousands)				(In years)	(In thousands)	
Outstanding as of December 31, 2022	4,960,553	\$ 8.04	8.59	\$	89					
Outstanding as of December 31, 2023						7,455,795	\$ 5.52	8.0	\$	—
Granted	3,738,555	\$ 2.75				626,970	\$ 0.55			
Exercised	(2,757)	\$ 2.82				—	\$ —			
Cancelled/forfeited	<u>(872,873)</u>	\$ 6.77				<u>(498,114)</u>	\$ 7.72			
Outstanding as of September 30, 2023	<u>7,823,478</u>	\$ 5.66	8.54	\$	-					
Exercisable as of September 30, 2023	<u>2,768,685</u>	\$ 7.19	7.66	\$	-					
Outstanding as of March 31, 2024						<u>7,584,651</u>	\$ 4.97	7.9	\$	314
Exercisable as of March 31, 2024						<u>3,049,352</u>	\$ 6.68	7.0	\$	13

- (1) The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock as of the end of the period.

Using the Black-Scholes option pricing model, the weighted average fair value of options granted to employees and directors during the **nine** **three** months ended **September 30, 2023** **March 31, 2024** and **2022** **2023** was **\$2.02** **\$0.41** and **\$5.88**, **\$1.95**, respectively. The following assumptions were used in determining the fair value of options granted during the **nine** **three** months ended **September 30, 2023** **March 31, 2024** and **2022**: **2023**:

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Risk-free interest rate	3.57 - 4.40 %	1.47 – 3.63 %	3.9 %	4.0 %
Expected dividend yield	0 %	0 %	0 %	0 %
Expected term (in years)	5.50 - 6.08	5.27 – 6.08	6.0	6.0 - 6.1
Expected volatility	81.69 - 87.32 %	80.75 – 87.64 %	87.7 %	82.3 %

As of **September 30, 2023** **March 31, 2024**, the Company had unrecognized stock-based compensation expense of **\$14.3 million** **\$10.6 million** related to stock options issued to employees and directors, which is expected to be recognized over a weighted-average period of **2.3** **2.0** years.

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Restricted Stock Units

In January 2024, the Company awarded 481,500 restricted stock units to certain employees of the Company. The restricted stock units vest in four equal annual installments beginning on the first anniversary of the grant date. The restricted stock units are generally forfeited if the individual's service relationship with the Company or any subsidiary terminates prior to vesting.

A summary of the Company's restricted stock unit activity and related information is as follows:

	Number of Shares of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2023	—	\$ —
Granted	481,500	\$ 0.55

Unvested as of March 31, 2024	481,500	\$	0.55

For the three months ended March 31, 2024, the Company recognized less than \$0.1 million of stock-based compensation expense related to these awards. As of March 31, 2024, the Company had unrecognized stock-based compensation expense of \$0.2 million related to these restricted stock units, which is expected to be recognized over 3.8 years.

Restricted Common Stock

A summary of the Company's restricted common stock activity and related information is as follows:

	Number of Shares of Restricted Stock	Weighted Average Grant Date Fair Value	Number of Shares of Restricted Common Stock	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2022	46,160	\$ 5.51		
Unvested as of December 31, 2023			5,617	\$ 5.51
Vested	(31,793)	\$ 5.51	(4,777)	\$ 5.51
Canceled/Forfeited	(1,293)	\$ 5.51		
Unvested as of September 30, 2023	13,074	\$ 5.51		
Unvested as of March 31, 2024			840	\$ 5.51

In June 2020, the Company granted 552,546 shares of common stock underlying restricted stock awards, and the Company has not subsequently granted any additional restricted stock awards. The aggregate fair value of the restricted stock awards that vested during the nine months ended September 30, 2023 March 31, 2024 and 2022 2023 was less than \$0.1 million and \$0.3 million, respectively. As of September 30, 2023, total unrecognized stock-based compensation expense related to unvested restricted stock awards was \$0.1 million, which is expected to be recognized over a weighted-average period of 0.4 years.

10. Net Loss Per Share

The following table sets forth the outstanding shares of common stock equivalents, presented based on amounts outstanding at each period end, that were excluded from the calculation of diluted net loss per share attributable to common stockholders during each period because including them would have been anti-dilutive:

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Unvested restricted common stock	13,074	64,458	840	30,714
Unvested restricted stock units			481,500	—
Outstanding stock options	7,823,478	4,999,256	7,584,651	6,087,600
Warrants	2,631	2,631	2,631	2,631
Unvested employee stock purchase plan shares	60,488	—	48,201	68,884

Total common stock equivalents	7,899,671	5,066,345	8,117,823	6,189,829

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11. Subsequent Events

Private Placement

On March 28, 2024, the Company entered into a securities purchase agreement with certain existing accredited investors pursuant to which the Company issued and sold an aggregate of 1,953,125 shares of its common stock at a purchase price of \$0.64 per share and, in lieu of shares of the Company's common stock, prefunded warrants to purchase up to an aggregate of 15,627,441 shares of its common stock at a purchase price of \$0.6399 per prefunded warrant, through a private placement. The private placement closed on April 2, 2024. The Company received aggregate gross proceeds of approximately \$11.3 million from the private placement, before deducting placement agent fees and expenses payable by the Company.

Gilead Additional Equity Investment

On April 3, 2024, pursuant to the terms of the Company's stock purchase agreement with Gilead, the Company exercised its right to the first of up to three additional private placements with Gilead and issued and sold 485,250 shares of its common stock at a purchase price of \$0.76 per share and prefunded warrants to purchase up to an aggregate of 3,882,450 shares of its common stock at a purchase price of \$0.7599 per prefunded warrant. The Company received aggregate gross proceeds of approximately \$3.3 million from the additional private placement with Gilead.

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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 condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended **December 31, 2022** **December 31, 2023**.

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, 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.

Overview

We are a clinical-stage biotechnology company discovering and developing tumor-activated immuno-oncology, or I-O, therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. We are leveraging our proprietary **geographically precise solutions, or GPS,** platform to build a pipeline of novel, tumor-activated **I-O molecules including antibodies, cytokines and other biologics, which that** are designed to optimize **their the** therapeutic index by localizing anti-tumor activity within the tumor **microenvironment. microenvironment, including tumor-activated cytokines and antibodies (including bispecifics) and immune cell engagers (including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers).** Current I-O therapies have curative potential for patients with cancer; however, their potential is significantly curtailed by systemic toxicity that results from activity of the therapeutic molecule outside the tumor microenvironment. Our molecules are engineered to localize activity within the tumor microenvironment with minimal systemic effects, resulting in the potential to achieve enhanced anti-tumor activity and increasing the population of patients who may be eligible to receive our medicines. Our most advanced tumor-activated, clinical-stage product candidates **are are:** **XTX101, an Fc-enhanced, anti-CTLA-4 monoclonal antibody, or mAb, mAb;** **XTX301, an interleukin 12, or IL-12, therapy; and** **XTX202, an interleukin 2, or IL-2, therapy, therapy.** To date, we have presented clinical data across these programs showing initial clinical validation for each of these molecules and **XTX301, an interleukin 12, or IL-12, therapy, our tumor-activated approach.** In addition to our clinical-stage product candidates, we are continuing to leverage our **GPS differentiated research platform and expertise in developing tumor-activated I-O therapies to advance preclinical development for tumor-activated bispecific molecules and immune cell engager molecules (including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers).** As a result of our strategic portfolio reprioritization announced in March 2024, we are focusing on rapidly advancing clinical development for **XTX301 and XTX101 and advancing differentiated bispecific and cell-engager molecules in preclinical development, and we plan to explore strategic opportunities to continue to develop additional tumor-activated immunotherapies, including product candidates XTX202 in combination with other agents while discontinuing further investment in XTX202 as a range of tumor targeting approaches. monotherapy.**

To date, we have financed our operations primarily from proceeds raised through private placements of preferred units and convertible preferred stock, a debt financing, **and** our initial public offering, or IPO, of common stock in October **2021. 2021,** private placements of our common stock and prefunded warrants, and **an upfront payment under our exclusive license agreement with Gilead Sciences, Inc., or Gilead.** We have not generated any revenue from product sales and do not expect to generate any revenue from product sales for at least the next several years, if at all. All of our programs are in early clinical or preclinical development. Our ability to generate product

revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve profitability. Even if we are able to generate revenue from product sales, we may not become profitable.

Liquidity and Going Concern Overview

Since inception, we have incurred significant operating losses, including net losses of \$58.7 million and \$17.2 million and \$65.8 million \$22.6 million for the nine three months ended September 30, 2023 March 31, 2024 and 2022, respectively. Our 2023, respectively, and a net loss of \$76.4 million for the year ended December 31, 2022 was \$88.2 million December 31, 2023. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of \$307.9 \$342.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future, particularly to the extent we:

- continue to advance our current research programs and conduct additional research programs;

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- advance our current product candidates and any future product candidates we may develop into preclinical and clinical development;
- seek marketing approvals for product candidates that successfully complete clinical trials, if any;
- obtain, expand, maintain, defend and enforce our intellectual property;

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- hire additional research, clinical, regulatory, quality, manufacturing and general and administrative personnel;
- establish a commercial and distribution infrastructure to commercialize products for which we may obtain marketing approval, if any;
- continue to discover, validate and develop additional product candidates;

- continue to manufacture increasing quantities of our current or future product candidates for use in preclinical studies, clinical trials and for any potential commercialization;
- acquire or in-license other product candidates, technologies or intellectual property; and
- incur additional costs associated with current and future research, development and commercialization efforts and operations as a public company.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of **September 30, 2023** **March 31, 2024**, we had cash and cash equivalents of **\$59.8** **\$34.0** million. **We believe** Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of **March 31, 2024**, together with the **\$30.0 million upfront payment received in April 2024 under our license agreement with Gilead and approximately \$14.6 million in aggregate gross proceeds received in April 2024 from private placements with certain existing investors and Gilead**, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the **end of the second quarter of 2024**. However, we have based this estimate on assumptions that **2025**. Since these amounts may prove to be wrong, and we could exhaust our available capital resources sooner than we anticipate. Since our cash and cash equivalents as of **September 30, 2023** are not expected to be sufficient to fund our operations for at least twelve months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there is substantial doubt about our ability to continue as a going concern. To continue to fund our operations, our management has developed plans, which in the near term primarily consist of raising additional capital through one or more of the following: equity or debt financings; collaborations, partnerships or licensing transactions; or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital. If we are not able to secure sufficient additional capital in the near term, we will need to implement cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs. In addition, if our efforts to secure sufficient additional capital in the near term are unsuccessful, we may in the future need to seek to engage in one or more other strategic alternatives, including without limitation, the sale or divestiture of some or all of our assets or proprietary technologies. For more information, refer to “—Liquidity and Capital Resources—Capital Requirements and Going Concern” below and Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recent Developments

Exclusive License Agreement and Stock Purchase Agreement with Gilead

In March 2024, we entered into an exclusive license agreement and a stock purchase agreement with Gilead. Under the license agreement, our wholly-owned subsidiary, Xilio Development, Inc., or Xilio Development, granted Gilead an exclusive global license to develop and commercialize **XTX301**, our tumor-activated **IL-12** product candidate, and specified other molecules directed to **IL-12**. Xilio Development is responsible for conducting clinical development for **XTX301** in the ongoing **Phase 1** clinical trial through an initial planned **Phase 2** dose expansion clinical trial. Following the delivery by Xilio Development of a specified clinical data package for **XTX301** related to the **Phase 1** clinical trial and planned **Phase 2** clinical trial, Gilead can elect to transition responsibilities for the development and commercialization of **XTX301** to Gilead, subject to the terms of the license agreement and payment by Gilead of a **\$75.0 million** transition fee. Under the stock purchase agreement, Gilead agreed to purchase up to **\$25.0 million** in common stock or, at Gilead's election, prefunded warrants, including approximately

\$13.5 million in our common stock in connection with entering into the license agreement and approximately \$11.5 million in up to three additional private placements through March 2025.

We have received approximately \$46.8 million to date under these agreements, including an upfront cash payment of \$30.0 million received in April 2024 under the license agreement and \$16.8 million in aggregate gross proceeds from the sale and issuance of common stock and prefunded warrants to Gilead under the stock purchase agreement. We are eligible to

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receive up to \$600.7 million in additional contingent payments under these agreements, which include (i) up to approximately \$8.2 million in proceeds from up to two additional private placements, (ii) the \$75.0 million transition fee and (iii) up to \$517.5 million in specified development, regulatory and sales-based milestones. Prior to the potential transition fee, up to \$25.7 million of the total additional contingent payments are related to the potential additional private placements and a near-term development milestone. In addition, we are eligible to receive tiered royalties ranging from high single digits to mid-teens on annual global net product sales.

March 2024 Private Placement

In March 2024, we entered into a securities purchase agreement with certain existing accredited investors, including Bain Capital Life Sciences and Rock Springs Capital, and issued and sold an aggregate of 1,953,125 shares of our common stock at a price of \$0.64 per share and prefunded warrants to purchase up to an aggregate of 15,627,441 shares of our common stock at a purchase price of \$0.6399 per prefunded warrant share, through a private investment in public equity financing. The prefunded warrants have an exercise price of \$0.0001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The private placement closed in April 2024, and we received aggregate gross proceeds of approximately \$11.3 million, before deducting placement agent fees and expenses payable by us. We expect to use the proceeds from the private placement to fund working capital and other general corporate purposes.

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of products since inception and do not expect to generate any revenue from the sale of products for at least the next several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments sales. For the foreseeable future, we expect substantially all of our revenue, if any, would be generated from third-party collaborators or licensors, our license agreement with Gilead.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our discovery efforts, research activities and development and testing of our programs and product candidates. These expenses include:

- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation expense for employees engaged in research and development functions;

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- costs incurred with third-party contract development and manufacturing organizations, or CDMOs, to acquire, develop and manufacture materials for both preclinical studies and current or future clinical trials;
- costs of funding research performed by third parties that conduct research and development and preclinical activities on our behalf;
- costs incurred with third-party contract research organizations, or CROs, and other third parties in connection with the conduct of our current or future clinical trials;
- costs of sponsored research agreements and outside consultants, including their fees and related expenses;
- costs incurred to maintain compliance with regulatory requirements;
- fees for maintaining licenses and other amounts due under our third-party licensing agreements;

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- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific deliverables using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our condensed consolidated balance sheets as prepaid expenses or accrued research and development expenses. We record cost-sharing payments under our clinical trial collaboration with F. Hoffmann-La Roche Ltd., which we refer to as **or** the Roche clinical collaboration, as a reduction of research and development costs upon the achievement of each study development event specified in the clinical supply agreement. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized as assets, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We use our personnel and infrastructure resources for our discovery efforts, including the advancement of our **GPS** platform **technology**, developing programs and product candidates and managing external research efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. We track these external costs, such as fees paid to CDMOs, CROs, preclinical study vendors and other third parties in connection with our manufacturing and manufacturing process development, clinical trials, preclinical studies and other research activities by program. Due to the number of ongoing programs and our ability to use resources across several projects, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will remain approximately the same or will continue to increase for the foreseeable future as we advance our programs and our current or future product candidates into and through the development phase. We expect our discovery research efforts and our related personnel costs to remain consistent with historical levels. In addition, as we progress our most advanced product candidates in clinical development, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into, or may enter into license, acquisition, option or other agreements to acquire the rights to future products and product candidates. In the event we are unable to raise sufficient additional capital in the near term to fund our operations, we will be required to adopt cost reduction strategies that seek to maintain our ability to continue the development of our most advanced product candidates in clinical development while otherwise reducing our overall research and development expenses.

At this time, we cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates or programs. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the scope, timing, costs and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to implement and maintain cost reduction strategies, as well as the timing of such cost reductions;
- our ability to maintain our current research and development programs;
- our ability to establish an appropriate safety profile for our product candidates with IND-enabling studies;

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- our ability to hire and retain key research and development personnel;
- the costs associated with the development of any additional product candidates we develop or acquire through collaborations;
- our successful enrollment in and completion of clinical trials;
- our ability to successfully complete clinical trials with safety, potency and purity profiles that are satisfactory to the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority;
- our receipt of regulatory approvals from applicable regulatory authorities;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others;
- the continued acceptable safety profiles of the product candidates following approval, if any;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder, if any;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved; and

- general economic conditions, including inflation; and
- the impact of public health crises, including epidemics and pandemics such as the COVID-19 pandemic, on our business, operations, strategy, goals and anticipated milestones, as well as our response to such epidemics or pandemics, inflation.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate we may develop.

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General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, recruiting and stock-based compensation, for personnel in our executive, finance, legal, business development, human resources and other administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional and consulting fees for accounting, auditing, tax, human resources and administrative consulting services; board of directors' fees; insurance costs; and facility-related expenses, which include depreciation costs and other allocated expenses for rent, maintenance of facilities and other general administrative costs. These costs relate to the operation of the business and are in support of but separate from the research and development function and our individual development programs. Costs to secure and defend our intellectual property are expensed as incurred and are classified as general and administrative expenses.

We anticipate that our general and administrative expenses will remain consistent with historical levels as we maintain our infrastructure to support our research and development activities. We also expect to continue to incur significant expenses associated with operating as a public company, including increased costs for accounting, audit, legal, regulatory and tax-related services attributable to maintaining compliance with exchange listing standards and U.S. Securities and Exchange Commission, or SEC, requirements, directors' and officers' liability insurance costs and investor and public relations costs. We also expect to continue to incur additional expenses related to intellectual property-related expenses property as we file patent applications to protect intellectual property arising from our research and development activities. In the event we are unable to obtain

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sufficient additional capital in the near term, we will need to implement cost reduction strategies that seek to reduce our general and administrative expenses while maintaining sufficient infrastructure to support our planned research and development activities and operations as a public company.

Restructuring

In connection with the March 2024 strategic portfolio reprioritization and restructuring, we undertook efforts to reduce our expenses and streamline our operations, including a reduction in headcount of 15 employees, representing approximately 21% of our workforce immediately prior to the workforce reduction. Restructuring expense consists of costs directly incurred as a result of restructuring initiatives, and includes employee severance payments, benefits continuation, outplacement services and related expenses.

Other Income, Net

Other income, net consists primarily of interest income earned from our cash and cash equivalents, interest expense principally on the note payable under our former debt arrangement with Pacific Western Bank, or PacWest, and amortization of the debt discount related to debt issuance costs.

Results of Operations

Comparison of the three months ended September 30, 2023 March 31, 2024 and 2022 2023

The following table summarizes our results of operations for the three months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

	Three Months Ended September 30,			Three Months Ended March 31,		
	2023	2022	Change	2024	2023	Change
Operating expenses						
Research and development	\$ 11,051	\$ 13,038	\$ (1,987)	\$ 10,400	\$ 16,131	\$(5,731)
General and administrative	6,310	7,168	(858)	6,139	7,395	(1,256)
Restructuring				948	—	948
Total operating expenses	17,361	20,206	(2,845)	17,487	23,526	(6,039)
Loss from operations	(17,361)	(20,206)	2,845	(17,487)	(23,526)	6,039
Other income, net						
Other income, net	613	416	197	284	880	(596)
Total other income, net	613	416	197	284	880	(596)
Net loss	\$ (16,748)	\$ (19,790)	\$ 3,042	\$(17,203)	\$(22,646)	\$ 5,443

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Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended **September 30, 2023** **March 31, 2024** and **2022** **2023** (in thousands):

	Three Months Ended September 30,			Three Months Ended March 31,		
	2023	2022	Change	2024	2023	Change
XTX101	\$ (967)	\$ 1,394	\$ (2,361)	\$ (523)	\$ 721	\$(1,244)
XTX202	2,741	1,452	1,289	3,164	1,744	1,420
XTX301	757	1,974	(1,217)	1,215	3,128	(1,913)
Other early programs and indirect research and development	3,744	2,861	883	1,698	4,663	(2,965)
Personnel-related (including stock-based compensation)	4,776	5,357	(581)			
Personnel-related				4,846	5,875	(1,029)
Total research and development expenses	<u>\$ 11,051</u>	<u>\$ 13,038</u>	<u>\$ (1,987)</u>	<u>\$10,400</u>	<u>\$16,131</u>	<u>\$(5,731)</u>

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Research and development expenses decreased by **\$2.0** **\$5.7** million from **\$13.0** **\$16.1** million for the three months ended **September 30, 2022** **March 31, 2023** to **\$11.1** **\$10.4** million for the three months ended **September 30, 2023** **March 31, 2024**. The changes in research and development expenses were primarily due to the following:

- XTX101 costs decreased by **\$2.4 million** **\$1.2 million** from **\$1.4 million** **\$0.7 million** for the three months ended **September 30, 2022** **March 31, 2023** to **\$(1.0)** **\$(0.5)** million for the three months ended **September 30, 2023** **March 31, 2024**, primarily driven by a \$2.0 million cost-sharing payment that we earned under our Roche clinical collaboration during the three months ended **September 30, 2023** **March 31, 2024** and recorded as a reduction in research and development expenses, and a \$0.2 million decrease due to the timing of manufacturing activities in the comparable period;

- ~~XTX202 costs increased by \$1.3 million, primarily driven by a \$1.8 million increase in clinical development activities related to our ongoing Phase 1/2 clinical trial, partially offset by a \$0.4 million decrease due to the timing of manufacturing activities in the comparable period;~~
- ~~XTX301 costs decreased by \$1.2 million, primarily driven by a \$1.2 million decrease due to the timing of manufacturing activities in the comparable period and a \$0.2 million decrease in preclinical activities, partially offset by a \$0.3 million~~ ~~\$0.7 million~~ ~~increase in clinical development activities related to our Phase 1 clinical trial;~~
- ~~XTX202 costs increased by \$1.4 million, primarily driven by an increase in clinical development activities related to our Phase 1/2 clinical trial;~~
- ~~XTX301 costs decreased by \$1.9 million, primarily driven by a \$2.0 million decrease in manufacturing activities relating to the initial supply of clinical trial material in the comparable period and a \$0.1 million decrease in preclinical activities, partially offset by a \$0.1 million increase in clinical development activities related to our Phase 1 clinical trial;~~
- other early programs and indirect research and development expenses ~~increased~~ ~~decreased~~ by ~~\$0.9 million~~ ~~\$3.0 million~~, primarily driven by ~~an increase~~ ~~a decrease~~ in external expenses related to preclinical research and development activities; and
- personnel-related costs decreased by ~~\$0.6 million~~ ~~\$1.0 million~~, primarily driven by a ~~\$0.9 million~~ decrease in salaries, bonuses and benefits due to lower research and development ~~headcount~~, ~~headcount~~ and a ~~\$0.1 million decrease in stock-based compensation.~~

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended ~~September 30, 2023~~ ~~March 31, 2024~~ and ~~2022~~ ~~2023~~ (in thousands):

	Three Months Ended		
	September 30,		Change
	2023	2022	
Personnel-related (including stock-based compensation)	\$ 3,779	\$ 3,808	\$ (29)
Professional and consulting fees	1,435	2,135	(700)
Facility-related and other general and administrative expenses	1,096	1,225	(129)
Total general and administrative expenses	<u>\$ 6,310</u>	<u>\$ 7,168</u>	<u>\$ (858)</u>

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	Three Months Ended		
	March 31,		Change
	2024	2023	

Personnel-related	\$ 3,575	\$ 4,281	\$ (706)
Professional and consulting fees	1,662	2,060	(398)
Facility-related and other general and administrative expenses	902	1,054	(152)
Total general and administrative expenses	\$ 6,139	\$ 7,395	\$ (1,256)

General and administrative expenses decreased by \$0.9 million \$1.3 million from \$7.2 million \$7.4 million for the three months ended September 30, 2022 March 31, 2023 to \$6.3 \$6.1 million for the three months ended September 30, 2023 March 31, 2024. The changes in general and administrative expenses were primarily due to the following:

- personnel-related costs decreased by \$0.7 million, primarily driven by a \$0.6 million decrease in salaries, bonuses and benefits due to lower general and administrative headcount and a \$0.2 million decrease in recruiting costs, partially offset by a \$0.1 million increase in stock-based compensation;
- professional and consulting fees decreased by \$0.7 million \$0.4 million, primarily driven by a \$0.7 million decrease in consulting fees, and other professional related fees, partially offset by a \$0.3 million increase in legal fees primarily related to the Gilead license and stock purchase agreements; and
- facility-related and other general and administrative expenses decreased by \$0.1 million \$0.2 million, primarily driven by lower costs related to directors' and officers' liability insurance and a reduction in other general and administrative expenses.

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Restructuring

We recognized \$0.9 million in restructuring expenses for the three months ended March 31, 2024. The restructuring expenses were associated with our strategic portfolio reprioritization and workforce reduction announced in March 2024 and consisted of employee severance and benefits continuation costs related to the workforce reduction.

Other Income, Net

Other income, net, increased decreased by \$0.2 million \$0.6 million from \$0.4 million \$0.9 million for the three months ended September 30, 2022 March 31, 2023 to \$0.6 million \$0.3 million for the three months ended September 30, 2023 March 31, 2024. The increase decrease in other income, net was primarily due to an increase a decrease in interest income earned on our cash and cash equivalents due to higher interest rates a lower average cash balance and lower interest expense on our note payable as a result of the commencement repayment of the repayment of remaining principal beginning under our loan agreement with PacWest in January 2023.

Comparison of the nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended		
	September 30,		Change
	2023	2022	
Operating expenses			
Research and development	\$ 40,400	\$ 44,204	\$ (3,804)
General and administrative	20,603	21,778	(1,175)
Total operating expenses	61,003	65,982	(4,979)
Loss from operations	(61,003)	(65,982)	4,979
Other income, net			
Other income, net	2,254	226	2,028
Total other income, net	2,254	226	2,028
Net loss	\$ (58,749)	\$ (65,756)	\$ 7,007

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended		
	September 30,		Change
	2023	2022	
XTX101	\$ 509	\$ 5,428	\$ (4,919)
XTX202	7,242	4,017	3,225
XTX301	5,088	9,253	(4,165)
Other early programs and indirect research and development	11,735	10,234	1,501
Personnel-related (including stock-based compensation)	15,826	15,272	554
Total research and development expenses	\$ 40,400	\$ 44,204	\$ (3,804)

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Research and development expenses decreased by \$3.8 million from \$44.2 million for the nine months ended September 30, 2022 to \$40.4 million for the nine months ended September 30, 2023. The changes in research and

development expenses were primarily due to the following:

- XTX101 costs decreased by \$4.9 million, primarily driven by a \$2.1 million decrease due to the timing of manufacturing activities in the comparable period, a \$2.0 million cost-sharing payment that we earned under our Roche clinical collaboration during the nine months ended September 30, 2023 and recorded as a reduction in research and development expenses and a \$0.6 million decrease in clinical development activities related to our ongoing Phase 1 clinical trial;
- XTX202 costs increased by \$3.2 million, primarily driven by a \$4.4 million increase in clinical development activities related to our ongoing Phase 1/2 clinical trial, partially offset by a \$1.0 million decrease due to the timing of manufacturing activities in the comparable period and a \$0.2 million decrease in preclinical activities;
- XTX301 costs decreased by \$4.2 million, primarily driven by a \$3.1 million decrease due to the timing of manufacturing activities in the comparable period, a \$2.5 million decrease in preclinical activities and a \$0.3 million decrease in regulatory activities, partially offset by a \$1.7 million increase in clinical development activities related to our Phase 1 clinical trial;
- other early programs and indirect research and development expenses increased by \$1.5 million, primarily driven by an increase in external expenses related to preclinical research and development activities; and
- personnel-related costs increased by \$0.6 million, primarily driven by an increase in salaries, bonuses and benefits due to consistent research and development headcount combined with an increase in average compensation.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended		
	September 30,		
	2023	2022	Change
Personnel-related (including stock-based compensation)	\$ 12,010	\$ 12,612	\$ (602)
Professional and consulting fees	5,252	5,221	31
Facility-related and other general and administrative expenses	3,341	3,945	(604)
Total general and administrative expenses	<u>\$ 20,603</u>	<u>\$ 21,778</u>	<u>\$ (1,175)</u>

General and administrative expenses decreased by \$1.2 million from \$21.8 million for the nine months ended September 30, 2022 to \$20.6 million for the nine months ended September 30, 2023. The changes in general and administrative expenses were primarily due to the following:

- personnel-related costs decreased by \$0.6 million, primarily driven by a \$1.0 million decrease in stock-based compensation, as the prior year period included \$0.6 million in non-recurring compensation expense resulting from the modification of previously issued stock options, partially offset by a \$0.4 million increase in salaries, bonuses and benefits; and
- facility-related and other general and administrative expenses decreased by \$0.6 million, primarily driven by lower costs related to directors' and officers' liability insurance and a reduction in other general and administrative expenses.

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Other Income, Net

Other income, net, increased by \$2.0 million from \$0.2 million for the nine months ended September 30, 2022 to \$2.3 million for the nine months ended September 30, 2023. The increase in other income, net was primarily due to an increase in interest income earned on our cash and cash equivalents due to higher interest rates and lower interest expense on our note payable as a result of the commencement of the repayment of principal beginning in January 2023. March 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in preclinical or early clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have financed our operations primarily from proceeds raised through private placements of preferred units, and convertible preferred stock, common stock and prefunded warrants, a debt financing, our IPO and our IPO, a license agreement. Through September 30, 2023 March 31, 2024, we have received an aggregate of \$350.9 million \$378.9 million in net gross proceeds from such transactions, including \$116.4 million \$225.5 million in net proceeds from our IPO, \$224.5 million in net gross proceeds from the sale and issuance of preferred units and convertible preferred stock, and \$10.0 million in net gross proceeds from our debt financing with PacWest. PacWest, \$129.9 million in gross proceeds from our IPO, and \$13.5 million in gross proceeds from the sale and issuance of common stock to Gilead in a private placement. As of September 30, 2023 March 31, 2024, we had cash and cash equivalents of \$59.8 \$34.0 million.

In April 2024, we received approximately \$44.6 million in aggregate gross proceeds related to the \$30.0 million upfront payment under our license agreement with Gilead and approximately \$14.6 million in aggregate gross proceeds from the sale and issuance of common stock and prefunded warrants to certain existing investors in a private placement and to Gilead in an additional private placement.

In November 2022, we filed a universal shelf registration statement on Form S-3 with the SEC, or Form S-3, to register for sale up to \$250,000,000 of our common stock, preferred stock, debt securities, units and warrants, which we may issue and sell from time to time in one or more offerings, which became effective on November 18, 2022 (333-268264). In November 2022, we also entered into a sales agreement, or the Sales Agreement, with Cowen and Company LLC, under which we may issue and sell shares of our common stock, from time to time, having an aggregate offering price of up to \$75.0 million, subject to the terms and conditions of the Sales Agreement. Through the filing date of this Quarterly Report on Form 10-Q, we have not issued or sold any shares of our common stock pursuant to the Sales Agreement. Issuances or sales of common stock pursuant to the Sales Agreement, if any, would be made under the Form S-3 and the corresponding prospectus related to the issuance and sale of shares of common stock pursuant to the Sales Agreement. The extent to which we use the Sales Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our

common stock, general market conditions, the extent to which we are able to secure funds from other sources, and whether we are then subject to limitations on our ability to use Form S-3 to sell more than one-third of the aggregate market value of our public float in the trailing 12-month period. Accordingly, we may not be able to sell shares under the Sales Agreement at prices or in amounts that we deem acceptable, and there can be no assurance that we will sell any shares of common stock pursuant to the Sales Agreement.

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Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

	Nine Months Ended		Three Months Ended	
	September 30,		March 31,	
	2023	2022	2024	2023
Net cash used in:				
Net cash provided by (used in):				
Operating activities	\$ (55,193)	\$ (57,500)	\$(10,502)	\$(25,250)
Investing activities	(486)	(1,358)	—	(170)
Financing activities	(4,916)	(48)	954	(1,688)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (60,595)</u>	<u>\$ (58,906)</u>	<u>\$ (9,548)</u>	<u>\$(27,108)</u>

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in research and development of our product candidates, including preclinical studies, clinical trials, manufacturing and manufacturing process development. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

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During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, net cash used in operating activities of **\$55.2** **\$10.5** million was primarily driven by our net loss of **\$58.7** million and changes in operating assets and liabilities of **\$3.5** million, partially offset by net non-cash expenses of **\$7.0** million.

During the nine months ended September 30, 2022, net cash used in operating activities of **\$57.5** million was primarily driven by our net loss of **\$65.8** **\$17.2** million, partially offset by changes in operating assets and liabilities of **\$0.1** **\$4.4** million and net non-cash expenses of **\$8.1** **\$2.3** million.

During three months ended March 31, 2023, net cash used in operating activities of **\$25.3** million was primarily driven by our net loss of **\$22.6** million and changes in operating assets and liabilities of **\$4.9** million, partially offset by net non-cash expenses of **\$2.3** million.

Investing Activities

We had no cash flows related to investing activities during the three months ended March 31, 2024. During the **nine** **three** months ended **September 30, 2023** and **2022**, **March 31, 2023**, net cash used in investing activities of **\$0.5** million and **\$1.4** million, respectively, **\$0.2** million consisted of purchases of property and equipment.

Financing Activities

During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, net cash **used in** provided by financing activities of **\$4.9** **\$1.0** million consisted of proceeds from the sale and issuance of common stock to Gilead in the initial private placement, partially offset by repayments of debt principal under our loan agreement with PacWest and payments on our finance lease for certain lab equipment, partially offset by proceeds from the issuance of common stock under our employee stock purchase plan and the exercise of stock options. **equipment.**

During the **nine** **three** months ended **September 30, 2022** **March 31, 2023**, net cash used in financing activities of less than **\$0.1** million **\$1.7** million consisted of repayments of debt principal under our loan agreement with PacWest and payments on our finance lease for certain lab equipment partially offset by proceeds received from the exercise of stock options. **equipment.**

Loan and Security Agreement

In November 2019, our wholly owned subsidiary, Xilio Development Inc., entered into a loan and security agreement with PacWest, as amended and restated in May 2023, with us as a guarantor, which we refer to as or the loan agreement. Under the loan agreement, in November 2019, we borrowed \$10.0 million under a term loan. Borrowings under the loan agreement **are** **were** collateralized by substantially all of the assets of Xilio Development, Inc., excluding intellectual property. Interest on amounts outstanding accrues **accrued** at a variable annual rate equal to the greater of (i) the prime rate plus 0.25% or (ii) 4.75%. As of September 30, 2023, the interest rate on the term loan was 8.75%. We made interest-only payments on the outstanding

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balance through December 31, 2022. We commenced making equal monthly payments of principal plus interest in January 2023, and we ~~will be~~ ~~were~~ required to make such payments until the term loan ~~matures~~ ~~matured~~ on June 30, 2024. ~~As~~ ~~In the first quarter of~~ ~~September 30, 2023, the~~ ~~2024, we repaid all amounts~~ outstanding ~~principal balance~~ under the loan agreement, ~~was~~ \$5.0 million.

The loan agreement contains customary representations, warranties and covenants ~~PacWest released all security interests in our~~ and ~~also includes customary events of default, including payment defaults, breaches of covenants, a change of control and occurrence of a material adverse effect.~~ ~~our subsidiaries' assets.~~

Capital Requirements and Going Concern

We expect our future capital requirements to increase substantially over time in connection with our ongoing research and development activities, particularly as we advance our current and planned clinical development of our product candidates and maintain the research efforts and preclinical activities associated with our other existing programs and discovery platform. In addition, we expect to continue to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies. Additionally, the United States is experiencing a workforce shortage, which in turn has created a competitive wage environment that may also increase our operating costs in the future.

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As of ~~September 30, 2023~~ ~~March 31, 2024~~, we had cash and cash equivalents of ~~\$59.8~~ ~~\$34.0~~ million. ~~We believe~~ ~~Based on our current operating plans, we anticipate~~ that our existing cash and cash equivalents ~~as of~~ ~~March 31, 2024, together with the \$30.0 million upfront payment received in April 2024 under our license agreement with Gilead and approximately \$14.6 million in aggregate gross proceeds received in April 2024 from private placements with certain existing investors and Gilead,~~ will be sufficient to enable us to fund our ~~planned~~ operating expenses and capital expenditure requirements into the ~~end of the~~ second quarter of ~~2024~~, ~~2025~~. However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our

available capital resources sooner than we expect anticipate. In addition, since our cash and cash equivalents as of September 30, 2023 are these amounts may not expected to be sufficient to fund our operating expenses and capital expenditures operations for at least twelve months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there is substantial doubt about our ability to continue as a going concern. We will require substantial additional capital Our management has developed plans to fund our operations, as we continue to advance our product candidates through clinical trials and maintain the infrastructure necessary to support these activities. To continue to fund our operations, our management has developed plans, which in the near term primarily consist of raising additional capital through one or more of the following: additional equity or debt financings; additional collaborations partnerships or licensing transactions; or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital. If we are not able to secure sufficient additional capital in the near term, we will may in the future need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs. In addition, if our efforts to secure sufficient additional capital in the near term are unsuccessful, we may in the future need to seek to engage in one or more other strategic alternatives, including without limitation, the sale or divestiture of some or all of our assets or proprietary technologies. The accompanying condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business for the foreseeable future. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into additional collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with advancing the research and development of our product candidates.

Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of research and development for our current and future product candidates, including our current and planned clinical trials for our clinical-stage product candidates, XTX101, XTX202 XTX301, and XTX301, XTX202, and ongoing preclinical development for our current and future product candidates;

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- our ability to implement and maintain cost reduction strategies, as well as the timing of such cost reductions;

- the scope, prioritization and number of our research and development programs;
- the scope, costs, timing and outcome of regulatory review of our product candidates;
- the costs of securing manufacturing materials for use in preclinical studies, clinical trials and, for any product candidates for which we receive regulatory approval, if any, commercial supply;
- the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval;
- the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;

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- the extent to which we may acquire or in-license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements;
- our ability to maintain our clinical collaboration to further develop XTX101, our Fc-enhanced tumor-activated anti-CTLA-4, in combination with atezolizumab, including the cost-sharing arrangements of such collaboration;
- the impact, timing and amount of public health crises, including epidemics, milestones, equity investments and pandemics such as the COVID-19 pandemic, on other contingent payments under our business, operations, strategy, goals and anticipated milestones, as well as our response to such epidemics or pandemics; partnership with Gilead for XTX301;
- the costs of maintaining our operations and continuing to operate as a public company; and
- whether we are able to overcome the substantial doubt about our ability to continue as a going concern.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if ever. Accordingly, we will need to obtain substantial additional capital to achieve our business objectives.

Our expectation with respect to our ability to fund our currently planned operations is based on estimates that are subject to various risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that our current operating plan will be achieved in the time frame anticipated by us, and we may exhaust our available capital resources sooner than we expect.

Adequate additional capital may not be available to us on acceptable terms, or at all. Market volatility resulting from the COVID-19 pandemic, adverse changes in domestic and international fiscal, monetary and other policies and political relations, regional or global conflicts, uncertainty around global economic conditions, instability in the financial markets, current or future pandemics, or other factors could also adversely impact our ability to access capital. capital as and when needed. To the extent that we raise additional capital through the sale of equity or securities convertible into or exchangeable for equity, the ownership interest of our existing stockholders may be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt and preferred equity, if available, may also 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 and may require that we issue warrants, which could potentially dilute the ownership interest of our existing stockholders.

If we raise additional capital through collaborations, partnerships, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or products, and we may be required to grant licenses on terms that may not be favorable to us. 33

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Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions

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or conditions. There Except as described in Note 2, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there have been no changes to our critical accounting policies appearing in our Annual Report filed on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an EGC, in which case we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required

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disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial and accounting officer evaluated the effectiveness of our disclosure controls and procedures as of **September 30, 2023** **March 31, 2024**. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that, as of **September 30, 2023** **March 31, 2024**, our disclosure controls and procedures were effective at a reasonable assurance level.

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Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II—OTHER INFORMATION

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

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

Our recurring losses from operations and the early development stage of our lead product candidates raise substantial doubt regarding our ability to continue as a going concern. If we are unable to raise sufficient additional capital in the near term, we will may in the future need to implement additional cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs.

As of **September 30, 2023** **March 31, 2024**, we had cash and cash equivalents of **\$59.8 million** **\$34.0 million**. We believe **Based on our current operating plans, we anticipate** that our existing cash and cash equivalents **as of March 31, 2024**, together with the **\$30.0 million** upfront payment received in April 2024 under our license agreement with Gilead Sciences, Inc., or Gilead, and approximately **\$14.6 million** in aggregate gross proceeds received in April 2024 from private placements with certain existing investors and Gilead, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the **end of the** second quarter of **2024** **2025**. However, since **our cash and cash equivalents as of September 30, 2023 are** **these amounts may** not **be expected to** be sufficient to fund our operations for at least twelve months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there is substantial doubt about our ability to continue as a going concern. **To** **Our future capital requirements and the period for which we expect our existing resources to support our operations may vary from what we expect, and we may not achieve the expected savings that we anticipate as a result of our recent portfolio reprioritization and workforce reduction. Our management has developed plans to** continue to fund our operations, **our management has developed plans, which in the near term** primarily consist of raising additional capital through one or more of the following: **additional** equity or debt financings; **additional** collaborations, partnerships or licensing transactions; or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital in the near term. If we are not able to secure sufficient additional capital, we **will may in the future** need to implement **additional** cost reduction strategies, which could include delaying, limiting, **further** reducing or eliminating both internal and external costs related to our operations and research and development programs. **In addition, if our efforts to secure sufficient additional capital** **For example, in March 2024, we announced that we would discontinue further investment in the near term are unsuccessful, we may** **development of XTX202 as a monotherapy and would undergo a workforce reduction to further reduce our expenses and streamline our operations, which workforce reduction was completed in the future need to seek to engage in one or more other strategic alternatives, including without limitation, the sale or divestiture of some or all of our assets or proprietary technologies. If we are unsuccessful in our efforts in the near term to raise additional capital or in the future to engage in one or more other strategic alternatives, we could be required to liquidate, dissolve or otherwise wind down our operations.** **April 2024.** Furthermore, our cash forecasts are based on assumptions that may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may exhaust our available capital sooner than

planned. Please see Note 1 to our condensed consolidated financial statements appearing elsewhere in our Quarterly Report on Form 10-Q for additional information on our assessment.

We expect to continue to incur operating losses in connection with our ongoing research and development activities, particularly as we advance our product candidates through clinical trials, maintain the infrastructure necessary to support these activities and incur costs associated with operating as a public company. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for any current or future product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial.

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Our future capital requirements, both short-term and long-term, will depend on many factors, including:

- our ability to implement and maintain further cost reduction strategies, as well as the timing of such cost reductions;
- the scope, progress, results and costs of research and development for our current and future product candidates, including our ongoing and planned clinical trials for our clinical-stage product candidates;

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- the scope, prioritization and number of our research and development programs;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaboration agreements;
- the timing and amount of payments we may receive or are obligated to pay under our collaboration agreements and license agreements;
- the scope, costs, timing and outcome of regulatory review of our product candidates;

- the costs of expanding manufacturing capacity through third-party manufacturers and securing manufacturing materials for use in preclinical studies, clinical trials and, for any product candidates for which we receive regulatory approval, **if any, use as commercial supply**;
- the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval;
- the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we may acquire or in-license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements;
- our ability to maintain **our current collaborations, including** our clinical collaboration to further develop XTX101, our **tumor-activated, Fc-enhanced tumor-activated** anti-CTLA-4, in combination with atezolizumab, including the cost-sharing arrangements of such **collaboration; collaboration, and our partnership with Gilead for XTX301;**
- the **impact timing and amount of public health crises, including epidemics milestones, equity investments and pandemics such as the COVID-19 pandemic, on other contingent payments under our business, operations, strategy, goals and anticipated milestones, as well as our response to such epidemics or pandemics; partnership with Gilead for XTX301;**
- the costs of maintaining our operations and continuing to operate as a public company; and
- whether we are able to overcome the substantial doubt about our ability to continue as a going concern.

We will require additional capital to sustain our operations. We currently do not have any committed external sources of funds and adequate additional capital may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening economic conditions, both inside and outside the **U.S., United States**, including without limitation heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential economic slowdown or recession, **the COVID-19 pandemic (including variants of COVID-19) and future pandemics**, geopolitical **events, tensions**, including trade wars or civil or political **unrest, unrest, or wars or other armed conflicts**. We can give no assurance that we will be able to secure additional capital to support our operations, or if such funds are available to us, that such additional funding will be sufficient to meet our needs. These factors raise substantial doubt about our ability to continue as a going concern, and our

failure to raise capital, on attractive terms or at all, would have a material adverse effect on our business, results of operations and financial condition.

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

Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt, collaborations, licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our plans for additional capital or the terms of such capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. For example, (i) when we issue shares of common stock upon the exercise of the prefunded warrants issued in connection with the private placements to existing accredited investors and to Gilead, each of which closed in April 2024, or (ii) if we issue shares of common stock in connection with the sale of additional shares of our common stock or additional prefunded warrants to Gilead in up to two additional potential private placements, our existing stockholders will suffer dilution. In addition, as a condition to providing additional funds to us, Gilead received, and future investors may receive, rights superior to those of existing stockholders. To the extent that we incur additional indebtedness, we would become obligated to make payments to repay the loan balance with interest. The incurrence of any additional

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indebtedness would result in additional payment obligations. Under our loan obligations and security agreement with Pacific Western Bank, or PacWest, we are required is likely to comply with certain involve restrictive covenants such as limitations on limiting our ability to incur additional debt, limitations on our ability to declare dividends, limitations on our ability to sell or dispose any part flexibility in conducting future business activities, and, in the event of insolvency, would be repaid before holders of our business or property and other operating restrictions that could adversely impact equity securities received any distribution of our ability to conduct our business, and any agreements governing any other indebtedness that we may incur could require us to comply with additional covenants. If we raise corporate assets. Additionally, in raising funds through our collaborations and licensing arrangements with third parties, we have had to, and may have in the future need to, relinquish valuable rights, partially or fully, to our technologies, future revenue streams, research programs or product candidates or and grant licenses on terms unfavorable to us. In addition, securing additional capital would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

We have incurred significant operating losses since our inception and have not yet generated any revenue. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses were \$58.7 million \$17.2 million and \$65.8 million \$22.6 million for the nine three months ended September 30, 2023 March 31, 2024 and 2022, respectively, and \$88.2 million for the year ended December 31, 2022, 2023, respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of \$307.9 million \$342.7 million. To date, we have funded financed our operations primarily from proceeds raised through proceeds from our initial public offering, or IPO, the sale private placements of preferred units and convertible preferred stock, and a debt financing. financing, our initial public offering, or IPO, of common stock in October 2021, private placements of our common stock and prefunded warrants, and an upfront payment under our exclusive license agreement with Gilead. We have devoted substantially all of our financial resources and efforts to research and development. We are still in the early stages of development of our product candidates, and we have not completed clinical development for our clinical-stage, tumor-activated product candidates, XTX101 (anti-CTLA-4), XTX301 (IL-12) and XTX202 (IL-2) and XTX301 (IL-12), and we have not commenced clinical development for any of our other product candidates. We have not generated any revenue from product sales to date. We expect to continue to incur significant expenses and operating losses for the foreseeable future, particularly to the extent we:

- continue to advance our current research programs and conduct additional research programs;
- advance our current product candidates and any future product candidates we may develop into preclinical and clinical development;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- obtain, expand, maintain, defend and enforce our intellectual property;

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- hire additional research, clinical, regulatory, quality, manufacturing and general and administrative personnel;
- establish a commercial and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- continue to discover, validate and develop additional product candidates;
- continue to expand manufacturing capacity through third-party manufacturers and manufacture increasing quantities of our current or future product candidates for use in preclinical studies, clinical trials and for any potential commercialization;
- acquire or in-license other product candidates, technologies or intellectual property; and

- incur additional costs associated with current and future research, development and commercialization efforts and operations as a public company.

Even if we successfully complete clinical trials and obtain regulatory approval for one or more of our product candidates, our product candidates may not be commercially successful. In addition, we will continue to incur substantial research and

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development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable and, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from our product candidates or product sales, we do not expect to generate any revenue from the sale of products for a number of years, and we may never generate revenue from the sale of products. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully complete our ongoing and planned preclinical studies and clinical trials for any current or future product candidates;
- successfully receive U.S. Food and Drug Administration, or FDA, clearance for any investigational new drug application, or IND, for any current or future product candidates;
- successfully initiate and complete clinical trials for our clinical-stage product candidates and any other current or future product candidates, including all safety and efficacy studies necessary to obtain U.S. and foreign regulatory approval for our product candidates;
- establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;

- obtain and maintain healthcare coverage and adequate reimbursement for our products, if and when approved;
- maintain a continued acceptable safety profile of our products following approval; and

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- enforce and defend intellectual property rights and claims.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating product revenue. In addition, we may never succeed in these activities, and, even if we do, we may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We are a clinical-stage biotechnology company with a limited operating history upon which investors can evaluate our business and prospects. Since inception, we have devoted substantially all of our financial resources and efforts to performing research and development activities. Our approach to the discovery and development of tumor-activated product candidates using our geographically precise solutions, or GPS, proprietary platform technology for tumor-activated molecules is unproven, and we do not know whether

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we will be able to develop any approved products of commercial value. In addition, each of our product candidates is either in early clinical or preclinical development, and all of our other development programs are still in discovery stages. We have not yet demonstrated an ability to successfully complete any clinical trials, obtain regulatory

approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

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

We have incurred substantial losses during our history. As of **December 31, 2022** **December 31, 2023**, we had federal and state net operating loss, or NOL, carryforwards of **\$177.5 million** **\$209.3 million** and **\$146.6 million** **\$180.9 million**, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we do not know whether or when we will generate taxable income necessary to utilize our NOLs.

In general, under **Section** **Sections 382 and 383** of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income is subject to limitations. We have not yet completed a detailed study of our inception to date ownership change activity under **Section** **Sections 382 and 383** of the Code. As a result of our prior private placements for preferred units and convertible preferred stock, our IPO or other transactions, we may have experienced such ownership changes in the past, and we may experience such ownership changes in the future as a result of changes in our stock ownership, some of which are outside our control. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset such taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described below in “Risks Related to Ownership of Our Common Stock—Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition,” the Tax Cuts and Jobs Act of 2017, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to the Discovery and Development of Our Product Candidates

Our business is highly dependent on the success of our current product candidates, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and commercially launch a product.

Our business and future success is highly dependent on our ability to obtain regulatory approval for, and if approved, successfully launch and commercialize, our current product candidates, including our clinical-stage, tumor-activated product candidates: XTX101 (anti-CTLA-4), XTX301 (IL-12) and XTX202 (IL-2), and XTX301 (IL-12). We are currently evaluating XTX101 in combination with atezolizumab (Tecentriq®) in Phase 1 combination dose escalation and XTX301 in ongoing a Phase 1 clinical trials and trial. Additionally, we have been evaluating XTX202 in an ongoing a Phase 1/2 clinical trial; however, as announced in March 2024, we plan to discontinue further investment in XTX202 as a monotherapy and plan to explore strategic opportunities to continue to develop XTX202 in combination with other agents. We also have a portfolio of programs that are in even earlier stages of preclinical development and may never advance to clinical-stage development.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies, or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory

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authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union, or EU.

To date, we have only had limited interactions with the FDA regarding our clinical development plans. We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of any future INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

We are not permitted to market any biological product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each

desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA is not guaranteed, and the review and approval process is expensive, uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidate that we develop based on the completed clinical trials.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for any current or future product candidates.

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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 current and any future product candidates, which may never occur. However, given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

All our product candidates are still in the early clinical stage or preclinical stage of development, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States, or similar applications in other

jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our current or future preclinical programs on the timelines we expect, if at

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all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our current and any future product candidates is high. It is impossible to predict when or if any of our product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, while we have conducted certain preclinical studies for each of our clinical stage product candidates, we do not know whether these product candidates will perform in our clinical trials as they have performed in these prior preclinical studies. For example, in preclinical mouse models, we observed XTX101 had tumor-selective activity and tumor growth inhibition superior to that of an ipilimumab analog, and that XTX202 had comparable tumor growth inhibition to aldesleukin and non-masked IL-2, with both XTX101 and XTX202 avoiding mortality and body weight loss. However, there is no guarantee these preclinical results will be replicated in clinical trials. Similarly, there can be no assurance that early, interim or preliminary clinical data or results will be predictive of or replicated in future clinical data or results, including without limitation, the preliminary Phase 1 data reported for XTX101, including the partial response observed in one patient treated with XTX101, the preliminary safety data into the third dose level reported for XTX301, or the preliminary Phase 1/2 clinical monotherapy data reported for XTX202, will be predictive of future clinical data or results. XTX202. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and

clinical trials, including previously unreported adverse events, or AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols,

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differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned and ongoing preclinical studies or clinical trials, or if we experience material changes in clinical data or results from those we have previously reported, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business, financial condition and results of operations would be materially and adversely affected.

We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials, including our Phase 1 clinical trial for XTX101, combination dose escalation portion of our Phase 1/2 clinical trial for XTX202 XTX101 in combination with atezolizumab or our Phase 1 clinical trial for XTX301, will be conducted as planned or completed on schedule, if at all. For example, in March 2024, we announced that we plan to discontinue further investment in XTX202 as a monotherapy. We may experience numerous unforeseen events leading up to, during or as a result of clinical trials that could delay or prevent the initiation or completion of a clinical trial or our ability to receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;

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- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, or subjects may fail to enroll or remain in clinical trials at the rate we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected **drug-related** **treatment-related** adverse effects;
- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators, or IRBs, or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;

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- we may need to add new or additional clinical trial sites;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may experience manufacturing delays, and any changes to manufacturing processes or third-party contractors that may be necessary or desired could result in other delays;

- we or our third-party contractors may experience delays due to complications resulting from the impact of public health crises, including epidemics and pandemics such as the COVID-19 pandemic; pandemics;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in current or future clinical trials;
- reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and

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- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of product candidates, we may:

- incur additional unplanned costs;
- be required to suspend or terminate ongoing clinical trials;
- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing or other requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- have the product removed from the market after obtaining marketing approval;
- be subject to lawsuits; or

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- experience damage to our reputation.

Conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions, which may be costly, time consuming and may not be successful at all.

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Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot guarantee that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to

successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. 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. The enrollment of patients depends on many factors, including:

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- AEs in our clinical trials and in third-party clinical trials of agents similar to our product candidates;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;

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- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control including the impacts of the COVID-19 pandemic, that may limit the availability of patients, principal investigators or staff or clinical sites, sites, such as public health crises, including epidemics and pandemics.

In addition, our clinical trials will compete with other clinical trials for product candidates 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. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process

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and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain sufficient additional capital.

Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Traditional cytokine therapies and checkpoint inhibitors have long been associated with severe toxicities, which can be life-threatening or fatal, that have resulted in the need to dose-reduce, dose-interrupt and discontinue many patients from treatment. As has been the case with traditional immuno-oncology, or I-O, treatments for cancer, it is possible that there may be side effects associated with the use of our current or future product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

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- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- regulatory authorities may withdraw or limit their approval of such product candidates;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- we may suffer reputational harm.

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

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Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time 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 publish interim top-line or preliminary data from our clinical trials. For example, in May 2023, we most recently reported preliminary monotherapy data from our Phase 1 clinical trial for XTX101 and in November/December 2023, we reported preliminary monotherapy data from our Phase 1/2 clinical trial for XTX202. XTX202 in March 2024 and preliminary Phase 1 safety data into the third dose level for XTX301 in January 2024. Preliminary and interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We expect to develop certain of our product candidates in combination with third-party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such third-party drugs.

We intend to develop our clinical-stage product candidates, and likely other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, as part of our ongoing Phase 1/2 clinical trial for XTX101, we plan to evaluate/are evaluating XTX101 in combination with atezolizumab (Tecentriq®) in Phase 1 combination dose escalation and plan to evaluate the combination in Phase 2 in patients with microsatellite stable colorectal cancer. Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results or prospects may be materially harmed.

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Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our plans to evaluate current or future product candidates in combination with other agents may result in AEs based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the

results of such trials could show that any positive previous trial results are attributable to the third-party drug and not our product candidate. Developments related to the third-party drug may also impact our clinical trials for the combination therapy as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third-party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third-party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

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We may not be successful in our efforts to use our GPS platform technology to enable the development of a pipeline of tumor-activated product candidates.

A key element of our strategy is to use our novel GPS platform technology to engineer and develop tumor-activated molecules with the potential to trigger anti-tumor immunity with minimal systemic toxicity in order to build a pipeline of product candidates. We may not be able to continue to identify and develop novel immuno-oncology I-O therapies. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, potential product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to or will not be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our GPS platform approach or take longer to do so than anticipated, we will not or may not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. We may in the future rely on third parties for certain research, and we will not have complete control over their performance and ability to successfully develop product candidates. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; and

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- it may take greater human and financial resources than we will possess to identify and advance additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

Our approach to the discovery and development of product candidates based on our technological approaches is unproven, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our technological approaches. While we have had favorable preclinical study results related to our clinical stage product candidates, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in current or future clinical trials or in obtaining marketing approval thereafter. We rely on matrix metalloproteases, or MMPs, to activate our molecules within the tumor microenvironment. If MMP activity in human tumors is not sufficient to cleave the masking protein domain, the potential efficacy of our product candidates would be limited. We have no assurance that our product candidates will successfully progress through clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in developing our initial product candidates and our future success is highly dependent on the outcome of our ongoing clinical trials and the successful development of our technology and product candidates.

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In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to **compliance** **comply** with these requirements.

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.

We have chosen to initially develop each of our clinical-stage product candidates for the treatment of various solid tumor types. Nevertheless, our development efforts will be limited to a small number of cancer types, and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

In addition, 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 viable product candidates. Similarly, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved

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products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media and social media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;

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- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact; and
- the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain sufficient product liability insurance coverage, we may be unable to secure such our current insurance coverage and any insurance coverage we obtain in the future may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

Risks Relating to Manufacturing and Supply

Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.

The manufacturing of biologics is complex and difficult and we may experience production issues or interruptions in supply for our product candidates, including variability of raw material, consumable or starting material variability in terms of quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, growth

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media contamination, equipment malfunctions or failures, operator errors, facility contamination, labor problems, quality system and regulatory inspection failures, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our control or the control of our third-party contract manufacturers, development and manufacturing organizations, or CMOs. CDMOs.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of In the event that raw materials that we anticipate will be required in our manufacturing process are need to be derived from biologic sources. Such raw materials sources, they may be difficult to procure and may be subject to contamination or recall.

Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects, out-of-specification analytical results or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical

development of any product candidates we may develop. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality that meet FDA, European Medicines Agency, or EMA, or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficacy efficiency that we are currently manufacturing is yet to be tested. If we or our third-party CMOs are CDMO is unable to scale our manufacturing at and meet the same levels of quality and efficiency, or provide sufficient manufacturing campaign slots to generate materials, we may not be able to supply the required number of doses for clinical trials or commercial supply. A material shortage, contamination event or manufacturing failure in the manufacture of any product candidates candidate we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

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We face risk risks related to our reliance on our current and any future CMOs CDMOs. For example, we and our CMOs CDMO are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities of the CMOs CDMO on which we rely may not continue to meet regulatory requirements, may have limited capacity or may experience interruptions in supply, any of which could adversely affect our development and commercialization plans for our product candidates. All entities involved in the preparation and storage of therapeutics for clinical trials or commercial sale, including any CMOs CDMOs of any product candidates we may develop, 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 clinical current Good Manufacturing Practices, or cGMP. 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 adventitious agents or other 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 in partnership with our CMO CDMO, must supply all necessary documentation in support of an IND for clinical product, and later in support of a BLA for any potential commercial product, on a timely basis and must adhere to the FDA's and EMA's current Good Laboratory Practices and current Good Manufacturing Practices cGMP regulations enforced through its the applicable regulatory authority's facilities inspection program. Our facilities and quality systems and the facilities and quality systems of our CMOs CDMO must pass a pre-approval inspection, for or PAI, to confirm validity of the information presented in the BLA and to confirm the capability of the facility to manufacture our product in compliance with the applicable regulations as regulations. The PAI is a condition of regulatory approval of any product candidates we may develop or any of our other potential products. If our or our CDMO's quality systems or facilities involved with the preparation of our product candidates do not pass the PAI, FDA approval of such product candidates will not be granted.

In addition, the regulatory authorities may, at any time, **audit** **conduct a routine** or **inspect** **for-cause inspection of a manufacturing facility involved with the preparation of our product candidates, or our which inspection is related to other potential products manufactured at the site** or the associated quality systems, for compliance with the regulations applicable to the activities being conducted. **If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.**

The regulatory authorities also may, at any time following approval of a product for sale, **audit** **inspect** our **facilities or the manufacturing facilities or those of our CMOs, CDMOs.** If any such inspection **or audit** identifies a failure to comply with applicable regulations, or if a violation of our product specifications or applicable regulations occurs independent of such an inspection, **or audit,** we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, **or** the temporary or permanent closure of a **facility, facility, or other remedial measures that may delay or**

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disrupt the manufacture or release of our product candidates or other potential products. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any **CMO CDMO** with which we contract for manufacturing and supply fails to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, **a clinical hold,** refusal to approve a pending application for a new drug product or biologic product, **or** revocation of a pre-existing **approval.** **approval, or an import alert.** As a result, our business, financial condition and results of operations may be materially harmed.

Currently, we depend on a single manufacturer for **developing** the manufacturing processes required to **develop** **supply** our product candidates. We cannot ensure that this manufacturer will remain in business or have sufficient capacity or supply to meet our needs. Our use of a single manufacturer exposes us to several risks, including price increases or manufacturing delays beyond our control. This **CMO CDMO is based in and** has significant operations in China, **where our product candidates are manufactured,** which subjects us to additional risks including those related to U.S. export control **laws.** **laws, potential sanctions or other trade restrictions imposed by the U.S. government.** Moreover, reliance on third-party manufacturers generally entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including geopolitical tensions or restrictions, such as export controls or sanctions, or the bankruptcy of the manufacturer or supplier;

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- the inability to import or obtain components or materials from alternate sources at acceptable prices or with acceptable quality in a timely manner; and
- substantial delays or difficulties related to the establishment of replacement manufacturers who meet regulatory requirements.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, import alert, or total or partial suspension of production.

Additionally, if supply from one approved manufacturer is interrupted, such as could be the case with our current CMO, CDMO, there could be a significant disruption in supply. While we believe there are alternate manufacturers who can provide the manufacturing processes required to develop and manufacture our product candidates, if we have to switch to a replacement manufacturer, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Furthermore, an alternative manufacturer must be able to demonstrate successful technology transfer of the manufacturing process and associated assays, and, to do so, may need to modify the manufacturing process required to develop our product candidates, and the alternative manufacturer would need to be qualified through additional regulatory filings, all of which could result in further delay and significant costs. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for clinical or commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully.

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Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue. revenue or market share with respect to any product that has received marketing approval.

If we or any CMOs CDMOs and suppliers we engage 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 any CMOs CDMOs and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of biological or hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair

our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party **CMOs** **CDMOs** and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to our Dependence on Third Parties

We expect to rely on third parties to conduct, supervise and monitor IND-enabling studies and clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations.

We expect to rely on CROs and research and clinical trial sites to ensure our IND-enabling studies and clinical trials are conducted properly and on time, and we expect to rely in the future on CROs for additional research programs. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of these studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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We and our CROs will be required to comply with the FDA's Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the preclinical and clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving any marketing applications. Upon inspection, the FDA may determine that our studies did not comply with GCPs.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our CROs do not successfully carry

out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements, or for any other reasons, our studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidates we may develop. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We have entered into, and may in the future seek to enter into, licenses, collaborations licenses or similar arrangements with third parties for the research, development and commercialization of certain of our current or future product candidates. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates.

In March 2024, our wholly-owned subsidiary, Xilio Development, Inc., or Xilio Development, entered into the license agreement with Gilead, pursuant to which Gilead was granted an exclusive global license to develop and commercialize XTX301, our tumor activated IL-12, and other specified molecules directed toward IL-12, which we refer to as our IL-12 program. We may in the future seek third-party collaborators or licensors for the research, development and commercialization of certain of our other current or future product candidates. If With respect to our license agreement with Gilead, and what we expect will be the case with any future collaboration agreements we enter into, any such arrangements with any third parties, we will have and would likely have limited control over whether such collaborators pursue the development of our product candidates or the amount and timing of resources that our collaborators dedicate to the development or commercialization of any our product candidates that we may seek to develop with them. Our For example, under the license agreement with Gilead, if Gilead exercises its right to transition responsibilities for the development and commercialization of XTX301 and the rest of our IL-12 program, it will have sole decision making authority with respect to the continued development and future commercialization of our IL-12 program and may elect to prioritize other assets that it believes are more competitive, or it may exercise its right to terminate the license and return the licensed IL-12 program assets to us. As a result, there can be no assurances that any of the programs covered by our existing or future collaborations or licenses will be developed further or reach commercialization. Further, our ability to generate revenues from these existing and future arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

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Collaborations, licenses or similar arrangements involving our research programs or any product candidates currently pose, and will continue to pose, numerous risks to us, including the following:

- collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements;

- collaborators or licensors may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators or licensors may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product

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candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators or licensors could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators or licenses may be acquired by a third party having competitive products or different priorities;
- collaborators or licensors with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidate(s);
- collaborators or licensors may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators or licensors and us that result in the delay or termination of the research, development, or commercialization of our product candidates or any of our product candidates or that result in costly litigation or arbitration that diverts management attention and **resources; resources or that jeopardize or invalidate our intellectual property or proprietary information;**
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations or licenses may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborations or license agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator or licensor of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If we enter into our current or future collaborations, licenses or similar transactions and such arrangements do not result in the successful development and commercialization of product candidates, or if one of our collaborators or licensors terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such agreement. agreement, we may lose valuable rights to our intellectual property, or we may incur significant costs in reestablishing the development and manufacturing of such product candidates. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or licensor or for us to attract new collaborators or licensors, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development,

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regulatory approval and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators or licensors.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration or license agreement with future partners will depend, among other things, upon our assessment of the resources and expertise of such third-party collaborator or licensor and the terms and conditions of the proposed collaboration or license. Further, if we license rights for use in any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

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If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we **have decided and may in the future** decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

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.

We may not be able to negotiate **future** 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 the product candidates for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay their potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the applicable product candidate.

Certain of our research and development and manufacturing activities take place in China through a third-party CROs, collaborators or manufacturers. CDMO. A significant disruption in the operation of those CROs, collaborators or manufacturers our ability to rely on this CDMO could materially adversely affect our business, financial condition and results of operations.

We have relied on **certain a third parties party** located in China to manufacture and supply certain raw materials used in our product candidates, and we expect to continue to use such third-party **manufacturers CDMO** for such purposes. A natural disaster, epidemic or pandemic, **including such as the recent** COVID-19 pandemic, trade war, political unrest, economic conditions, changes in legislation, including the passage of the People's Republic of China Biosecurity law, which became effective on April 15, 2021, and subsequent legislation that China **or the United States** may adopt in the future, or other events in China could disrupt **the business or operations of our ability to continue to rely upon** CROs, collaborators, manufacturers or other third parties with whom we conduct business now or in the future. Any disruption in China **or the United States** that significantly impacts such third parties, including services provided by CROs for our research and development programs, or our manufacturers' ability to produce **and export raw or manufactured** materials in adequate quantities to meet our needs, could impair our ability to operate our business on a day-to-day basis and impede, delay, limit or prevent the

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research, development or commercialization of our current and future products or product candidates. In addition, for any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic or geopolitical conditions, including sanctions in China or against certain Chinese companies; changes in U.S. export laws and or the imposition by the United States of trade barriers; sanctions; limitations on uses of U.S. government executive agency contract, grant or loan funds; or other restrictions on doing business with certain Chinese companies, including our CDMO, which could have a material adverse effect on our business. Additionally, we may be exposed to fluctuations in the value of the local currency in China for goods and services. Our costs for any of these services or activities could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and/or the availability of skilled labor declines in China.

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Risks Related to Commercialization

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators.

We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties. Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. To the extent we need to rely upon one or

more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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

The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our current product candidates for the treatment of cancer and have not completed clinical development for our clinical-stage, tumor-activated product candidates, XTX101 (anti-CTLA-4), XTX301 (IL-12) or XTX202 (IL-2) or XTX301 (IL-12), and we have not commenced clinical development for any of our other product candidates or received marketing approval for any of our product candidates. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies

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or replacing existing therapies with our product candidates. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

XTX101, if approved, may face competition from other anti-CTLA-4 based therapies. For example, Yervoy (ipilimumab), an anti-CTLA-4, is approved to treat melanoma, renal cell carcinoma and certain cancers of the large

intestine, and Imjudo (tremelimumab) is approved as a combination therapy to treat unresectable hepatocellular carcinoma. In addition, we are aware that several companies have anti-CTLA-4 programs in development, including Adagene, Inc., Agenus Inc., AstraZeneca plc, BioAtla, Inc., Bristol-Myers Squibb Inc., CytomX Therapeutics, Inc., MacroGenics, Inc. and OncoC4, Inc.

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With respect to XTX301, there are no approved IL-12 therapies currently on the market for the treatment of cancer; however, we are aware of several other companies that have modified IL-12 or intra-tumoral IL-12 delivery programs for the treatment of cancer in development, including Amunix Pharmaceuticals, Inc., AstraZeneca plc / Moderna, Inc., Cullinan Management Inc., Dragonfly Therapeutics, Inc., ImmunityBio, Inc., PDS Biotechnology Corporation, Philogen S.p.A., Sonnet BioTherapeutics, Werewolf Therapeutics, Inc., Xencor Inc. and Zymeworks Inc.

XTX202, if approved, may face competition from other IL-2-based cancer therapies. For example, Proleukin (aldesleukin), a synthetic protein very similar to IL-2, human recombinant interleukin-2 product, is approved and marketed for the treatment of metastatic renal cell carcinoma and melanoma. In addition, we are aware that a number of other companies have modified or low-dose IL-2 programs in development for the treatment of cancer, including Alkermes plc, Anaveon AG, Ascendis Pharma A/S, Asher Biotherapeutics, Inc., Aulos Bioscience, Inc., Bright Peak Therapeutics, Cue Biopharma, Inc., Cugene Inc., Cullinan Management Inc., Egle Therapeutics SAS, GI Innovation, Iovance Biotherapeutics, Inc., Kymab Ltd., Medicenna Therapeutics Corp., Medikine, Inc., Modulate Therapeutics, Inc., Neoleukin Therapeutics, Inc., Philogen S.p.A., Proviva Therapeutics, Inc., Roche AG, Sanofi, Selexcine, SyntheKine, Inc., Trutino Biosciences Inc., Werewolf Therapeutics, Inc., XOMA Corporation and Zydus Cadila.

With respect to XTX301, there are no approved IL-12 therapies currently on the market for the treatment of cancer; however, we are aware of several other companies that have modified IL-12 or intra-tumoral IL-12 delivery programs for the treatment of cancer in development, including Amunix Pharmaceuticals, Inc., AstraZeneca plc / Moderna, Inc., Cullinan Management Inc., Dragonfly Therapeutics, Inc., ImmunityBio, Inc., PDS Biotechnology Corporation, Philogen S.p.A., Sonnet BioTherapeutics, Werewolf Therapeutics, Inc., Xencor Inc. and Zymeworks Inc.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, 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. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced products would harm our business, financial condition and results of operations.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business could be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the **release of clinical trial data**, the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on

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a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;

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- our receipt of approvals by the FDA, EMA and comparable regulatory authorities in other jurisdictions, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- our ability to manufacture and supply clinical trial materials to our clinical trial sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization development of our product candidates; candidates or the potential commercialization of any of our product candidates, if approved; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected.

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

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable with an FDA-licensed reference biologic product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic.

Under the BPCIA, reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval licensure of a competing biologic, so long as their BLA does not rely on the reference product or sponsor’s data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved licensed in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for

biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference

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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. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing, reimbursement and our ability to create meaningful value propositions for patients, prescribers and payors. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions **proves** **prove** to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable insurance coverage, adequate reimbursement levels and cost-effective pricing policies with third-party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, such products may not be considered cost-effective and/or the resulting reimbursement payment rates may be insufficient or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to

country. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

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No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States and coverage and reimbursement for products can therefore differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our ability to demonstrate to these third-party payors that any of our approved product candidates creates a meaningful value proposition for patients, prescribers and payors will be important to gaining market access and reimbursement and there is no guarantee that we will be successful in doing so. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success.

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including:

- the product's efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;

- the product's convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- the approval of other new products for the same indications; and

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- our ability to offer the product for sale at competitive prices.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

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Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Specifically, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a different masking moiety that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or have licensed with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. The United States U.S. Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Our or our licensor's failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case. Moreover, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, to the extent that we license intellectual property in the future, we cannot guarantee that those licenses will remain in force.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions and has have in recent years been the subject of much litigation. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license. Under the Leahy-Smith America Invents Act enacted in 2011, or the AIA, the United

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States moved to a first-to-file system in early 2013 (whereby, assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent), from the previous system under which the first to make a claimed invention was entitled to the patent. Publications of discoveries in the scientific and academic literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications. Furthermore, for U.S.

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applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, external academic scientific collaborators, CROs, CMOs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection.

The issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the

patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art, pre- or post-issuance opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, third parties may have certain ownership interest in some of our owned and in-licensed patents and patent applications. 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

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competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the sponsor may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. 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. Noncompliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates or technology could be found invalid or unenforceable if challenged in court or the USPTO.

Despite the measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms

include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates or technology. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal

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complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on new

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legislation and decisions by the federal courts, and the USPTO, 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, **although currently under review by the U.S. Supreme**

Court, in the case *Amgen v. Sanofi* *the Federal Circuit*, held that broad functional antibody claims are invalid for lack of enablement. In addition, in *Juno v. Kite*, the Federal Circuit held *claims reciting broad antibody and chimeric antigen receptor claims supported by few examples* *genus based on function* invalid for lack of written description. Recently, the Federal Circuit issued a precedential decision in *In re Cellect* (No. 22-1293) that could shorten or eliminate an extended patent term awarded under patent term adjustment if challenged on the basis of *obviousness-type double patenting*. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have obtained allowed patents in the United States that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of our product candidates outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, 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 lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with

respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

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We rely on in-license agreements for patent rights with respect to our product candidates and may in the future acquire or in-license additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses or that we may be unable to acquire or in-license third-party intellectual property that may be necessary or important to our business operations.

We rely on third-party license agreements pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our development programs and product candidates. For example, under our cross-license agreement with AskGene, we have exclusively in-licensed patent rights relating to our IL-2 program. In addition, under our license agreement with City of Hope, we have exclusively in-licensed certain patent rights that cover our anti-CTLA-4 antibody. We also have a license agreement with WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, pursuant to which we received an exclusive worldwide license to specified monoclonal antibodies, or mAbs, and patent rights and know-how controlled by WuXi Biologics, including certain patent rights related to our anti-CTLA-4 mAb program. These license agreements impose diligence, milestone payment, royalty payment and other obligations on us.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third-party intellectual property, technology, processes, and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or manufacturing processes, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

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, in the event we do in-license third-party intellectual property rights, 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.

Under our agreement with City of Hope, we are responsible for the achievement of certain diligence milestones, and our failure to timely achieve such milestones could result in City of Hope's termination of the agreement or conversion of our exclusive licenses under the licensed patents to non-exclusive licenses. If City of Hope terminates the agreement or converts our licenses to non-exclusive licenses as a result of our failure to meet these diligence milestones, then our ability to commercialize products comprising our anti-CTLA-4 antibody may be impaired or we may face increased competition in the commercialization of anti-CTLA-4 antibody products. Furthermore, our agreement with City of Hope is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by one or more third parties, including the licensor.

Under our agreement with AskGene, AskGene retained co-exclusive rights to exploit antigen-binding IL-2 and IL-15 products. Therefore, AskGene could develop and commercialize one or more antigen-binding IL-2 or IL-15 products on a more timely basis than us, if we ever develop such a product, or that are more effective or have more commercial success than products that we may develop. Additionally, AskGene is responsible for prosecution and maintenance of the licensed patents under the agreement and any future third party from whom we may license patent rights may similarly be responsible for prosecution and maintenance of such patents. We have limited control over the activities that are the responsibility of AskGene and would have limited control over the activities that are the responsibility of any future licensor, and it is possible that prosecution and maintenance of licensed patents by AskGene or any future licensor may be less vigorous than had we conducted such activities ourselves.

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Disputes may arise regarding intellectual property subject to our current or any future license agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the amount and timing of payments owed under the license agreements;
- our or our licensor's ability to defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and any partners of ours; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our 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 described in this Quarterly Report on Form 10-Q with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately obtain or protect this intellectual property, our ability to commercialize products could suffer.

Our current and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical or similar to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Any licensor of ours may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that such licensor is 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.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive development of intellectual property.

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We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. 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. Third parties may challenge the validity, enforceability or scope thereof. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. Various post-grant review proceedings, such as *inter partes* review, post-grant review and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such post-grant review proceedings. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates or technology is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. On the other hand, the possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the AIA implemented in March 2013, moved the United States from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the

invention earlier. The AIA includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a USPTO-administered post-grant review system that has affected patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents;

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- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or technology we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

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Our proprietary position depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from designing around or using the same product candidate for another use.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We cannot be certain, however, that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates, and instead may need to rely on secondary intellectual property, including patents or patent applications with claims covering formulations, methods of use and/or methods of manufacture. Method of use patents protect a specified method of using a product, such as a method of treating a particular medical indication. This type of patent may only be enforced against a competitor through indirect infringement, *i.e.*, inducement or contributory infringement, which is more difficult to prove than direct infringement. A competitor may be able to circumvent this type of patent by skinny labelling. Furthermore, 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 products for our targeted indications, physicians may prescribe these products “off-label” for those uses that are covered by our method of use patents. 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 by enforcing patent rights or otherwise.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. For example, significant elements of our product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions and related processes are based on unpatented trade secrets that are not publicly disclosed. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed to publicly or to competitors. We cannot be certain 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 trade secrets and other confidential proprietary know-how, information, or technology both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful.

Third-party claims of intellectual property infringement or violations may prevent or delay our discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and violation of other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation or other adversarial proceedings by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents may ultimately issue because many patent filings cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe **third party** **third-party** intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If any of our product candidates is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods

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of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents or patent applications, the scope of pending or issued patent claims, or the expiration of relevant patents are complete, 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 to commercialization of our product candidates in any jurisdiction. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant third-party patents or incorrectly interpret the relevance, scope, or expiration of a third-party patent or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and

patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Currently, we have certain intellectual property rights under patents and patent applications that we own or have rights to under our inbound license agreements related to our product candidates. Our development of additional product candidates may require the use of proprietary rights held by third parties, and the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and rights to such formulation technology may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others. We may be unable to acquire or in-license any compositions, methods of use, formulations, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by

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such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. 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.

Additionally, we may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration or sponsorship. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Third parties may initiate post-grant proceedings and the Patent Trial and Appeal Board of the USPTO may institute such proceedings to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 this

type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees, consultants and advisers were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. Some of these employees, consultants, advisers, and members of management executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we take steps to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, advisers, and members of management have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

In the future, we may in-license intellectual property that may have been discovered through government funded programs and thus may be subject to federal regulations and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Any of the intellectual property rights that we have licensed or may license in the future and that have been generated through the use of U.S. government funding are subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose, generally referred to as "march-in rights." To our knowledge, none of our current product candidates are subject to march-in rights. However, intellectual property rights that we license in the future could be subject to such limitations. The U.S. government also has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times or be able to rectify any lapse in compliance with these requirements.

In addition, the U.S. government requires that any products embodying the subject invention or produced using the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit

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our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we do not obtain patent term extension for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman **Amendments Act**. The

Hatch-Waxman Amendments permit Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended for each marketing approval and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. 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 the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, 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/or to seek the cancellation of 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.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;

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- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drug and biologic products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of an NDA or BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product

candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Further, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA, or NDA or supplement to an NDA, for certain biological products and drug products, respectively, must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate

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is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain

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may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

Accordingly, any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Disruptions in the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency 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.

Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several in recent years, including for 35 days beginning on December 22, 2018, in 2018 and 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA have and the Securities and Exchange Commission, or the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact

In addition, disruptions may result from events similar to the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. As in the event of early 2022, a similar public health emergency in the FDA has resumed inspections of domestic and foreign facilities to ensure timely reviews of applications for medical products. However, future, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required. In response to the COVID-19 pandemic, the FDA

issued numerous guidance documents and took other actions to facilitate research and development of new drug products. The public health emergency declarations related to COVID-19 ended on May 11, 2023. As a result, the FDA ended some COVID-19-related policies, allowed others to continue for a specified time period and plans to retain certain COVID-19-related policies with changes. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates, extended. Regulatory authorities outside the U.S. have adopted or United States facing similar circumstances may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic a similar public health emergency and may also experience delays in their regulatory activities.

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If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the EU and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the United

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States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, on June 23, 2016, the electorate we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom voted in favor as a result of leaving the withdrawal of the United Kingdom from the EU, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the EU on January 31, 2020 and a transition period to December 31, 2020, was established to allow the United Kingdom and the EU to negotiate the United Kingdom's withdrawal. As a result, effective January 1, 2021, the The United Kingdom is no longer part of the European Single Market and European Union EU Customs Union. A co-operation agreement was signed between the United Kingdom and the EU in December 2020, which was applied provisionally beginning on January 1, 2021 and entered into force on May 1, 2021. The agreement addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. As both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

The U.K.'s withdrawal from the EU took place on January 31, 2020. The EU and the U.K. reached an agreement on their new partnership in the Trade and Cooperation Agreement, or the TC Agreement, which was applied provisionally beginning on January 1, 2021 and which entered into force on May 1, 2021. The TC Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the EU and the U.K. will form two separate markets governed by two distinct regulatory and legal regimes. As such, the TC Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the U.K. is no longer part of the single market. As of January 1, 2021, the Medicines and Healthcare Products products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland continues to be Protocol, Northern Ireland is currently subject to EU rules rules. The United Kingdom and EU have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916), as amended, or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the EU.

Since a significant proportion of the regulatory framework for pharmaceutical products in the U.K. covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales,

and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime Protocol, including with respect to the development, manufacture, importation, regulation of medicinal products in the United Kingdom. Once implemented, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval and commercialization of in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the U.K. For example, context of the U.K. is no longer covered by the centralized procedures Pharmaceutical Strategy for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the U.K. Until December 31, 2023, it is possible for the MHRA to rely on a decision taken Europe initiative, launched by the European Commission or in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the EC, duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the approval pharmaceutical industry and our business in the long term.

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Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling

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abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

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

We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals ~~to~~ **for** the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the Agency to mean the “indication or use.” Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if

we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the

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indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we

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could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in

determining the intended use of a drug or biologic. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

Failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

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

penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU notably under Directive 2001/83EC, as amended, and are also subject to EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all

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areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

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

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and

validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act, or PIE Act, signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

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

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and

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

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States and PRIME Designation in the EU, but we might not

receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME

enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to

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conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

Accelerated approval by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of any of our current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

With passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed; and use expedited procedures to withdraw accelerated approval of a new drug application or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations

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for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDA's guidance closely if we seek accelerated approval for any of our products. Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for

one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a “standard” marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. Pursuant to subsequent legislation, however, these Medicare sequester reductions were reduced and suspended through the end of June 2022, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriation Act’s health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act, which was signed by President Trump on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018 June 17, 2021, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well.

The U.S. Supreme Court heard this case dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such other challenges to repeal or replace the ACA or the health reform measures of the Biden administration will impact the ACA or our business.

[Table](#) In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of [Contents](#)the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Current and future legislative efforts may limit the prices for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services, or HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently That

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regulation was challenged in a lawsuit by the subject Pharmaceutical Research and Manufacturers of ongoing litigation, America, or PhRMA, but at least six the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states (Vermont, Colorado, Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and New Hampshire) Wisconsin) have passed laws allowing for the importation of drugs from Canada with Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting approval. On January 5, 2023, the intent of

developing SIPs FDA approved Florida's plan for review and approval by the FDA. Canadian drug importation.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration until January 1, 2026 by the Infrastructure Investment and Jobs Act. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with the passage of the Inflation Reduction Act of 2022, or the IRA, has been delayed by Congress to January 1, 2032.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B, to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been

licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100% of the cost of their prescriptions until they reach

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the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

We expect that current or future litigation involving provisions of the IRA will have unpredictable and uncertain results on the implementation and impact of the IRA on biotechnology industry generally, as well as our business and current or future products. For example, in June 2023, on June 6, 2023, Merck & Co., or Merck, filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, have including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be affected, effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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

Finally, outside the United States, in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished future profits and earnings, if any.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and

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third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

- *Anti-Kickback Statute.* The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- *False Claims Laws.* The federal false claims laws and civil monetary penalties laws, including the civil False Claims Act and the Civil Monetary Penalty Law, impose criminal and civil penalties, including those from civil

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whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- *HIPAA.* The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program.
- *HIPAA and HITECH.* HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- *False Statements Statute.* The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.
- *Transparency Requirements.* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Department of Health and Human Services information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers, and ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, applicable manufacturers are also required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

- *Analogous State and Foreign Laws.* Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. Payments made to physicians

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in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do

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business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifiable information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the **U.S., United States**, EU and **U.K. United Kingdom**. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission, or FTC, and state attorneys general all are aggressive in reviewing privacy and data security protections for consumers. In addition, new laws have been enacted or are

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considered at both the federal and state levels. As a result, we will need to seek to ensure our business practices comply with evolving rules and guidance at the federal and state level related to privacy and data security in order to mitigate our risk for any potential enforcement action, which may be costly. In addition, if we are subject to an enforcement action and settlement order, we may **by require be required** to adhere to very specific privacy and data security practices or pay fines and adhere to specified compliance requirements, all of which could be costly and adversely impact our business.

For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce, and is in the process of developing rules related to commercial surveillance and data security.

Similarly, in 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California

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residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In addition, the California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents

regarding retention of information. The CPRA also created the California Privacy Protection Agency, a new enforcement agency whose sole responsibility is to enforce the CPRA.

In addition to California, at least 11 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of “sensitive” data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York, Hampshire and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the U.S., United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the EC to offer adequate data protection legislation, such as the U.S., United States. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S., United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S., United States. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S., United States generally and increase our costs of compliance with data privacy legislation, as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The EU initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the [U.S. United](#)

[States](#). However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business at the international level.

[Following](#) Furthermore, while the [withdrawal of the U.K. from the EU, the U.K. Data Protection Act of 2018 applies](#) in the United Kingdom that “implements” and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. The Trade and Cooperation Agreement provides for a transitional period during which the United Kingdom will be treated like a EU member state in relation to processing and transfers of personal data for four months from January 1, 2021. This may be extended by two further months. After such period, the United Kingdom will be a “third country” under the GDPR unless the European Commission adopts an adequacy decision in respect of transfers of personal data to the United Kingdom. The United Kingdom has already determined that [takes place in the U.K. and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the U.K. and it considers all of the EU have determined, through separate “adequacy” decisions,](#) 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data [transfers between flows from the two jurisdictions are in compliance with United Kingdom to the U.K. Data Protection Act 2018 and the GDPR, respectively. Any changes or updates to these adequacy decisions have the potential to impact our business. EU/EEA remain unaffected.](#)

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

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the **U.S. United States** regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We are subject to U.S. and certain foreign export control, import, sanctions, anti-corruption, and anti-money laundering laws and regulations with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 202, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

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Noncompliance with the laws and regulations described above could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China. In March 2018, the Trump administration announced the imposition of tariffs on steel China, and, aluminum entering the United States most recently, proposing legislation that, if passed, would restrict trade with certain Chinese companies that provide biopharmaceutical research, development and in June 2018 announced further tariffs targeting goods imported from China, manufacturing services. Recently, both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities, barriers. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry, industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S.-based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on our CDMO and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to provide or to enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, which could cause us to reevaluate our relationship with our current CDMO, which is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives, located in China. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as export controls, capital controls, tariffs or tariffs, other trade restrictions, may affect the demand for our drug products, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to our manufactured product candidates that we import from China, including pursuant to our manufacturing arrangements and license agreement with WuXi Biologics. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain 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, however 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.

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

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations

applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EC and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters which outline the terms of employment with each of our executive officers, each of them may terminate their employment with us at any time. As such, these employment offer letters do not guarantee our retention of our executive officers for any period of time. In addition, insurance coverage is increasingly expensive, including with respect to directors' and officers' liability insurance, or D&O insurance. We may not be able to maintain D&O insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. An inability to secure and maintain D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is and will be critical to our success. The loss of the services of our executive officers or other key employees could impede, delay or prevent the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize products in the life sciences industry, and specifically our product candidates. We are based in Massachusetts, a state that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their

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former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Additionally, the United States is experiencing a workforce shortage, which

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in turn has created a competitive wage environment, which is likely to further exacerbate the foregoing risks and may impact our ability to retain our executive officers or other key employees. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited and could adversely affect our business, prospects, financial condition and results of operations.

Subject Our cost savings plan and the associated workforce reduction implemented in March 2024 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In connection with our strategic portfolio reprioritization in March 2024, we implemented a workforce reduction, representing approximately 21% of our workforce prior to the reduction in headcount. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. For the three months ended March 31, 2024, we recognized one-time costs of \$0.9 million primarily related to employee severance and benefits continuation. The workforce reduction was completed in April 2024. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results of current and financial condition could be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or future clinical trials and restructuring activities in the future. Furthermore, our workforce reduction may be disruptive to our operations, or could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to raise sufficient additional capital attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to

support our growth strategy, we expect business. Any failure to grow attract or retain qualified personnel could prevent us from successfully developing and commercializing our organization product candidates in the future, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of October 31, 2023, we had 81 full-time employees. Subject to the results of current or future clinical trials and our ability to raise sufficient additional capital to support our growth strategy, we expect to experience future growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory and medical affairs, and, if any of our product candidates receive marketing approval, sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we would need to continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage any such expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations could also lead to significant costs and could divert our management and business development resources. Our inability to effectively manage the expansion of our operations could result in weaknesses in our infrastructure or give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. In addition, growth in our number of employees or scope of our operations could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage any future growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy. approved.

We depend on our information technology systems and associated those of our third-party service providers, and any failure of these systems could harm our business. Security breaches, loss of data, inability to access systems, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability or competitive or reputational harm, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. Our internal information technology systems and infrastructure, and those of our contractors, consultants, vendors, service providers and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, intentional or accidental actions or inactions by persons inside our organization or by persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, supply chain attacks, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, attackers may use artificial intelligence and machine learning to launch more

automated, targeted and coordinated attacks against targets. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. We also may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs,

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viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and

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these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs.

Any security compromise affecting us, our partners, our service providers or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials

could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition. While we do maintain cyber liability insurance, our insurance coverages may not be sufficient in type or amount to cover us against any such losses, claims, or liabilities related to security breaches, cyber-attacks, cyber intrusion, or other related breaches or disruptions.

A variety of risks associated with marketing our product candidates internationally, if approved, could materially adversely affect our business.

We also plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating, including conducting marketing and sales activities, in international jurisdictions if we obtain the necessary approvals, including:

- regulatory requirements in foreign countries that differ from those in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or other comparable foreign regulations;

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- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

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- business interruptions resulting from geo-political geopolitical actions, including war, armed conflicts and terrorism or natural disasters, including pandemics or other outbreaks of infectious disease, earthquakes, typhoons, floods and fires.

Any of these factors, along with other risks associated with international operations, could materially adversely affect our future international expansion and operations and, consequently, our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain sufficient additional capital, which may not be available on favorable terms or at all. These transactions may not be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize any or all potential benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

The impact of the COVID-19 pandemic may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned and any future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, each of which could result in adverse effects on our business, on raising capital and on our operations.

The COVID-19 pandemic has continued to have significant impact, both direct and indirect, on businesses and commerce, including worker shortages and supply chain disruptions. While the FDA approved emergency use authorization of vaccines in December 2020, the emergence of new variants has limited their overall efficacy. Therefore, the future progression of the outbreak and its effects on our business and operations continue to be uncertain. We and our CMOs and CROs may face disruptions in the future that affect our ability to initiate and complete preclinical studies or clinical trials, including recruitment and retention of critical employees, and

disruptions or delays in completing manufacturing activities or in procuring items that are essential for our research and development activities, such as raw materials used in the manufacture of any product candidates we may develop, laboratory supplies used in our preclinical studies, or animals that are used for preclinical testing for which there are shortages because of ongoing efforts to address the outbreak. For example, in 2020, we experienced a temporary shortage of raw material used in the manufacturing process for one of our product candidates.

We may experience additional delays in the future as a result of the impacts of the COVID-19 pandemic or otherwise, which could delay our product development timelines. We and our CMOs and CROs may also face disruptions related to our future IND-enabling studies and clinical trials arising from delays in preclinical studies, manufacturing disruptions, and the ability to obtain necessary IRB, IBC or other necessary site approvals, as well as other delays at clinical trial sites. The global response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that could adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. The COVID-19 pandemic has in the past caused significant disruptions in the financial markets, and may cause such disruptions in the future, which could impact our ability to raise additional funds through the capital markets and may also impact the volatility of our stock price and trading in our stock. In addition, a recession, depression, inflation or other sustained adverse market event resulting from the COVID-19 pandemic, directly or indirectly, could materially and adversely affect our business and the value of our common stock. We cannot be certain what the overall

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impact of the COVID-19 pandemic will be on our business, and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a catastrophic event, such as a terrorist attack, war or other armed conflict, geopolitical tensions or trade wars, pandemic or natural disaster.

We depend on our employees, consultants, CMOs, CDMOs, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including terrorist attacks, wars or other armed conflicts, geopolitical tensions or trade wars, pandemics or natural disasters, these events could result in significant disruptions to our research and development, manufacturing, preclinical studies, clinical trials, and, ultimately, if approved, the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, such as natural disasters, which are increasing in frequency due to the impacts of climate change, the outbreak of wars or other armed conflicts, the escalation of hostilities, geopolitical tensions or trade wars, acts of terrorism or “acts of God,” particularly involving geographies in which we or third parties on whom we depend have offices, manufacturing or

clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us, our CMOs, CDMOs, our CROs, regulatory agencies or other parties with which we are engaged could have a material adverse effect on our operations and financial performance.

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Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may never develop or be sustained.

Although our common stock is listed on the Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, or at all.

The price of our common stock has been, and could continue to be, subject to volatility related or unrelated to our operations and purchasers of our common stock could suffer a decline in value.

The market price of our common stock has been, and may fluctuate significantly continue to be, subject to significant fluctuations in response to numerous factors, many of which are beyond our control. 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, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the results from our preclinical studies and clinical trials;
- the commencement, enrollment or results of any current or future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- clinical trial results from, or regulatory developments regarding, a competitor's product candidate;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- regulatory or legal developments in the United States and foreign countries;

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- 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;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the U.S. Securities and Exchange Commission, or SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, collaborations, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- lower than expected market acceptance of our product candidates, if approved;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;

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- the clinical results of our competitors or potential competitors;
- introduction of new products or services by our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our common stock;
- conditions or trends in our industry;
- our cash position;
- sales of our common stock by us or our stockholders in the future;
- adoption of new, or changes to current accounting standards;
- ineffectiveness of our internal controls;

- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in the structure of healthcare payment systems;
- investors' general perception of our company and our business;

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- overall performance of the equity markets;
- trading volume of our common stock;
- potential inclusion or exclusion of our common stock in exchange, industry, or other tracking indices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws, intellectual property laws or pharmaceutical pricing in the United States or foreign jurisdictions, or speculation regarding such changes;
- future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- developments with respect to public health epidemics or pandemics, such as the COVID-19 pandemic; pandemic, and any recession, depression, or other sustained adverse market event or economic impact resulting from such epidemics or pandemics;

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- general political, economic, industry and economic market conditions; and
- other events or factors described in this “Risk Factors” section, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies’ stock. This risk is especially relevant for us, because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management’s attention and resources from our business.

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

We are required to comply with the continued listing requirements of the Nasdaq Stock Market LLC, or Nasdaq, including, among other things, maintaining a minimum closing bid price of \$1.00 per share, referred to as the minimum bid price requirement, or shares of our common stock may be subject to delisting, which would have a material adverse effect on our business. In January 2024, we received a deficiency letter from the Listing Qualifications Department, or the Nasdaq Staff, informing us that we were not in compliance with the continued listing requirements of the Nasdaq Global Select Market because the bid price for our common stock had closed below \$1.00 per share for 30 consecutive business days. On April 12, 2024, we receive written notification from the Nasdaq Staff informing us that we had regained compliance with the minimum bid price requirement as a result of our common stock maintaining a closing bid price of \$1.00 per share or greater for at for at least 10 consecutive business days. However, there can be no assurance that we will be able to continue to maintain compliance with the minimum bid price requirement or any of the other Nasdaq continued listing requirements.

Any potential delisting of our common stock could have a material adverse effect on the market for, and liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Any delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares of our common stock in the public market.

If securities or industry analysts do not publish research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. A limited number of securities and industry analysts currently publish research on our company. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If

one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

Unfavorable Unstable global economic and political conditions, including economic uncertainty tied to interest rates and heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and results of operations. ability to raise capital.

General Unstable global economic and political conditions, both inside including economic uncertainty tied to interest rates and outside heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and ability to raise capital. The global economy, in particular the U.S., financial markets, have recently experienced significant disruption and volatility, including without limitation, as a result of heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential volatility in commodity prices,

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decline in consumer confidence and economic slowdown or recession, growth, supply chain disruptions, banking disruptions, the COVID-19 pandemic (including variants of COVID-19) and uncertainty resulting from geopolitical events, including trade wars, civil or and political unrest, wars or and other armed conflicts, have resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an inability to raise additional capital. conflicts. In addition, market volatility, high levels of inflation and high interest rate fluctuations rates may increase our cost of financing or restrict our access to potential sources of future capital. For example, Furthermore, our stock price may further decline due in part to the prime rate has recently exceeded volatility of the interest rate floor of 4.75% under

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our loan stock market and security agreement with PacWest, which has increased any general economic downturn. If the amount of cash needed disruption and volatility persist or deepen, we may be unable to service our outstanding indebtedness. Adequate raise sufficient additional financing may not be available to us capital on

acceptable terms, or at all. If we are unable to raise sufficient additional capital, on attractive terms or at all, our business, financial condition, stock price and results of operations could be adversely affected, and we will need to implement cost reduction strategies, which could be forced to delay, reduce include delaying, reducing or altogether terminate one or more current or future terminating both internal and external costs related to our operations and research and development programs. In addition, there is a risk that one or more political developments impacting government spending and international trade, including changes in trade agreements, trade disputes, tariffs and investment restrictions, such as the ongoing trade dispute between the United States and China, may negatively impact markets and cause weaker macroeconomic conditions. These global economic and political factors could also strain certain of our current service providers, suppliers and manufacturers, and other partners may not survive such difficult economic times, which could directly affect including our primary CDMO, possibly resulting in supply disruptions or increased raw material or manufacturing costs, or adversely impacting their ability to attain manufacture clinical trial materials for our operating goals on schedule and on budget. product candidates. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic and geopolitical climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

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

As of October 31, 2023 March 31, 2024, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned shares in the aggregate representing a majority of our outstanding common stock. As a result of their share ownership, these stockholders, if they act together, would have the ability to influence our management and policies and would be able to significantly affect the outcome of matters requiring stockholder approval, such as elections of directors, amendments of our organizational documents or approvals 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 our stockholders may feel are in their best interest.

Some of these persons or entities may have interests different than our unaffiliated stockholders. For example, because many of these stockholders, purchased their shares at prices substantially below the current market price and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- entrench our management and board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have broad discretion regarding use of our cash and cash equivalents, and we may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure

by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value.

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 determination to pay dividends in the future will be at the sole discretion of our board of directors. In addition, the terms of any future debt agreements

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may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

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We are an “emerging growth company” and a “smaller reporting company” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2026, although if the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have annual gross revenues of \$1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- 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 control 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
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404.

We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to “opt out” of such extended transition period or (2) no longer qualify as an EGC or a smaller reporting company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We have incurred and will continue to incur substantial costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and will continue to incur substantial legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection

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Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly.

We are evaluating evaluate developments in these rules and regulations as they are promulgated and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be materially adversely effected.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC or a smaller reporting company with less than \$100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal

control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC or a smaller

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reporting company with less than \$100 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. **We could be an emerging growth company for up to five years.** An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to

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incur the expense of remediation, which could have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition.

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

As a public company, we are subject to certain reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal control over financial reporting, 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. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

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

Changes in tax law may adversely affect our business or financial condition. The Tax Act, enacted on December 22, 2017, as amended by the CARES Act, enacted on March 27, 2020, contained significantly revises the Code. The Tax Act contains, among other things, significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), and the limitation of the deduction for NOLs net operating losses to 80% of current-year taxable income for losses arising in taxable years beginning after December 31, 2017 to 80% of current-year taxable income (though any such NOLs net operating losses may be carried forward indefinitely). In addition, beginning in 2022, the Tax Act eliminates the option to deduct research and elimination of the carryback for NOLs arising in taxable development expenditures currently and requires corporations to capitalize and amortize them over five years beginning after December 31, 2020, the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on or fifteen years (for expenditures attributable to foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits. research).

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, additional economic relief legislation has been was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. The IRA introduced new tax provisions, including a 1% excise tax imposed on certain stock repurchases by publicly traded corporations. The 1% excise tax generally applies to any acquisition by the publicly traded corporation (or certain of its affiliates) of stock of the publicly traded corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the Tax Act, the CARES Act, the IRA, and such additional legislation is and continues to be forthcoming. Such guidance

could ultimately increase or lessen the impact of these laws on our business and financial condition. Congress may enact additional legislation in connection with the COVID-19 pandemic, and as a result of changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may also be enacted, which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, and additional tax legislation.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our second amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to

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replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

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- limit the manner in which stockholders can remove directors from our board of directors;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will 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, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. 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 restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law,

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be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. 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 exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find the either exclusive forum provision contained in our restated certificate of incorporation 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 materially adversely affect our business, financial condition and operating results.

Item 5. Other Information

(c) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as such terms are defined in Items 408(a) and 408(c) of Regulation S-K, respectively) during the quarterly period covered by this report.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit	
Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Exchange Commission on October 26, 2021)
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Exchange Commission on April 3, 2023)
10.1# 4.1	Second Amended Form of Prefunded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Restated Employment Exchange Commission on March 28, 2024)
10.1+*	License Agreement, dated August 3, 2023 March 27, 2024, by between Xilio Development, Inc. and Gilead Sciences, Inc.
10.2+*	Common Stock Purchase Agreement, dated March 27, 2024, between the Registrant and Christopher Frankenfield Gilead Sciences, Inc.
10.3+*	Investor Rights Agreement, dated March 27, 2024, between the Registrant and Gilead Sciences, Inc.
10.4	Securities Purchase Agreement, dated March 28, 2024, among the Registrant and the persons party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Exchange Commission on August 3, 2023 March 28, 2024)
10.2# 10.5	Employment Registration Rights Agreement, dated September 5, 2023 March 28, 2024, by and between among the Registrant and Kevin Brennan the persons party thereto (incorporated by reference to Exhibit 10.1 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Exchange Commission on September 5, 2023 March 28, 2024)
10.3#*	Consulting Agreement, dated September 8, 2023, by and between the Registrant and Martin Huber, M.D.
10.4# 10.6#*	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-40925), filed with the Securities and Exchange Commission on August 14, 2023)

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31.1*	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
31.2*	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

- 32.1+ [Certifications 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](#)
- 101.INS* XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
- 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 (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

Indicates management contract or compensatory plan or arrangement.

† Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information is not material and is a type of information that the Registrant treats as private or confidential.

+ The certifications attached as Exhibit 32.1 are being furnished solely to accompany this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference into such filing.

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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.

XILIO THERAPEUTICS, INC.

Date: November 9, 2023 May 14, 2024

By: /s/ René Russo
René Russo, Pharm.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2023 May 14, 2024

By: /s/ Kevin Brennan
Kevin Brennan
Senior Vice President, Finance and Accounting
(Principal Financial and Accounting Officer)

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Exhibit 10.1

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

LICENSE AGREEMENT

between

XILIO DEVELOPMENT, INC.

and

GILEAD SCIENCES, INC.

Dated as of March 27, 2024

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LICENSE AGREEMENT

This Consulting License Agreement (the “**Agreement**”), effective is made and entered into as of September 8, 2023 (the March 27, 2024 (the “**Effective Date**”), is entered into by and between Xilio Therapeutics, Development, Inc. (the “**Company Xilio**”), a Delaware corporation (“**Company Xilio**”) and Martin Huber, M.D. (the “**Gilead Sciences, Inc.**”, a Delaware corporation (“**Consultant Gilead**”) and with respect to Section 15.7 only, Xilio Therapeutics, Inc., a Delaware Corporation (“**Xilio Parent**”). Xilio and Gilead are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

RECITALS

WHEREAS, Xilio owns and controls certain intellectual property rights with respect to the Company desires to retain the services of the Consultant IL-12 Molecules (as defined herein) and the Consultant desires to perform certain services for the Company; and

WHEREAS, the Consultant is IL-12 Products (as defined herein) in the business of providing Territory (as defined herein); and

WHEREAS, Xilio wishes to grant to Gilead, and Gilead wishes to take, an exclusive license under such services intellectual property rights to develop, manufacture and has agreed to provide such services pursuant to commercialize IL-12 Molecules and IL-12 Products in the Territory, in each case, in accordance with the terms and conditions set forth in this Agreement. below.

NOW, THEREFORE, in consideration of the premises and the mutual covenants promises and promises contained conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which is are hereby acknowledged, by the parties hereto, the parties Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. “Accounting Standards” means, with respect to a Party or its Affiliates or its or their (sub)licensees/Sublicensees, United States Generally Accepted Accounting Principles, International Financial Reporting Standards or such other accounting standards as may be used by such entity, in each case, consistently applied.

1.2. “Action” means any claim, action, suit, arbitration, inquiry, audit, proceeding or investigation by or before, or otherwise involving, any court or other governmental authority.

1.3. “Affiliate” means, with respect to a Party, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party, for as long as such control exists. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or

corporate governance or otherwise; or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.4. **"Agreement"** has the meaning set forth in the preamble hereto.

1.5. **"Alliance Manager"** means the individual appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement.

1.6. **"Annual Net Sales"** means, with respect to a Lead Product or Back-Up Product, as applicable, total Net Sales in the Territory of such Lead Product or Back-Up Product, as applicable, in a particular Calendar Year, calculated in accordance with Accounting Standards.

1.7. **"Anti-Corruption Laws"** means any Applicable Law relating to government procurement, conflicts of interest, bribery, corruption, money laundering or kickbacks, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

1.8. **"Applicable Law"** means, individually and collectively, any and all applicable laws, ordinances, directives, administrative circulars, treaties (including tax treaties), rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time with respect to the applicable jurisdiction, including good laboratory practices, good manufacturing practices and good clinical practices (and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Territory).

1.9. **"[**]"** has the meaning set forth in Section [**].

1.10. **"[**]"** has the meaning set forth in Section [**].

1.11. **"Assigned Regulatory Approvals"** has the meaning set forth in Section 7.2.1(b).

1.12. **"Assigned Regulatory Documentation"** has the meaning set forth in Section 7.2.1(b).

1.13. **"Audit Decision"** has the meaning set forth in Section 8.15.2.

1.14. **"Audit Dispute"** has the meaning set forth in Section 8.15.2.

1.15. **"Auditor"** has the meaning set forth in Section 8.15.2.

1.16. **"Back-Up Molecule"** means (a) each of the IL-12 Molecules [**], (b) any IL-12 Molecule that (i) [**] and (ii) [**] and (c) any IL-12 Molecule that [**]. For clarity, [**].

1.17. “Back-Up Product” means an IL-12 Product containing or comprising any Back-Up Molecule, [**]. For clarity, Back-Up Products include [**].

1.18. “BLA” means a Biologics License Application, as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.19. “Biosimilar Product” means, on a country-by-country basis, with respect to an IL-12 Product, a product that is sold by a Third Party (other than a Sublicensee of Gilead or any of its Affiliates (excluding, for clarity, Settlement Sublicensees)) (a) that has been licensed as a biosimilar or interchangeable biological product by the FDA pursuant to section 351(k) of the PHSA, or any subsequent or superseding law, statute or regulation, and for which an IL-12 Product is the reference product, as defined by section 351(i)(4) of the PHSA, (b) that has been granted a marketing authorization as a similar biological medicinal product by the European Union pursuant to Directive 2001/83/EC and Parliament and Council

Regulation No. (EC) 726/2004, each as may be amended, or any subsequent or superseding law, statute or regulation, and for which such IL-12 Product is the reference medicinal product as defined by Article 10(2)(A) of Directive 2001/83/EC, or (c) whose licensing, approval or marketing authorization from a Regulatory Authority relies on, in whole or in part, (i) a prior Regulatory Approval granted for such IL-12 Product by such Regulatory Authority or (ii) any data generated in support of a prior Regulatory Approval granted for such IL-12 Product by such Regulatory Authority.

1.20. “Breaching Party” has the meaning set forth in Section 13.2.1.

1.21. “Business Day” means a day on which banking institutions in Boston, Massachusetts and Foster City, California are open for business, excluding (a) any Saturday or Sunday, (b) December 26 through December 31 and (c) the seven (7)-day period that begins on a Sunday and ends on a Saturday during which period July 4th occurs.

1.22. “Calendar Quarter” means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

1.23. “Calendar Year” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.24. “Cessation Event” has the meaning set forth in Section 13.3.

1.25. “Change of Control” means, with respect to a Party, any of the following events: (a) any Third Party becomes the beneficial owner, directly or indirectly, as a result of a single transaction or a series of related transactions, of fifty percent (50%) or more of the total voting power of all classes of shares of capital stock or other interests of such Party (or, if applicable, a controlling Affiliate of such Party) then outstanding and normally entitled to vote in the general election of directors of such Party (“**Voting Stock**”), (b) such Party (or, if applicable, a controlling Affiliate of such Party) consolidates with or merges into a Third Party, or any such Third Party consolidates with or merges into such Party (or, if applicable, a controlling Affiliate of such Party), in either event pursuant to a transaction in which fifty percent (50%) or more of the total voting power of all Voting Stock of the surviving entity (or, if applicable, a controlling Affiliate of the surviving entity) then outstanding is not held by the Persons holding at least fifty percent (50%) of the total voting power of all Voting Stock of such Party (or, if applicable, a controlling Affiliate of such Party) outstanding immediately prior to such consolidation or merger; or (c) such Party and its Affiliates convey, transfer or lease all or substantially all of the assets relating to the subject matter of this Agreement to a Third Party through one (1) or more related transactions.

1.26. “Combination Arm” means the arm of the Phase 1 Clinical Trial set forth in the Development Plan that is designed to evaluate the safety, tolerability, pharmacological activity or pharmacokinetics of the Combination Therapy, as further set forth in the Development Plan.

1.27. “Combination Clinical Data” means all data (including raw data) and results generated by or on behalf of a Party or any of its Affiliates, or jointly by or on behalf of Gilead or any of its Affiliates, on the one hand, and Xilio or any of its Affiliates, on the other hand, arising from the performance of the Combination Arm, but excluding any Combination Sample Analysis Results.

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1.28. “Combination Product” means any IL-12 Product that [**].

1.29. “Combination Sample Analysis Results” means all data (including raw data) and results generated by or on behalf of a Party or any of its Affiliates, or jointly by or on behalf of Gilead or any of its Affiliates, on the one hand, and Xilio or any of its Affiliates, on the other hand, arising from the performance of the activities in the sample analysis plan for the Combination Arm.

1.30. “Combination Samples” means any urine, blood, tissue or other biological sample from any patient enrolled (or seeking enrollment) in the Combination Arm.

1.31. “Combination Therapy” means a single therapeutic regimen of the concomitant or sequential administration of (a) a Lead Molecule, on the one hand, and (b) [**], on the other hand. For clarity, Combination Therapy does not include [**].

1.32. “Commercial Milestone Event” has the meaning set forth in Section 8.4.

1.33. “Commercial Milestone Payment” has the meaning set forth in Section 8.4.

1.34. "Commercialization" means any and all activities directed to the preparation for sale of, offering for sale of or sale of an IL-12 Product, including activities related to storing, marketing, promoting, detailing, distributing and importing such IL-12 Product, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, **"to Commercialize"** and **"Commercializing"** mean to engage in Commercialization and **"Commercialized"** has a corresponding meaning.

1.35. "Commercially Reasonable Efforts" means, [**].

1.36. "Competing Product" means any molecule that that contains, comprises or incorporates IL-12.

1.37. "Competing Program" has the meaning set forth in Section 5.6.2(a).

1.38. "Competitive Infringement" has the meaning set forth in Section 9.4.1.

1.39. "Compulsory License" means, with respect to an IL-12 Product in a country or territory, a license or rights granted to a Third Party by a governmental agency (or by Gilead as required by a governmental agency) within such country or territory to sell or offer for sale such IL-12 Product in such or territory under any Patents or Information owned or controlled by either Party or its Affiliates.

1.40. "Compulsory Licensee" means a Third Party granted a Compulsory License.

1.41. "Confidential Information" has the meaning set forth in Section 10.1.

1.42. "Confidentiality Agreement" has the meaning set forth in Section 10.1.

1.43. "Continuation Date" means the date upon which Xilio receives payment of the Continuation Fee in accordance with Section 4.1.2.

1.44. "Continuation Fee" means a Seventy-Five Million Dollar (\$75,000,000) fee to be paid in accordance with Section 4.1.2(a) in the event that Gilead delivers a Continuation Notice.

1.45. "Continuation Notice" has the meaning set forth in Section 4.1.2(a).

1.46. "Control" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 5.1 and Section 5.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party. [**].

1.47. “Covered” or “Cover” means, with respect to a given subject matter and a Patent, that, in the absence of a license granted under, or ownership of, such Patent and in the absence of the benefit of the safe harbor provision under 35 U.S.C. Section 271(e)(1) or other Applicable Law, the making, use, offering for sale, sale or importation or other Exploitation of such subject matter would infringe a Valid Claim (or, for any pending Valid Claim, infringe such Valid Claim as if it were issued) included in such Patent.

1.48. “CT Know-How” means any Information [**]. For clarity, CT Know-How includes [**].

1.49. “CT Patent” means any Patent that [**].

1.50. “Data Package” means (a) the Information set forth on **Schedule 1.50**, (b) the Data Package Disclosure Schedule, as applicable, and (c) as of the Data Package Delivery Date, [**].

1.51. “Data Package Delivery Date” has the meaning set forth in Section 11.2.

1.52. “Data Package Disclosure Schedule” has the meaning set forth in Section 11.3.1.

1.53. “Data Package Trigger Date” means the date on which the following data is available: [**].

1.54. “Data Protection Law” means all Applicable Laws relating to privacy, Processing of Personal Data and security, including the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations and any other law related to the use and disclosure of patient health and medical information, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), and any other data protection, privacy or data security laws applicable to either Party in connection with this Agreement.

1.55. “Defense Proceeding” has the meaning set forth in Section 9.3.1.

1.56. “Development” means all activities related to research, pre-clinical and other non-clinical testing, toxicology, formulation, translational (target engagement, biomarker) studies, clinical studies, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, **“to Develop”** and **“Developing”** means to engage in Development and **“Developed”** has a corresponding meaning.

1.57. “Development/Regulatory Milestone Event” has the meaning set forth in Section 8.3.2.

1.58. “Development/Regulatory Milestone Payment” has the meaning set forth in Section 8.3.2.

1.59. “Development Period” means the period commencing on the Effective Date and ending on the earlier of (a) the date that is [**] after the receipt by Gilead of the complete Data Package (as determined in accordance with Section 4.1.1(b)) and (b) the Continuation Date.

1.60. “Development Plan” means the plan setting forth in reasonable detail the Development activities to be performed by or on behalf of Xilio with respect to the IL-12 Molecules and IL-12 Products, including (a) a reasonably detailed budget of Out-of-Pocket Costs to be incurred with respect thereto and (b) the protocols, statistical analysis plans and sample analysis plans for all clinical trial(s) set forth therein. The initial Development Plan is attached as **Schedule 1.60** to this Agreement.

1.61. “Development Plan Performance Failure” has the meaning set forth in Section 3.7.

1.62. “Dispute” means any dispute, claim or controversy (other than matters that are within the decision-making authority of the JSC pursuant to Section 2.1.3) arising from or related to this Agreement or to the interpretation, application, breach, termination or validity of this Agreement, including any claim of inducement of this Agreement by fraud or otherwise.

1.63. “[]”** has the meaning set forth in [**].

1.64. “Dollars” or “\$” means United States Dollars.

1.65. “Effective Date” has the meaning set forth in the preamble.

1.66. “EMA” means the European Medicines Agency and any successor agency thereto.

1.67. “European Union” or “EU” means the economic, scientific and political organization of member states of the European Union, as its membership may be constituted from time to time.

1.68. “Executive Officer” means, with respect to Xilio, its [**] and with respect to Gilead, its [**].

1.69. “Existing Agreements” means any agreement existing as of the Effective Date and the Data Package Delivery Date, as applicable, by and between Xilio and any of its Affiliates, on the one hand, and one (1) or more Third Parties, on the other hand, [**].

1.70. “Existing Patents” has the meaning set forth in Section 11.2.1.

1.71. “Existing Regulatory Documentation” means the Regulatory Documentation Controlled by Xilio or any of its Affiliates as of the Effective Date or the Data Package Delivery Date, as applicable.

1.72. “Exploit” means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. **“Exploitation”** means the act of Exploiting.

1.73. “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.74. "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.75. "Field" means all human and non-human diagnostic, prophylactic and therapeutic uses, including the prevention, treatment or control of any disease, disorder or condition.

1.76. "Firewall Procedures" has the meaning set forth in Section 5.6.2(b)(iv).

1.77. "First Commercial Sale" means, with respect to an IL-12 Product and a country, the first commercial sale of such IL-12 Product in such country by Gilead, its Affiliates or its or their Sublicensees to a Third Party after all Regulatory Approvals required to market and sell such IL-12 Product have been obtained in such country. **[**]**.

1.78. "FTE" means the equivalent of the work of one (1) full time employee or consultant (i.e., one (1) fully-committed or multiple partially-committed employees or consultants aggregating to one (1) full-time employee or consultant for one (1) Calendar Year (consisting of **[**]** per Calendar Year or such other number as may be agreed by the Parties)) employed or engaged by Xilio (or its Affiliate) who directly performs activities under this Agreement. With respect to any employee or consultant who works fewer than **[**]** per Calendar Year (or such other number as may be agreed by the Parties), such employee or consultant shall be treated as an FTE on a *pro rata* basis based upon the actual number of hours worked in a Calendar Year divided by **[**]**; *provided* that in no event shall any employee or consultant count as more than one (1) FTE regardless of the number of hours worked by such employee or consultant. For clarity, sixty (60) minutes of work performed by one (1) employee or consultant (or aggregated across multiple employees or consultants) on a relevant activity shall be considered one (1) "FTE-hour." In no event shall FTEs include any indirect personnel, including support functions such as managerial, financial, legal and business development.

1.79. "FTE Costs" means, with respect to Xilio for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of Xilio performing the relevant activities under this Agreement.

1.80. "FTE Rate" means **[**]**. With respect to any FTE, all (a) costs and expenses for such FTE, including salaries, wages, bonuses, commissions, benefits, profit sharing, stock option grants, Federal Insurance Contributions Act (FICA) costs and other similar ex-U.S. costs, travel, meals and entertainment, training, recruiting, relocation, operating supplies and equipment and other disposable goods, (b) equipment maintenance costs, utilities, general, administrative and facilities expenses, including allocated building operating costs and depreciation and repairs and maintenance and (c) other overhead, in each case ((a), (b) and (c)), whether internal costs and expenses or amounts paid to Third Parties, are included in the FTE Rate and will not constitute Out-of-Pocket Costs for the purposes of this Agreement.

1.81. "Fully Burdened Manufacturing Cost" means, with respect to an IL-12 Molecule or IL-12 Product, whether as active pharmaceutical ingredient or finished form, supplied by Xilio to Gilead pursuant to Section 6.1 or Section 6.2: **[**]** (a) the Out-of-Pocket Costs paid by Xilio or its Affiliate to subcontractors in connection with the Manufacture and supply of such IL-12 Molecule or IL-12 Product, **[**]** and (b) any internal costs (as measured by FTE Costs for employees) incurred by Xilio **[**]**. In no case shall Fully Burdened Manufacturing Costs include **[**]**. All components of Fully Burdened Manufacturing Costs shall be allocated on a basis consistent with Accounting Standards and consistent with the cost accounting policy applied by Xilio to other similar products that it produces. For clarity, Fully Burdened Manufacturing Costs will not include **[**]**.

1.82. "Gilead" has the meaning set forth in the preamble.

1.83. "Gilead Competitor" means a Third Party company that **[**]**.

1.84. "Gilead CT Know-How" means any CT Know-How **[**]**; *provided, however*, that Gilead CT Know-How excludes **[**]**.

1.85. "Gilead CT Patent" means any CT Patent that **[**]**.

1.86. "Gilead Grantback Know-How" means any Information that is (a) **[**]** (b) **[**]** and (c) **[**]**.

1.87. "Gilead Grantback Patent" means any Patent that **[**]**.

1.88. "Gilead Indemnitees" has the meaning set forth in Section 12.2.

1.89. "Government Official" means (a) any Person employed by or acting on behalf of a government, government-controlled or government-owned agency or entity or public international organization, (b) any political party, party official or candidate, or Person employed by or acting on behalf of any of the foregoing, (c) any Person categorized as a government official under local law or (d) any Person who holds themselves out to be the authorized intermediary of any of the foregoing.

1.90. "IL-12" means **[**]**.

1.91. "IL-12 Molecule" means any molecule owned or controlled by Xilio or its Affiliates that contains, comprises or incorporates IL-12, including **[**]**.

1.92. "IL-12 Product" means any product containing an IL-12 Molecule **[**]**.

1.93. "IND" means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.94. "Indemnification Claim Notice" has the meaning set forth in Section 12.3.1.

1.95. **"Indemnified Party"** has the meaning set forth in Section 12.3.1.

1.96. **"Indication"** means, [**].

1.97. **"Industry Experts"** has the meaning set forth in Section 14.3.

1.98. **"Information"** means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed and that is not generally known to the public.

1.99. **"Initial Disclosure Schedule"** has the meaning set forth in Section 11.2.

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1.100. **"Initiation"** means, with respect to a clinical trial, the [**] dosing of the first human subject in such clinical trial.

1.101. **"Insolvency Event"** means (a) the commencement of any bankruptcy, insolvency, moratorium, liquidation, judicial reorganization proceeding, dissolution, arrangement or proceeding under any creditors' rights law or other similar proceeding by or against Xilio, (b) any applications for, consent by Xilio or acquiescence by Xilio in, the appointment of any trustee, receiver or other custodian for Xilio or a substantial part of its property, (c) any appointment of a trustee, receiver or other custodian for Xilio or a substantial part of its property or (d) any assignment by Xilio for the benefit of creditors.

1.102. **"Investor Rights Agreement"** means the Investor Rights Agreement attached as Schedule 1.102.

1.103. **"[**]"** has the meaning set forth in [**]."

1.104. **"[**]"** means [**].

1.105. **"IRA"** means 42 U.S.C. §§ 1320f *et seq.* and all its subsequent amendments and replacements.

1.106. **"IRA Reduction Event"** has the meaning set forth in Section 8.5.3(c).

1.107. **"Joint CT Know-How"** means any CT Know-How [**].

1.108. **"Joint CT Patent"** means any CT Patent [**].

- 1.109. “Joint Intellectual Property Rights”** has the meaning set forth in Section 9.1.2(a).
- 1.110. “Joint Know-How”** has the meaning set forth in Section 9.1.2(a). For clarity, Joint Know-How [**].
- 1.111. “Joint Patents”** has the meaning set forth in Section 9.1.2(a). For clarity, Joint Patents includes [**].
- 1.112. “Joint Product Patent”** means any Joint Patent that [**].
- 1.113. “Joint Steering Committee” or “JSC”** has the meaning set forth in Section 2.1.1.
- 1.114. “JSC Co-Chairperson”** has the meaning set forth in Section 2.1.1.
- 1.115. “Knowledge”** means [**], of the [**] of Xilio (or any personnel positions equivalent to such job titles).
- 1.116. “Lead Molecule”** means (a) XTX301 [**] and (b) any IL-12 Molecule that [**]. For clarity, [**].
- 1.117. “Lead Product”** means an IL-12 Product [**]. For clarity, [**].
- 1.118. “License”** has the meaning set forth in Section 5.1.
- 1.119. “Licensed Know-How”** means all Information that is Controlled by Xilio or its Affiliates as of the Effective Date or during the Term that [**].

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- 1.120. “Licensed Patents”** means all Patents that are Controlled by Xilio or its Affiliates as of the Effective Date or during the Term that [**].
- 1.121. “Losses”** has the meaning set forth in Section 12.1.
- 1.122. “Major European Market”** means each of [**].
- 1.123. “Manufacture” and “Manufacturing”** means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of an IL-12 Molecule, IL-12 Product or any intermediate or component thereof, including pre-clinical, clinical and commercial manufacture, process development, test method development, manufacturing scale-up, qualification and validation and quality assurance/quality control, release and stability testing.
- 1.124. “Manufacturing Process”** has the meaning set forth in Section 6.4.
- 1.125. “Manufacturing Technology Transfer”** has the meaning set forth in Section 6.4.
- 1.126. “Manufacturing Transition Plan”** has the meaning set forth in Section 6.4.

1.127. "Maximum Fair Price" means a maximum fair price under the IRA's drug price negotiation program as defined in 42 U.S.C. §1320f(c)(3) and all its subsequent amendments and replacements and guidance or regulations promulgated thereunder or any future Applicable Law in the United States that sets or imposes a cap on the price for a drug product that will be charged to, or reimbursed by, the United States (or any department or agency thereof) or any healthcare program administered by or on behalf thereof.

1.128. "Medicare Price" means, in respect of an IL-12 Product, the average negotiated price (as defined in Section 1860D-2(d) of the Social Security Act) under prescription drug plans or medicare advantage prescription drug plans for such IL-12 Product.

1.129. "Net Sales" means [**].

1.130. "Non-Breaching Party" has the meaning set forth in Section 13.2.1.

1.131. "Notice Period" has the meaning set forth in Section 13.2.1.

1.132. "Other Components" has the meaning set forth in the definition of "Combination Product."

1.133. "Out-of-Pocket Costs" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards consistently applied) by a Party (or its Affiliate) directly incurred in the conduct of any applicable activities under this Agreement [**].

1.134. "Party" and "Parties" have the meaning set forth in the preamble hereto.

1.135. "Patent Challenge" has the meaning set forth in Section 13.2.2.

1.136. "Patents" means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from

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the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.137. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.138. "Personal Data" means any information relating to an identified or identifiable individual or household or that is otherwise regulated under Data Protection Law. Personal Data shall include "protected health information" as that term is defined at 45 C.F.R. § 160.103.

1.139. "Pharmacovigilance Agreement" has the meaning set forth in Section 3.4.2(a).

1.140. "Phase 1 Clinical Trial" means a human clinical trial of an IL-12 Product, the principal purpose of which is a preliminary determination of safety, tolerability, pharmacological activity or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended, or the corresponding foreign regulations.

1.141. "Phase 2 Clinical Trial" means a controlled human clinical trial of an IL-12 Product, the principal purpose of which is to evaluate the effectiveness of such IL-12 Product for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with such IL-12 Product, including the trials referred to in 21 C.F.R. § 312.21(b), as amended, or the corresponding foreign regulations.

1.142. "[]"** has the meaning set forth in Section [**].

1.143. "Phase 2a Monotherapy Dose Expansion Study" means the clinical trial referred to in the Development Plan as the "Phase 2A: Monotherapy Proof-of-Concept for XTX301" as of the Effective Date, which is designed to evaluate the efficacy and safety of XTX301 as a monotherapy in pre-specified tumor types.

1.144. "Phase 3 Clinical Trial" means, with respect to an IL-12 Product, (a) a human pivotal clinical trial for such IL-12 Product, the results of which, together with prior data and information concerning such IL-12 Product, would (if such human clinical trial meets its primary endpoints) be sufficient to support the filing of a BLA for such IL-12 Product in the United States or (b) a foreign clinical trial that is equivalent to the one described in the preceding clause (a). For clarity, a human clinical trial that does not meet the foregoing criteria when it is Initiated, but later meets the foregoing criteria shall constitute a Phase 3 Trial for purposes of this Agreement only at the time the applicable Regulatory Authority acknowledges that such human clinical trial meets such criteria and, for purposes of Section 8.3, such Phase 3 Trial shall be deemed to be Initiated as of the date of such acknowledgement.

1.145. "PHSA" means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.146. "PMDA" means Pharmaceuticals and Medical Devices Agency of Japan and any successor agency thereto.

1.147. "Pre-Existing Entities" has the meaning set forth in Section 5.6.2(a).

1.148. "Price Applicability Period" has the meaning set forth in 42 U.S.C. § 1320f(b)(2).

1.149. "Processing" means any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, including collection, recording, organization, storage, retention, access, adaptation, alteration, retrieval, consultation, use, disclosure, dissemination, making available, alignment, combination, blocking, deleting, erasure or destruction.

1.150. "Product Agreement" has the meaning set forth in Section 4.3.2.

1.151. "Product Information" has the meaning set forth in Section 10.1.

1.152. "Product Patent" means any Licensed Patent that [**]. As of the Effective Date, the Product Patents are set forth on **Schedule 1.152**.

1.153. "Product Trademarks" means the Trademark(s) used or to be used by Gilead or its Affiliates or its or their Sublicensees for the Commercialization of IL-12 Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory, including any unregistered Trademark rights related to the IL-12 Products as may exist through use before, on or after the Effective Date (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or its or their (sub)licensees/Sublicensees).

1.154. "Proposal" has the meaning set forth in Section 14.3.

1.155. "Purchase Agreement" means the Purchase Agreement attached as **Schedule 1.155**.

1.156. "Regulatory Approval" means, with respect to a country in the Territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market an IL-12 Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

1.157. "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of IL-12 Molecules or IL-12 Products in the Territory, including the FDA in the United States, the EMA in the European Union and the PMDA in Japan.

1.158. "Regulatory Documentation" means: all (a) applications (including all INDs and BLAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint

files; and (c) clinical and other data contained or referenced in any of the foregoing; in each case ((a), (b) and (c)), relating to [**].

1.159. “Regulatory Exclusivity” means, with respect to an IL-12 Product in any country in the Territory, an additional market protection, other than Patent protection, granted by a Regulatory Authority

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in such country that (a) confers an exclusive Commercialization period during which Gilead or its Affiliates or its or their Sublicensees have the exclusive right to market and sell such IL-12 Product in such country for all indications and other conditions of use, routes of administration, dosage forms and strengths approved in such country, or (b) prohibits a Person from (i) relying on safety or efficacy data generated by or on behalf of a Party with respect to such IL-12 Product in an application for Regulatory Approval of a Biosimilar Product or (ii) otherwise submitting such an application or obtaining such Regulatory Approval, in each case ((i) and (ii)), for all indications and other conditions of use, routes of administration, dosage forms and strengths approved for such IL-12 Product in such country.

1.160. “Restricted Purpose” means the purpose of obtaining any Regulatory Approval for or otherwise promoting or commercializing the Combination Therapy [**], including obtaining any expansion or modification of any Regulatory Authority-approved label for an IL-12 Product to reference the Combination Therapy [**].

1.161. “Requirements” has the meaning set forth in Section 14.3.

1.162. “Reversion Product” means [**].

1.163. “Royalty-Bearing Patent” means, for a given Lead Product or Back-Up Product in a given country in the Territory, [**].

1.164. “Royalty Term” means, with respect to a Lead Product or Back-Up Product, as applicable, and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Lead Product or Back-Up Product, as applicable, in such country and ending on the latest to occur of: (a) the [**] anniversary of the First Commercial Sale of the first Lead Product or Back-Up Product, as applicable, in the Field in such country; (b) the first date on which [**] in such country; and (c) the first date on which [**] in such country.

1.165. “RP2D” means the recommended dose of a Lead Product for dosing of such Lead Product in the Phase 2a Monotherapy Dose Expansion Study, as such dose has been determined by the conduct of Phase 1 Clinical Trials to be safe and tolerable.

1.166. “Safety Concern” means, with respect to any IL-12 Product, [**].

1.167. “Selected Drug” means a drug selected under the IRA's drug price negotiation program, as described in 42 U.S.C. § 1320f-1.

1.168. “[**]” means [**].

1.169. “**Serious Adverse Event**” has the meaning set forth in 21 C.F.R. § 312.32 (as may be amended or replaced).

1.170. “**Settlement Sublicensee**” means a Third Party to which Gilead or its Affiliate grants a sublicense to [**].

1.171. “**Step-In Activities**” has the meaning set forth in Section 3.7.

1.172. “**Step-In Know-How**” means any Information [**] that [**].

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1.173. “**Sublicensee**” means a Third Party, other than a distributor and other than a Settlement Sublicensee, that is granted a sublicense by Gilead or its Affiliate under the grants in Section 5.1, as provided in Section 5.3.

1.174. “**Supply Agreement**” has the meaning set forth in Section 6.3.2.

1.175. “**Term**” has the meaning set forth in Section 13.1.

1.176. “**Termination Notice**” has the meaning set forth in Section 13.2.1.

1.177. “**Territory**” means the entire world.

1.178. “**Third Party**” means any Person other than: Xilio, Gilead and their respective Affiliates.

1.179. “**Third Party Claims**” has the meaning set forth in Section 12.1.

1.180. “**Third Party Infringement Claim**” has the meaning set forth in Section 9.6.

1.181. “**Third Party Payments**” has the meaning set forth in Section 8.7.

1.182. “**Third Party Right**” has the meaning set forth in Section 9.7.1(a).

1.183. “**Trademark**” means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design, business symbol, domain name, URL, social media tag or handle, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.184. “**Transferred Xilio Materials**” has the meaning set forth in Section 3.6.

1.185. "United States" or "U.S." means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.186. "UPC Opt-In" means, with respect to a Patent that has previously been opted out of the exclusive competence of the Unified Patent Court pursuant to Article 83(3) of the Agreement on a Unified Patent Court ((2013/C 175/01), 20.6.2013, OJEU 175/1), withdrawing the UPC Opt-Out of such Patent pursuant to Article 83(4) of the Agreement on a Unified Patent Court.

1.187. "UPC Opt-Out" means, with respect to a Patent, opting such Patent out of the exclusive competence of the Unified Patent Court pursuant to Article 83(3) of the Agreement on a Unified Patent Court ((2013/C 175/01), 20.6.2013, OJEU 175/1).

1.188. "U.S. Bankruptcy Code" has the meaning set forth in Section 13.4.

1.189. "Valid Claim" means a claim of any (a) United States or foreign pending patent application that has not, in the country in question, been finally cancelled, finally rejected, withdrawn, expired or abandoned, without the opportunity for appeal or (b) issued and unexpired Patent, where the claim (i) has not been subject to irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer, (ii) is neither admitted to be invalid or unenforceable through reissue nor subject to ongoing reissue proceedings and (iii) has not been held permanently revoked, invalid or unenforceable by a holding,

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finding or decision of a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal; *provided* that Valid Claim shall exclude any such pending claim that has not been granted within [**] following the earliest priority filing date for such application unless and until such pending claims are granted.

1.190. "Voting Stock" has the meaning set forth in the definition of "Change of Control."

1.191. "[]"** has the meaning set forth in [**]."

1.192. "[]"** means [**].

1.193. "[]"** means [**].

1.194. "Xilio" has the meaning set forth in the preamble hereto.

1.195. "Xilio CT Know-How" means any CT Know-How, including any Combination Clinical Data, that [**].

1.196. "Xilio CT Patent" means any CT Patent that [**].

1.197. "Xilio Indemnitees" has the meaning set forth in Section 12.1.

1.198. "Xilio Obligations" has the meaning set forth in Section 15.7.

1.199. "Xilio Ongoing Activities" has the meaning set forth in Section 5.2.1.

1.200. "Xilio Parent" has the meaning set forth in the preamble hereto.

1.201. "XTX301" means the [**].

1.202. "[**]" means [**].

ARTICLE 2 GOVERNANCE

2.1. Joint Steering Committee.

2.1.1. **Membership.** Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC") to coordinate, oversee and, as applicable, approve Xilio's Development and Manufacturing activities related to the IL-12 Molecules and IL-12 Products in accordance with this Article 2. The JSC shall consist of [**] representatives from each Party (or such other number as the Parties may agree). Each Party shall designate one (1) of its representatives of the JSC as a co-chairperson of the JSC (each, a "JSC Co-Chairperson"). Each Party may replace its appointed JSC representatives at any time upon reasonable written notice to the other Party. The JSC Co-Chairpersons, in consultation with the Alliance Managers, shall have the following roles and responsibilities: (a) to call meetings, send notice of each such meeting and designate the time, date and place of each such meeting; (b) to convene or poll the representatives by other permitted means; and (c) to approve (including via email) the final minutes of any meeting of the JSC. The JSC Co-Chairpersons shall have no other authority or special voting power.

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2.1.2. Responsibilities.

The responsibilities of the JSC shall be:

(a)[**];

[**]; and

(j)to perform such other functions as expressly set forth in this Agreement or as appropriate to further the purposes of this Agreement, as determined by the Parties.

2.1.3. **Decision-Making.** The JSC shall make decisions unanimously, with each Party's representatives collectively having one (1) vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one representative appointed by each Party. In the event the JSC cannot reach agreement regarding any matter within the JSC's authority for a period of [**], then either Party may elect to submit such matter to the Parties' Executive Officers, and if a Party makes an election to refer a matter to the Executive Officers, then the Executive Officers shall [**]. If the Executive Officers are unable to reach

consensus on any such matter within [**] after its submission to them, then, subject to Section 2.1.4, such matter shall be resolved in accordance with the provisions of this Section 2.1.3:

(a) prior to the Continuation Date:

(i) subject to Section 2.1.4, Gilead shall have the final decision-making authority for [**];

(ii) subject to Section 2.1.4, Xilio shall have final decision-making rights with respect to [**]; and

(iii) except as set forth in clause (i) or (ii), neither Party shall have final decision-making rights with respect to all other matters within the jurisdiction of the JSC (and such matters shall not be resolved, and the *status quo* shall remain, without written agreement of the Parties at the JSC), including: [**].

(b) From and after the Continuation Date:

(i) neither Party shall have final decision-making rights with respect to (and any such matter shall not be resolved, and the *status quo* shall remain, without written agreement of the Parties at the JSC) [**]; and

(ii) except as set forth in clause (i) and subject to Section 2.1.4, [**].

For clarity, subject to the foregoing provisions of this Section 2.1.3, each Party will have final decision-making authority over [**].

2.1.4. Limitations. Notwithstanding Section 2.1.3, no Party may, without the other Party's prior written consent, exercise its final decision-making authority on any matters in a manner that (a) requires that the other Party take or decline to take any action that would result in a violation of Applicable Laws or any agreement with any Third Party that exists as of the Effective Date or is otherwise entered into after the Effective Date in accordance with this Agreement or the infringement of intellectual property rights of any Third Party, (b) reduces the other Party's rights under this Agreement, or (c) updates or amends the then-current Development Plan in a manner that would increase the other Party's total Out-of-Pocket Costs, in the aggregate, by [**] of the total Out-of-Pocket Costs that were included in the last

budget provided to the JSC and corresponding to the most recent Development Plan approved by the JSC without a Party's exercise of its final decision-making right in Section 2.1.3. The JSC shall have no authority other than that expressly set forth in Section 2.1.2 and, specifically, shall have no authority to (v) make a decision that is expressly stated to require the consent or approval of the other Party in this Agreement, (w) make a determination as to whether a particular milestone or other criteria has been achieved or that any of a Party's obligations under this Agreement have been fulfilled, (x) amend or add to a Party's consent or approval rights, (y) amend, modify or waive

compliance with this Agreement, each of which may only be amended or modified as provided in Section 15.6 or compliance with which may only be waived as provided in Section 15.9, or (z) determine whether or not a breach of this Agreement has occurred.

2.1.5. JSC Meetings. No later than [**] after the Effective Date, the JSC shall hold a meeting to establish the JSC's operating procedures, and the JSC shall meet [**] thereafter, unless the Parties agree in writing to a different frequency. Additional meetings of the JSC may be held with the consent of each Party (such consent not to be unreasonably withheld, conditioned or delayed), as required under this Agreement or to resolve any matter or dispute referred to the JSC in accordance with this Agreement. In the case of any matter or dispute referred to the JSC, such meeting shall be held within [**] following such referral to the JSC. Employees or consultants of either Party that are not representatives of the Parties on the JSC may attend JSC meetings with prior notice and with respect to any consultants, prior consent, of the other Party; *provided, however*, that such attendees: (a) shall not vote; (b) shall not be counted when determining whether a quorum exists at any such meeting; and (c) shall be bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article 10. A JSC meeting may be held either in person or by audio, video or internet teleconference with the consent of each Party. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in the JSC meetings.

2.1.6. Duration and Scope of JSC and Subsequent Information Sharing. The JSC shall continue to exist until the first to occur of (a) completion of the Xilio Ongoing Activities described in clause (a) or clause (b) of the definition thereof, (b) the Parties agreeing in writing to disband the JSC, (c) termination of this Agreement in accordance with the terms hereof and (d) [**]. Upon the occurrence of any of the foregoing, (i) the JSC shall disband, have no further responsibilities or authority under this Agreement and shall be considered dissolved by the Parties; (ii) any requirement of a Party to provide Information or other materials to the JSC shall be deemed a requirement to provide such Information or other materials to the other Party; and (iii) [**].

2.2. Additional Subcommittees and Working Groups. The JSC may establish other subcommittees or working groups as needed to further the purposes of this Agreement, including any responsibilities assigned to the JSC under this Agreement; *provided, however*, that the JSC shall not delegate its dispute resolution authority. The purpose, scope and procedures of any such subcommittee or working group shall be agreed in writing by the JSC.

2.3. Alliance Managers. Promptly following the Effective Date, each Party shall designate in writing (which may be via email) an Alliance Manager to serve as the primary point of contact for the Parties regarding all activities contemplated under this Agreement. Each Alliance Manager shall, among other things: (a) facilitate communication and coordination of the Parties' activities under this Agreement relating to the IL-12 Molecules and the IL-12 Products; (b) coordinate meetings between members of each Party's Development Plan teams; and (c) attempt to resolve conflicts with respect to the Development Plan. The Alliance Managers shall be non-voting members of the JSC. The Alliance Managers shall be allowed to attend meetings of the JSC, as well as any subcommittee or working group established by the JSC of

which the Alliance Manager is not a member. From time to time, each Party may substitute its Alliance Manager at any time upon written notice to the other Party.

2.4. [**].

ARTICLE 3 DEVELOPMENT PERIOD

3.1. Development Plan.

3.1.1. Attached hereto as **Schedule 1.60** is the initial Development Plan. The JSC shall review the Development Plan [**] for the purpose of considering appropriate amendments thereto, and either Party, through its representatives on the JSC, may propose amendments to the Development Plan at any time, *provided* that no amendment to the Development Plan shall be effective until it is approved by the JSC in accordance with Section 2.1.3. Once approved by the JSC, each amended Development Plan shall replace the prior Development Plan. For clarity, [**]. At least once per Calendar Year, [**].

3.1.2. Without limiting Section 3.1.1, the Parties acknowledge and agree that (a) notwithstanding anything to the contrary herein, [**] and (b) the Development Plan as of the Effective Date contains clinical trial(s) (or arms thereof) that are not yet set forth in the protocol for such clinical trial(s) [**], and the JSC shall develop and approve [**], in each case, for incorporation into the Development Plan. For clarity, [**].

3.1.3. Neither Party shall perform any Development activities with respect to any IL-12 Molecule or IL-12 Product during the Development Period that are not set forth in the Development Plan.

3.2. **Performance; Costs.** Xilio shall [**]; *provided* that Xilio shall not be held liable or responsible for any delay or failure to perform any Development activities under the Development Plan to the extent such delay or failure is attributable to [**]. Except as otherwise agreed in writing by the Parties, Xilio shall bear all costs and expenses incurred by or on behalf of it in the performance of the Development activities in the Territory set forth in the Development Plan. Xilio shall perform, or cause to be performed, any such Development activities [**] to complete such Development activities in accordance with the Development Plan.

3.3. **Subcontracting.** Prior to the Continuation Date, Xilio shall [**]; *provided* that [**]. From and after the Continuation Date, Xilio shall [**]. As between the Parties, Xilio shall (a) be responsible for the acts and omissions of its subcontractors and (b) ensure that its Third Party subcontractors comply with the applicable terms and conditions of this Agreement, including Article 9 (including supporting all grants and assignment of rights and ownership hereunder) and Article 10.

3.4. Combination Arm.

3.4.1. Generally.

(a) **Sites.** Notwithstanding any provision to the contrary in this Agreement, Xilio shall [**].

(b) **Informed Consent.** Xilio shall [**]. Any proposed changes to the template informed consent form requested by an institutional review board or Combination Study site

that would [**]. Xilio shall consider in good faith any comments provided by Gilead and shall incorporate any reasonable comments provided by Gilead with respect to [**]. Xilio shall ensure that each informed consent form for the Combination Arm [**].

(c) **Use of Combination Samples from Patients in the Combination Arm.** Xilio shall [**].

(d) **Sample Analysis Results.** Xilio shall provide to Gilead any Combination Sample Analysis Results generated by or on behalf of Xilio, [**] after the Continuation Date or, if such Combination Sample Analysis Results are generated after the Continuation Date, then [**].

3.4.2. Data and Information Sharing.

(a) **Pharmacovigilance Agreement.** Prior to [**], the Parties shall enter into a pharmacovigilance agreement to ensure the exchange of relevant safety data with respect to the Combination Therapy within appropriate timeframes and in appropriate format to enable the Parties to fulfill their respective regulatory reporting obligations and to facilitate appropriate safety reviews, all in accordance with Applicable Laws ("**Pharmacovigilance Agreement**"). From and after the effective date thereof, each Party shall perform its obligations under the Pharmacovigilance Agreement. In the event of a conflict between the terms of this Agreement and the terms of the Pharmacovigilance Agreement, the terms of the Pharmacovigilance Agreement shall control to the extent related to pharmacovigilance matters, and the terms of this Agreement shall control in all other respects. Without limiting the foregoing, any disagreement regarding pharmacovigilance matters under the Pharmacovigilance Agreement shall be resolved in accordance with the applicable dispute resolution mechanism set forth in the Pharmacovigilance Agreement.

(b) **Final Study Report.** Without limiting Section 3.9, [**], Xilio shall provide Gilead with [**], and Gilead shall [**]. Xilio shall consider in good faith any comments provided by Gilead and shall incorporate any comments provided by Gilead with respect to [**]. Xilio shall provide to Gilead [**]. Notwithstanding the foregoing, if [**], then the Parties shall [**].

(c) [**].

3.4.3. Compliance.

(a) **Financial Disclosure.** Xilio shall (i) track and collect financial disclosure information from all "clinical investigators" involved in the Combination Arm and (ii) subject to Section 3.5, prepare and submit the certification or disclosure of the same in accordance with all Applicable Law, including 21 C.F.R. Part 54 (Financial Disclosure by Clinical Investigators) and related FDA guidance documents. Prior to the initiation of clinical activities under the Combination Arm, but in any event within [**] or such other date as the Parties may agree in writing, the Parties shall determine whether Xilio shall track and collect from all "clinical investigators" involved in the Combination Arm separate certification or disclosure forms for each of Gilead and Xilio or one (1)

“combined” certification or disclosure form for both Gilead and Xilio. For purposes of this Section 3.4.3(a), the term “clinical investigators” shall have the meaning set forth in 21 C.F.R. 54.2(d).

(b) **Transparency Reporting.** The Parties acknowledge that Gilead may be required to disclose certain payments and other transfers of value, including [**] made to health care professionals (including investigators, steering committee members, data monitoring committee members and consultants) in connection with the Combination Arm in accordance with reporting requirements under Applicable Law, including the federal Open Payments Program and state and foreign laws, the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and Xilio shall be solely responsible for providing such information to Gilead in a form and manner and on a timeline reasonably specified by Gilead. [**] Xilio shall provide to Gilead, in writing, Xilio’s point of contact for purposes of receiving information from Gilead pursuant to this Section 3.4.3(b) along with such contact’s full name,

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email address and telephone number. Where applicable, Gilead shall provide to such Xilio contact all information regarding [**] required for such reporting. Xilio acknowledges that, notwithstanding any provision to the contrary in this Agreement, information about the payments and reimbursements provided hereunder may be disclosed without notice by Gilead and may be made publicly available by the recipient federal or state agency, in each case, to the extent required by Applicable Law.

(c) **Clinical Trial Registry.** Xilio shall register the Combination Arm with the Clinical Trials Registry located at www.clinicaltrials.gov as well as the EudraCT database (and any other foreign equivalent) and shall list Gilead as a collaborator with respect to the Combination Arm; *provided, however*, that the content and wording of any such listing shall be approved by Gilead in writing prior to such registration, such consent not to be unreasonably withheld, conditioned or delayed.

3.4.4. No Exclusivity. Subject to each Party’s obligations under Section 3.1.3, Article 9 and Article 10 and Xilio’s obligations in Section 5.6 and the License grant in Section 5.1, nothing in this Agreement is intended or shall be construed to create any exclusive relationship between the Parties or otherwise prohibit or restrict either Party, directly or indirectly, from developing, commercializing or otherwise pursuing any product, program, technology or process, whether or not similar to or competitive with the Combination Therapy or any other product, program, technology or process.

3.5. Regulatory. Prior to the Continuation Date:

3.5.1. As between the Parties, Xilio shall have the sole right to prepare, obtain and maintain INDs and other Regulatory Documentation and other submissions to Regulatory Authorities in the Territory and to conduct communications with the Regulatory Authorities in the Territory for IL-12 Products, including with respect to the Combination Arm.

3.5.2. Xilio shall provide Gilead with all Regulatory Documents for IL-12 Products [**] (and (a) in the case of any IND, [**] and (b) in the case of other filings or communications (including

any IND or protocol amendment filing), [**] (or, if less, the longest reasonably possible time period consistent with any deadline specified by the applicable Regulatory Authority)) of the submission thereof for Gilead's review and comment. Xilio shall consider in good faith any such comments of Gilead, and to the extent such filing, communication or document [**] not proceed with such filing, communication or document unless and until such filing, communication or document is approved by Gilead in writing; *provided* that nothing set forth herein will prohibit Xilio from taking such actions necessary to comply with its obligations under Applicable Law or requirements of any Regulatory Authority. Xilio shall provide to Gilead an as-filed copy of any such regulatory filing, communication or document promptly after it is made.

3.5.3. Xilio shall provide Gilead with prior written notice of any scheduled meeting, conference or discussion (including any advisory committee meeting) with a Regulatory Authority with respect to any IL-12 Product within [**] after Xilio or its Affiliate first receives notice of the scheduling of such meeting, conference or discussion (or within such shorter period as may be necessary in order to give Gilead a reasonable opportunity to attend such meeting, conference or discussion). Upon Gilead's request, to the extent reasonably practicable, Gilead shall have the right to [**]; *provided* that if Gilead [**].

3.5.4. In connection with any filing, meeting or other communication (written or oral) to any Regulatory Authority, Xilio shall [**].

3.5.5. Without limiting the foregoing, each Party shall provide to the other Party a copy of any written communication received by such Party from any Regulatory Authority with respect to the IL-12 Products (including the Combination Arm and Combination Therapy) [**].

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3.6. Transfer of Materials. Prior to the Continuation Date, Xilio shall transfer to Gilead or its designee [**] of materials (including the IL-12 Molecules and IL-12 Products) as Gilead may request [**] (the "**Transferred Xilio Materials**") [**]. Until the Continuation Date, Gilead shall only use the Transferred Xilio Materials: [**].

3.7. Gilead Step-In. If, at any time during the Development Period, [**] Gilead shall have the right, upon written notice to Xilio [**] to elect to conduct the activities to be conducted by Xilio under the Development Plan as of the date of such notice [**] (the "**Step-In Activities**") itself in accordance with this Section 3.7.

3.7.1. If Gilead provides such notice, then (a) Xilio shall [**] to conduct such Step-In Activities, including that [**].

3.7.2. If Gilead exercises its step-in right pursuant to this Section 3.7 and does not provide a Continuation Notice prior to the end of the Development Period, then Gilead shall [**].

3.8. Records. Xilio shall maintain, in good scientific manner, complete and accurate books and records pertaining to its Development activities, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for patent and regulatory purposes,

in compliance with Applicable Law and that properly reflect all work done and results achieved in the performance of such activities. Such books and records shall record only such activities and shall not include or be commingled with records of activities outside the scope of this Agreement. Such books and records shall be retained by Xilio for [**] or for such longer period as may be required by Applicable Law. Gilead shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of Xilio maintained pursuant to this Section 3.8; *provided* that (a) Gilead shall maintain such records in confidence in accordance with Article 10 and (b) such inspections may not (i) be conducted for any Calendar Quarter [**], (ii) be conducted [**] or (iii) be repeated for any Calendar Quarter. Without limiting the foregoing, Xilio shall provide Gilead with access to or copies of any such records relating to the Combination Arm or, from and after the Continuation Date, relating to the IL-12 Molecules or IL-12 Products, in each case, as reasonably requested by Gilead from time to time.

3.9. Reports. Without limiting Section 3.8 or Section 4.3, [**] during which Xilio performs any Development activities, Xilio shall provide to Gilead a detailed report of such activities it has performed, or caused to be performed, since the preceding report, its activities in process, the future activities it expects to initiate during [**] and all Information (including all Combination Clinical Data) from Development activities performed under the Development Plan. Without limiting the foregoing, Xilio shall [**].

ARTICLE 4

DATA PACKAGE; CONTINUATION NOTICE

4.1. Submission of Data Package; Continuation Notice.

4.1.1. Delivery of Data Package.

(a) Within [**] after the Data Package Trigger Date [**], Xilio shall deliver to Gilead the Data Package and shall provide Gilead with electronic access to all data and other Information included or referenced in such Data Package, in each case, in a form and format agreed by the JSC.

(b) Gilead will [**] either (i) confirm to Xilio that such Data Package is complete, or (ii) [**]. If Gilead [**], then Xilio shall [**] *provided* that, for clarity, Xilio shall not have any

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obligation under this Section 4.1.1(b) to perform any Development activities other than those set forth in the Development Plan as of the Data Package Trigger Date. In addition, Xilio shall [**] such other Information relating to its then-current or previously completed Development activities that is in the possession or control of Xilio or any of its Affiliates as Gilead may reasonably request, which requests, for clarity, shall not extend the Development Period or be deemed part of the Data Package.

4.1.2. Continuation Notice.

(a) At any time prior to expiration of the Development Period, Gilead shall have the right to deliver a written notice to Xilio that it desires to continue the further Development and other Exploitation of IL-12 Molecules and IL-12 Products (the “Continuation Notice”) in accordance with Section 15.5, in which case Xilio will provide an invoice to Gilead for the Continuation Fee within [**] after Xilio's receipt of the Continuation Notice, and Gilead shall pay to Xilio the non-refundable and non-creditable Continuation Fee within [**] after the receipt of such invoice.

(b) From and after the Continuation Date, subject to the terms of this Agreement, including Section 4.3.3, Gilead shall have sole control of the Development, Manufacture, Commercialization and Exploitation of all IL-12 Molecules and IL-12 Products and, subject to Xilio's performance of the Xilio Ongoing Activities, shall have the right to perform all global Development, Manufacture and Commercialization of the IL-12 Molecules and IL-12 Products thereafter.

4.2. Expiration of Development Period Without Continuation Notice. If Gilead does not provide a Continuation Notice on or before the end of the Development Period in accordance with Section 4.1.2, then this Agreement shall be deemed to be terminated in its entirety pursuant to Section 13.2.3; *provided* that the effective date of termination in such case will be the date of expiration of the Development Period.

4.3. Transfers at Continuation Date. After the Continuation Date, Xilio shall (and shall cause its Affiliates to) cooperate with Gilead (and its designees) and provide reasonable assistance and technology transfers of the items and support set forth below in this Section 4.3 to Gilead (and its designees) to enable Gilead (and its designees) to Develop, Manufacture, Commercialize and otherwise Exploit the IL-12 Molecules and IL-12 Products, including by (a) providing Gilead (and its designees) such assistance with respect to Development (including regulatory) and Manufacturing matters related to such IL-12 Molecules and IL-12 Products [**], and (b) providing Gilead (and its designees) with [**] to Xilio personnel (and personnel of its Affiliates and Third Party subcontractors) involved in the Exploitation of IL-12 Molecules or IL-12 Products to assist Gilead (and its designees) with Development (including regulatory) and Manufacturing matters and to answer questions related to such IL-12 Molecules and IL-12 Products. [**] the JSC shall develop and, subject to Section 2.1.3(b)(ii), approve a written plan to operationalize the transition obligations of the Parties set forth in this Section 4.3; *provided* that [**]. The Parties shall perform each activity allocated to such Party under the transition plan and implement each transfer to Gilead or its designee in accordance with the transition plan. Except as set forth in Section 4.3.3, if applicable, each Party shall be responsible for its costs incurred in connection with performing its activities under the transfer plan. Without limiting the foregoing:

4.3.1. Licensed Know-How and Regulatory Documentation. Xilio shall, and shall cause its Affiliates to, disclose or make available to Gilead, to the extent not previously provided, in such form and format as Gilead may reasonably request (including by providing copies thereof), all (a) Licensed Know-How and (b) Regulatory Documentation in Xilio's or its Affiliates' possession or control, in each case ((a) and (b)), (i) that is in existence as of the Continuation Date, including Assigned Regulatory Documentation, [**] or (ii) that comes into existence after the Continuation Date, [**]. Without limiting the foregoing, Xilio shall, [**] after the Continuation Date, provide to Gilead (x) all non-clinical data,

research and analyses with respect to the Development of the IL-12 Molecules and IL-12 Products and all Regulatory Documentation via a secure file transfer service and in a format designated by and reasonably acceptable to Gilead, and (y) copies of all correspondence, as of the Continuation Date, to and from any Regulatory Authority that relates to the IL-12 Molecules.

4.3.2. Product Agreements. With respect to any agreements (including any statements of work or other ancillary agreements) with a Third Party (including any such agreement with any Third Party manufacturer) specifically relating to the Development, Manufacture or Commercialization of any IL-12 Molecule or IL-12 Product to which Xilio or any of its Affiliates is a party (excluding any in-license agreements pursuant to which Xilio solely obtains a license or other rights to a Third Party Right and does not otherwise collaborate with, or perform or receive services or goods from, such Third Party with respect to the Development, Manufacture or Commercialization of any IL-12 Molecule or IL-12 Product under such agreement) (each, a **"Product Agreement"**), upon Gilead's request after the Continuation Date, Xilio shall (a) assign to Gilead such Product Agreement solely to the extent applicable to the IL-12 Molecules and IL-12 Products, (b) facilitate, cooperate with and assist Gilead in entering into its own agreement with such Third Party or (c) terminate such Product Agreement solely to the extent applicable to IL-12 Molecules and IL-12 Products; *provided* that to the extent that the assignment by Xilio of any Product Agreement pursuant to this Section 4.3.2 requires the separation of such agreement into an agreement that is retained by Xilio or such Affiliate and an agreement that is assignable to (or entered into by) Gilead, or the assignment of a statement of work or other ancillary agreement to Gilead and the retention by Xilio of a master agreement relating to such statement of work or other ancillary agreement, the Parties will reasonably cooperate to negotiate such separation as soon as practicable, *provided* that [**]. Notwithstanding any provision to the contrary set forth in this Agreement, if the performance of any Xilio Ongoing Activities requires the retention by Xilio of a Product Agreement, then Xilio shall [**]. Without limiting the foregoing, the Parties will cooperate reasonably to take any actions with respect to the Product Agreements that are necessary to provide the rights granted to Gilead under Section 3.7.1(c) and this Section 4.3.2 with respect to the Product Agreements.

4.3.3. Clinical Trials. Promptly after the Continuation Date, with respect to any clinical trials being conducted by or on behalf of Xilio or its Affiliates as of the Continuation Date, Xilio shall[**], (a) if Xilio has not completed the activities set forth under the Development Plan as of the Continuation Date, then Xilio shall continue to complete the Development activities set forth in such Development Plan (including survival follow-up) in accordance with Section 3.2, [**], (b) unless expressly prohibited by any Regulatory Authority, transfer control to Gilead of such clinical trial(s) and continue to conduct such clinical trial(s) until such transfer is completed to enable such transfer to be completed without interruption of any such clinical trial(s); *provided* that with respect to each clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, Xilio or its Affiliates shall continue to conduct such clinical trial to completion or (c) wind down such clinical trial(s) (with due regard for patient safety and the rights of any subjects that are participating in any such clinical trial(s)). If, after the Continuation Date, [**], then Gilead shall [**].

4.3.4. Global Safety Database. Promptly after the Continuation Date, Xilio shall transfer to Gilead the global safety database and datasets for the IL-12 Products. Following such transfer, Gilead shall hold and maintain (at Gilead's cost and expense) the global safety database for IL-12 Products. Xilio shall provide Gilead with all information necessary for Gilead to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug

experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States), from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies with an IL-12 Product, in each case, in the form reasonably requested by Gilead. If Gilead determines that a pharmacovigilance agreement is necessary with respect to Gilead's ongoing Development of IL-12 Products, the Parties shall

negotiate in good faith and execute a written pharmacovigilance agreement with respect to the IL-12 Products. Such agreement shall (a) provide that Gilead shall hold and control the maintenance of the global safety database for the IL-12 Products and (b) include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as between the Parties) of adverse event reports, pregnancy reports and any other information concerning the safety of the IL-12 Products.

4.3.5. Transfer of Inventory. Promptly after the Continuation Date, Xilio shall (a) provide Gilead with a written summary of all of the inventory of IL-12 Molecules and IL-12 Products [**], which summary will include a description of the remaining shelf-life of such inventory of IL-12 Molecules and IL-12 Products and (b) as and to the extent requested by Gilead in its sole discretion, either (i) deliver to Gilead [**] at a location designated by Gilead [**] other than any such inventory needed to complete the Xilio Ongoing Activities or (ii) destroy such inventory, other than any such inventory needed to complete the Xilio Ongoing Activities, and provide Gilead written certification of such destruction.

4.3.6. Patents. Xilio shall assist and cooperate with Gilead, as Gilead may reasonably request, in the transition of the prosecution, maintenance, enforcement and defense of the Product Patents from Xilio to Gilead. Within [**] after the Continuation Date, Xilio shall transfer to Gilead all documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Product Patents; *provided that* Xilio shall not be obligated hereunder to transfer any privileged communications between counsel and Xilio related to such documents or materials until such time as the Parties put in place procedures to safeguard privilege, including if applicable, by entering into a common interest agreement or equivalent.

4.3.7. Costs and Expenses. Except as otherwise expressly set forth in Section 4.3.3, each Party shall be solely responsible for the costs and expenses it incurs in connection with its activities set forth in this Section 4.3.

ARTICLE 5

GRANT OF RIGHTS

5.1. Grants to Gilead. Subject to the terms and conditions of this Agreement, Xilio (on behalf of itself and its Affiliates) grants to Gilead an exclusive (including with regard to Xilio and its Affiliates), non-transferable (except in accordance with Section 15.3) license (or sublicense), with the right to grant sublicenses in accordance with Section 5.3, under the Licensed Patents, the Licensed

Know-How and Xilio's interests in the Joint Patents and the Joint Know-How to (a) Exploit the IL-12 Molecules and IL-12 Products in the Field in the Territory and (b) otherwise exercise Gilead's rights in accordance with Article 9 (the license in this Section 5.1, the "License").

5.2. Grants to Xilio. Subject to the terms and conditions of this Agreement, Gilead (on behalf of itself and its Affiliates) hereby grants to Xilio:

5.2.1. a non-exclusive, non-sublicensable, worldwide, royalty-free sublicense under the Licensed Know-How, Licensed Patents and Xilio's interest in the Joint Patents and the Joint Know-How, in each case, as licensed to Gilead pursuant to the License in Section 5.1, solely to perform (a) the Development activities set forth in the Development Plan as set forth in Section 3.2, (b) the transition activities set forth in Section 3.7, Section 4.3 and Section 6.4, and (c) the Manufacturing activities set forth in Section 6.1 and Section 6.2 (clauses (a)-(c), the "Xilio Ongoing Activities") and (d) otherwise exercise Xilio's rights in accordance with Article 9.

5.2.2. a non-exclusive, non-sublicensable, worldwide, royalty-free (a) license under (i) any Patent Controlled by Gilead that Covers the Combination Therapy, (ii) any Gilead CT Know-How and

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(iii) any Gilead CT Patents and (b) "right of reference" as defined in 21 C.F.R. 314.3(b), or similar "right of reference" as defined in applicable regulations of jurisdictions outside the United States, with respect to any Regulatory Documentation Controlled by Gilead with respect to [**], in each case ((a) and (b)), solely for the purposes of (A) conducting the Combination Arm in accordance with this Agreement and the protocol for the Combination Arm, and (B) performing its activities under the sample analysis plan for the Combination Arm in accordance therewith. For clarity, (1) the foregoing sentence is not intended and shall not be construed to grant to Xilio any license or right of reference for the Restricted Purpose, and (2) nothing in this Agreement shall grant Xilio any right to directly access any chemistry, manufacturing and controls data in any Regulatory Documentation with respect to [**].

5.3. Sublicenses. Gilead shall have the right to grant sublicenses, through multiple tiers of sublicensees, under the License granted in Section 5.1, to its Affiliates and other Persons; provided that (a) any such sublicenses shall not be inconsistent with the terms and conditions of this Agreement, and (b) Gilead shall remain responsible for performance of its obligations under this Agreement and shall be responsible for all actions of each such Sublicensee as if such Sublicensee were the Party hereunder. Gilead will notify Xilio promptly in writing after the execution of any such sublicense to a Sublicensee of material Commercialization rights in one (1) or more countries for one (1) or more IL-12 Products.

5.4. Retention of Rights.

5.4.1. Except as expressly provided herein, Xilio grants no other right or license, including any rights or licenses to the Licensed Patents, the Licensed Know-How, Xilio's interest in

the Joint Patents and the Joint Know-How or any other Patent or intellectual property rights not otherwise expressly granted herein.

5.4.2. Except as expressly provided herein, Gilead grants no right or license, including any rights or licenses to the Assigned Regulatory Approvals, Assigned Regulatory Documentation or any Patent or intellectual property rights not otherwise expressly granted herein.

5.5. [**].

5.6. Exclusivity; Change of Control.

5.6.1. Exclusivity. In any country in the Territory, during the Term of this Agreement, Xilio shall not, and shall cause its Affiliates not to, (a) directly or indirectly, develop, manufacture or commercialize or (b) license, authorize, permit, appoint or otherwise enable any Third Party to, directly or indirectly, develop, manufacture or commercialize, in either case ((a) or (b)), any Competing Product, except for the performance of Xilio's activities under and in accordance with this Agreement.

5.6.2. Change of Control.

(a) If, during the Term, Xilio or any of its Affiliates undergoes any Change of Control, then (i) Xilio shall provide Gilead with written notice of such Change of Control of Xilio [**] and (ii) Gilead shall have the right [**] by written notice, which notice must be delivered to Xilio (or its successor) [**], to (A) require Xilio and the Change of Control party to adopt Firewall Procedures to prevent disclosure of Product Information to the Change of Control party or any of its Affiliates (other than Xilio) and (B) if such Change of Control occurs during the Development Period [**] (but for clarity, not Xilio or any of its Affiliates prior to such Change of Control or any of their successors or assigns) (each, a "Pre-Existing Entity" and collectively, the "Pre-Existing Entities") [**].

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(b) Notwithstanding Section 5.6.1, subject to the remainder of this Section 5.6.2(b), if during the Term, Xilio or any of its Affiliates undergoes a Change of Control and any Pre-Existing Entity [**], then Xilio shall not be in violation of Section 5.6.1 [**], unless and until Xilio fails to comply with the following terms and conditions:

(i) Xilio shall provide Gilead with written notice [**] whether it intends to: [**].

(ii) If Xilio notifies Gilead in writing [**] that it intends to [**], then Xilio or its Affiliate, shall: (A) [**] after Xilio's delivery of such written notice to Gilead [**]; and (B) [**].

(iii) If Xilio notifies Gilead in writing [**] that it intends to Divest the Competing Program, then Xilio or its relevant Affiliate shall [**]; *provided, however*, that [**].

(iv) If (A) Xilio notifies Gilead [**] that it intends to implement and maintain Firewall Procedures [**], then the following shall apply during the Term, or (B) Xilio notifies

Gilead [**] that it [**]: Xilio shall, and shall cause its Affiliates to, implement reasonable internal safeguards to: (1) ensure that the Pre-Existing Entities (and any successor thereto) do not obtain any rights or access to, or employ or benefit from the services of any Person who has access to, the Confidential Information of Gilead or its Affiliates or any other Information generated under or in connection with this Agreement or in the Development or Manufacture of IL-12 Molecules or IL-12 Products; (2) [**]; and (3) [**] (clauses (1)-(3), "Firewall Procedures").

5.6.3. Acknowledgement. Xilio acknowledges and agrees that [**].

5.7. Existing Agreements; Product Agreements. Xilio shall not, and shall cause its Affiliates not to, (a) enter into any subsequent agreement or understanding with any Third Party to an Existing Agreement that modifies, amends or terminates any such Existing Agreement, or waives any right or obligation thereunder or (b) without limiting Section 3.3, enter into any new Product Agreement, in each case ((a) and (b)), in any manner that would adversely affect, in any material respect, Gilead's rights or interests under this Agreement or would impose any obligation on Gilead (including in the event of the occurrence of the Continuation Date) without Gilead's prior written consent. Xilio shall not, and shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause breach or termination of any of its Existing Agreements or Product Agreements where such breach or termination would adversely affect, in any respect, Gilead's rights or interests under this Agreement or impose any obligation on Gilead (including in the event of the occurrence of the Continuation Date). Xilio shall promptly provide Gilead with notice of any alleged, threatened or actual breach of any Existing Agreement or Product Agreement. During the Development Period, without limiting Section 3.3, Xilio shall ensure that the terms of any new Product Agreement are consistent with this Agreement. Xilio shall promptly provide Gilead with notice and a copy of each such Product Agreement entered into by Xilio or any of its Affiliates.

ARTICLE 6

MANUFACTURING AND SUPPLY

6.1. Development Plan Supply.

6.1.1. Prior to the Continuation Date, Xilio shall be solely responsible, at its sole cost and expense, for supplying quantities of IL-12 Molecules and IL-12 Products as may be required for its performance of Development activities set forth in the Development Plan. Without limiting Section 6.2, if

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(a) the Continuation Date occurs (or Gilead exercises its step-in right pursuant to Section 3.7) prior to Xilio's completion of Development activities set forth in the Development Plan, then Xilio shall supply clinical quantities of the IL-12 Molecules and IL-12 Products for use by Gilead in the completion of such Development activities at a price equal to [**] or (b) during the Development Period, Gilead reasonably requests that Xilio Manufacture and supply clinical quantities of the IL-12 Molecules and IL-12 Products to prepare for the conduct of Development activities following the Continuation Date, Xilio shall [**]; *provided that*, with respect to this clause (b), [**].

6.1.2. [].**

6.2. Post-Continuation Date Supply. After the Continuation Date, until the earlier of (a) [**] after the Continuation Date and (b) [**] Xilio shall supply clinical quantities of the IL-12 Molecules and IL-12 Products for use by Gilead in the Development of IL-12 Products as contemplated hereunder at a price equal to [**].

6.3. Supply Terms. If either Party supplies clinical quantities of the IL-12 Molecules, IL-12 Products or [**] for use by the other Party in the Development of IL-12 Products as set forth in Section 6.1 or Section 6.2, the following shall apply:

6.3.1. The supplying Party shall Manufacture (or have Manufactured) all such IL-12 Molecules, IL-12 Products or [**], as applicable, in accordance with Applicable Law and any applicable manufacturing and quality agreements and, for purposes of Xilio's supply to Gilead, shall only use Third Party contract manufacturers that are used by Xilio as of the Effective Date or are approved by Gilead in writing in advance. The supplying Party represents and warrants that each IL-12 Molecule, IL-12 Product or [**] supplied to the other Party (a) will be Manufactured in accordance with Applicable Law, including current good manufacturing practices, (b) will not be adulterated or misbranded under the FFDCa and may be introduced into interstate commerce pursuant to the FFDCa and (c) complies with the applicable specifications with respect thereto in the then-current IND for the IL-12 Product or [**], as applicable.

6.3.2. Gilead and Xilio will use good faith efforts to negotiate and execute [**] an agreement for the Manufacture and supply (a) to Gilead of the IL-12 Molecules and IL-12 Products as set forth above or (b) to Xilio of [**] as set forth above (each of (a) and (b), a **"Supply Agreement"**), which Supply Agreement will include customary terms for supply of material to a collaboration partner for clinical trials, including a related quality agreement. Each Supply Agreement (and any quality agreement) will be subordinate to this Agreement.

6.4. Manufacturing Technology Transfer. Without limiting the generality of the obligations in Section 4.3, [**] Xilio shall transfer to Gilead or its designee all Licensed Know-How relating to the Manufacture of the IL-12 Molecules and the IL-12 Products and all intermediates and components thereof, including the then-current process for the Manufacture of the IL-12 Molecules and IL-12 Products (the **"Manufacturing Process"**), and provide such support as may be necessary or useful to Gilead or its designee to use and practice the Manufacturing Process, including by assisting Gilead or its designee to enter into agreements with any of Xilio's Third Party manufacturers (such transfer and support, as more fully described in this Section 6.4, the **"Manufacturing Technology Transfer"**). The Manufacturing Technology Transfer shall be sufficient to enable Gilead or such designee to perform the then-current Manufacturing Process and Manufacture the IL-12 Molecules and IL-12 Products. [**] the JSC shall develop and, subject to Section 2.1.3(b)(ii), approve a written plan to operationalize the Manufacturing Technology Transfer obligations of the Parties set forth in this Section 6.4 (the **"Manufacturing Transition Plan"**), which plan will include a detailed budget of the FTE Costs and Out-of-Pocket Costs expected to be incurred in the performance of the activities set forth in the such Manufacturing Transition Plan; *provided that* [**]. The Parties shall perform each activity allocated to such Party under the Manufacturing Transition

Plan and shall use Commercially Reasonable Efforts to implement the Manufacturing Technology Transfer to Gilead or its designee in accordance with the Manufacturing Transition Plan. Each Party shall be initially responsible for its costs incurred in connection with performing each Manufacturing Technology Transfer and Gilead shall reimburse Xilio for its reasonable and verifiable FTE Costs and Out-of-Pocket Costs incurred in connection with the assistance provided under this Section 6.4 in accordance with Section 6.5. Without limitation to the foregoing, in connection with each Manufacturing Technology Transfer, Xilio shall provide, and shall use commercially reasonable efforts to cause its Third Party manufacturers to provide, such other assistance as Gilead (or its Affiliate or designated Third Party manufacturer, as applicable) may reasonably request to enable Gilead (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process and otherwise to Manufacture IL-12 Molecules and IL-12 Products.

6.5. Transferred Xilio Materials; Manufacturing Technology Transfer Cost Reimbursement. **[**]** Gilead will reimburse Xilio for its reasonable and verifiable (a) Out-of-Pocket Costs and (b) FTE Costs in excess of **[**]** FTE hours in the aggregate, in each case ((a) and (b)), incurred by or on behalf of Xilio in connection with its provision of Transferred Xilio Materials pursuant to Section 3.6 or performing the Manufacturing Technology Transfer(s) pursuant to Section 6.4.

6.6. Future Combination Study Supply. If, at any time after the Continuation Date, Xilio desires to perform a clinical trial of a combination therapy (*i.e.*, a single therapeutic regimen of the concomitant or sequential administration) of (a) XTX301, on the one hand, and (b) a pharmaceutical product owned or controlled by Xilio, on the other hand, then Xilio shall **[**]**. For clarity, the foregoing does not include clinical trials of a Combination Product as a single pharmaceutical product.

ARTICLE 7

GILEAD DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

7.1. Gilead Rights. As between the Parties, from and after the Continuation Date, Gilead shall have the sole right, at its sole cost and expense, to further Develop, Manufacture, Commercialize and otherwise Exploit the IL-12 Molecules and IL-12 Products in the Field in the Territory (subject to Xilio's performance of the Xilio Ongoing Activities) and will have the sole authority and discretion to make any and all decisions (or take any and all actions) with respect thereto. Without limiting the generality of the foregoing, as between the Parties, Gilead shall have the sole right to (a) file all Regulatory Documentation for Regulatory Approval and make all other filings with the Regulatory Authorities, and to otherwise seek all Regulatory Approvals, for IL-12 Products in the Territory, as well as to conduct all correspondence and communications with Regulatory Authorities regarding such matters, (b) report all adverse events to Regulatory Authorities if and to the extent required by Applicable Law and (c) invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the IL-12 Products in the Territory and perform or cause to be performed all related services. Gilead shall perform, or cause to be performed, all Development, Manufacturing, Commercialization and other Exploitation of the IL-12 Molecules and IL-12 Products in the Field in the Territory in good scientific manner and in compliance with all Applicable Law.

7.2. Regulatory.

7.2.1. Regulatory Documentation; Regulatory Support.

(a) As between the Parties, from and after the Continuation Date, Gilead shall have the sole right to prepare, obtain and maintain all Regulatory Documentation (including all BLAs and Regulatory Approvals) and to prepare other submissions to, and conduct communications with, all

Regulatory Authorities, in each case, for the IL-12 Molecules and IL-12 Products in the Territory, including the setting of the overall regulatory strategy therefor.

(b) All Regulatory Documentation (including all BLAs and Regulatory Approvals) with respect to the IL-12 Molecules or IL-12 Products in the Territory developed or granted after the Continuation Date shall, as between the Parties, be owned by and shall be the sole property and held in the name of Gilead. Without limiting Section 4.3, upon the Continuation Date, Xilio and its Affiliates hereby assign to Gilead all of their rights, title and interests in and to all Regulatory Documentation (including such Regulatory Approvals) owned or Controlled by Xilio or its Affiliates with respect to the IL-12 Molecules or IL-12 Products that is in existence as of the Continuation Date or that is developed or granted thereafter (including all Existing Regulatory Documentation (including any existing Regulatory Approvals)) with respect to the Territory (collectively, the “**Assigned Regulatory Documentation**” and “**Assigned Regulatory Approvals**”, as applicable). Xilio shall duly execute and deliver such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements and instruments, as may be necessary under or as Gilead may reasonably request in connection with its rights under, this Section 7.2.1.

(c) Xilio shall support Gilead, as may be reasonably requested by Gilead, in obtaining Regulatory Approvals for the IL-12 Products and supporting activities, including providing all documents or other materials as may be necessary or reasonably useful for Gilead to obtain and maintain Regulatory Approvals for the IL-12 Products and attending meetings with Regulatory Authorities with respect thereto, provided that Gilead shall reimburse Xilio for its reasonable and verifiable FTE Costs and Out-of-Pocket Costs incurred in connection therewith (which, for clarity, shall not apply to the assignment set forth in Section 7.2.1(b)).

7.2.2. Recalls, Suspensions or Withdrawals. As between the Parties, from and after the Continuation Date, Gilead shall have the sole right to make all determinations with respect to and to implement any recall, market suspension, market withdrawal or other corrective action with respect to an IL-12 Molecule or IL-12 Product in the Territory. Xilio shall, and shall cause its Affiliates to, cooperate in any recalls, market suspensions, market withdrawals or other corrective actions undertaken pursuant to this Section 7.2.2 with respect to any IL-12 Molecules or IL-12 Products Manufactured by Xilio. Subject to Article 12, Gilead shall be responsible for all costs of any such recall, market suspension, market withdrawal or other corrective action in the Territory, except in the event and to the extent that a recall, market suspension, market withdrawal or other corrective action resulted from (a) any inventory of IL-12 Molecules and IL-12 Products (including intermediates and components thereof and material therefor) transferred or supplied by Xilio to Gilead pursuant to Section 4.3.5, Section 6.1 or Section 6.2, except to the extent resulting from an action or inaction of

Gilead or its Affiliates or Sublicensees after transfer or supply thereof to Gilead or its designee, or (b) Xilio's or its Affiliate's breach of its obligations hereunder or from Xilio's or its Affiliate's fraud, gross negligence or willful misconduct, in which case ((a) and (b)), Xilio shall bear the expense of such recall, market suspension or market withdrawal.

7.3. Diligence. Gilead shall [**] Develop, obtain Regulatory Approval for and Commercialize one (1) Lead Product in the United States and in at least [**] Major European Markets. Xilio acknowledges and agrees that nothing in this Section 7.3 is intended, or shall be construed, to require Gilead to Develop or Commercialize a specific Lead Product. [**]. Xilio further acknowledges that Gilead is in the business of Exploiting pharmaceutical products and nothing in this Agreement shall be construed [**], as either (a) [**]; or (b) [**].

7.4. Subcontracting. Gilead shall have the right to subcontract any of its Development, Manufacturing or Commercialization activities to a Third Party. Gilead shall (a) be responsible for the acts and omissions of its subcontractors and (b) ensure that its Third Party subcontractors comply with the

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applicable terms and conditions of this Agreement, including Article 9 (including supporting all grants and assignment of rights and ownership hereunder) and Article 10.

7.5. [].** [**] prior to the first receipt of a Regulatory Approval for an IL-12 Product in the United States and [**] Major European Markets, [**].

7.6. Records. Gilead shall maintain, in good scientific manner, complete and accurate books and records pertaining to its Development and Commercialization activities, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for patent and regulatory purposes, in compliance with Applicable Law and that properly reflect all work done and results achieved in the performance of such activities. Such books and records shall be retained by Gilead for [**] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

ARTICLE 8 PAYMENTS AND RECORDS

8.1. Upfront Payment. In partial consideration of the rights granted by Xilio to Gilead hereunder and subject to the terms and conditions of this Agreement, within [**] after the Effective Date, Gilead shall pay Xilio a one-time upfront payment of Thirty Million Dollars (\$30,000,000), which shall be non-creditable and non-refundable.

8.2. Equity Investment. As of the Effective Date, Gilead and Xilio Therapeutics, Inc. have entered into the Purchase Agreement and Investor Rights Agreement, pursuant to which (a) Gilead shall purchase an initial amount of common stock of Xilio Parent and (b) for up to one (1) year following the Effective Date, Gilead shall be obligated, in certain circumstances described in the Purchase Agreement, to purchase additional common stock from Xilio Parent.

8.3. Development and Regulatory Milestone Payments.

8.3.1. [].** In partial consideration of the rights granted by Xilio to Gilead hereunder and subject to the terms and conditions of this Agreement, unless (a) the Continuation Date occurs and Gilead takes over further conduct of the clinical trial(s) set forth in the Development Plan pursuant to Section 4.1.2(b) or (b) Gilead exercises its step-in right pursuant to Section 3.7, in either case ((a) and (b)), prior to the occurrence of the [**], Gilead shall pay to Xilio a one-time, non-creditable, non-refundable milestone payment of [**]. For clarity, the milestone payment set forth in this Section 8.3.1 (x) shall be payable only once, upon the first achievement of the [**], and no amounts shall be due for subsequent or repeated achievements of such [**] (for any IL-12 Product) and (y) shall not be payable if the [**] is achieved after (i) the Continuation Date occurs and Gilead takes over further conduct of the clinical trial(s) set forth in the Development Plan pursuant to Section 4.1.2(b) or (ii) Gilead exercises its step-in right pursuant to Section 3.7. Xilio shall promptly notify Gilead upon the achievement of the [**] and shall submit an invoice to Gilead for such payment. Gilead shall pay the corresponding milestone payment [**] following receipt of such invoice. The amount payable by Gilead under this Section 8.3.1 shall not exceed [**].

8.3.2. [] Development/Regulatory Milestone Payments.** In partial consideration of the rights granted by Xilio to Gilead hereunder and subject to the terms and conditions of this Agreement (including Section 8.10), Gilead shall pay to Xilio the one-time, non-creditable, non-refundable milestone payments set forth in the table below in this Section 8.3.2 after the first achievement of the applicable milestone events by a Lead Product, whether such achievement is by or on behalf of Gilead, its Affiliate or

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its or their Sublicensee (each event, a “Development/Regulatory Milestone Event” and each payment, a “Development/Regulatory Milestone Payment”).

Development/Regulatory Milestones				
Number	Development/Regulatory Milestone Event	Development/Regulatory Milestone Payment		
		1 st Indication	2 nd Indication	3 rd Indication
1	[**]	[**]	[**]	[**]
2	[**]	[**]	[**]	[**]
3	[**]	[**]	[**]	[**]
4	[**]	[**]	[**]	[**]

For clarity, subject to Section 8.10, each Development/Regulatory Milestone Payment in this Section 8.3.2 shall be payable only once upon the first achievement of the corresponding Development/Regulatory Milestone Event by a Lead Product (or a Back-Up Product as set forth in Section 8.10), which need not be the same Lead Product (or Back-Up Product) [**], and no amounts shall be due for subsequent or repeated achievements of such Development/Regulatory Milestone Event by a different IL-12 Product or for any additional Indications.

Gilead shall promptly notify Xilio upon the achievement of each Development/Regulatory Milestone Event and shall pay the corresponding Development/Regulatory Milestone Payment [**] following receipt of an invoice from Xilio for such Development/Regulatory Milestone Payment. If Gilead or its Affiliates or its or their Sublicensees achieve all Development/Regulatory Milestone Events (regardless of the number of times such events occur), then the maximum aggregate Development/Regulatory Milestone Payments payable by Gilead under this Section 8.3.2 (including for Back-Up Products as set forth in Section 8.10) is [**].

If Development/Regulatory Milestone Event #1 in this Section 8.3.2 is skipped with respect to a particular Indication (i.e., a later Development/Regulatory Milestone Payment is payable before Development/Regulatory Milestone Payment #1 is payable for such particular Indication), then Development/Regulatory Milestone Event #1 for such Indication will be deemed to have been achieved upon the achievement of the subsequent Development/Regulatory Milestone Event(s) for such Indication, and in such a case, Development/Regulatory Milestone Payment #1 shall be payable at the same time as the Development/Regulatory Milestone Payment for the later Development/Regulatory Milestone Event for such Indication.

8.4. Commercial Milestone Payments. In partial consideration of the rights granted by Xilio to Gilead hereunder and subject to the terms and conditions of this Agreement (including Section 8.10), Gilead shall pay to Xilio the one-time, non-creditable, non-refundable milestone payments set forth

in the table below in this Section 8.4 within [**] after the end of the Calendar Year after the first achievement of the applicable sales milestone event (each event, a “**Commercial Milestone Event**” and each payment, a “**Commercial Milestone Payment**”).

Commercial Milestones		
Number	Commercial Milestone Events	Commercial Milestone Payments

1.1	Services. The Consultant agrees to perform First occurrence of a Calendar Year in which Net Sales of a Lead Product in such consulting and advisory services Calendar Year exceed [**]	[**]
2	First occurrence of a Calendar Year in which Net Sales of a Lead Product in such Calendar Year exceed [**]	[**]
3	First occurrence of a Calendar Year in which Net Sales of a Lead Product in such Calendar Year exceed [**]	[**]
4	First occurrence of a Calendar Year in which Net Sales of a Lead Product in such Calendar Year exceed [**]	[**]

For clarity: (a) if multiple Commercial Milestone Events are achieved in the same Calendar Year, then the Commercial Milestone Payments for all such Commercial Milestone Events achieved shall be payable with respect to such Calendar Year; and (b) each of the Commercial Milestone Payments shall be payable only once regardless of the number of times the corresponding Commercial Milestone Event is achieved. If Gilead or its Affiliates or its or their Sublicensees achieve all of the Commercial Milestone Events (regardless of the number of times such events occur), then the maximum aggregate Commercial Milestone Payments payable by Gilead under this Section 8.4 (including for Back-Up Products as set forth in Section 8.10) is [**].

8.5. Royalties on Net Sales.

8.5.1. As further consideration of the rights granted by Xilio to Gilead hereunder and subject to the terms and conditions of this Agreement (including this Section 8.5), Gilead shall pay to Xilio, on a country-by-country and Lead Product-by-Lead Product basis in the Territory, royalties on Annual Net Sales of each Lead Product for each Calendar Year during the applicable Royalty Term calculated at the applicable royalty rates set forth below:

Royalties	
Portion of Annual Net Sales of a Lead Product	Royalty Rate
On the portion of Annual Net Sales of such Lead Product up to and for the Company as may be reasonably requested from time to time by the Company, as specified on Schedule A to this Agreement.including [**]	[**]

	Royalties
Portion of Annual Net Sales of a Lead Product	Royalty Rate
2. On the portion of Annual Net Sales of such Lead Product greater than [**] and up to and including [**]	Term. The term [**]
On the portion of this Agreement shall commence on Annual Net Sales of such Lead Product greater than [**] and up to and including [**]	[**]
On the Effective Date portion of Annual Net Sales of such Lead Product greater than [**] and shall continue through December 31, 2023 (the "Expiration Date"), unless terminated earlier pursuant up to and including [**]	[**]
On the provisions portion of Section 4 (such period being referred to as the "Consultation Period"), Annual Net Sales of such Lead Product greater than [**]	[**]

8.5.2. Royalty Term. Upon expiration of the Royalty Term for a Lead Product in a given country, (a) no further royalties will be payable in respect of sales of such Lead Product in such country and no further Net Sales of such Lead Product in such country will accrue toward the achievement of royalty tiers or the Commercial Milestone Events and (b) subject to the proviso included in the last sentence of Section 13.1, the License granted to Gilead under Section 5.1 shall remain exclusive and automatically become fully-paid, royalty-free, perpetual and irrevocable with respect to such Lead Product in such country.

8.5.3. Royalty Reductions. Notwithstanding Section 8.5.1, but subject to Section 8.8:

(a) in the event that, and in such case from and after the date on which, a Lead Product is Commercialized in a country in the Territory and is no longer Covered by a Valid Claim of a Royalty-Bearing Patent in such country, then royalties payable under Section 8.5.1 with respect to such Lead Product each shall be reduced by [**] in such country;

(b) in the event that (i) sales of all Biosimilar Products with respect to a Lead Product in a country [**] of Net Sales of such Lead Product in such country [**], the royalties payable under Section 8.5.1 with respect to Net Sales of such Lead Product in such country each shall be reduced by [**] for the remainder of the Royalty Term for such Lead Product in such country, and (ii) sales of all Biosimilar Products with respect to a Lead Product in a country in any Calendar Quarter equal [**] of Net Sales of such Lead Product in such country [**] in which the first such Biosimilar Product was launched in such country, the royalties payable under Section 8.5.1 with respect to Net Sales of such Lead Product in such country each shall be reduced by [**] for the remainder of the Royalty Term for such Lead Product in such country; and

(c) in the event that a Lead Product is designated as a Selected Drug by the Secretary of the U.S. Department of Health and Human Services and Gilead or any of its Affiliates or its or their Sublicensees is required to negotiate, and is ultimately subject to, a Maximum Fair Price that will apply to sales of such Lead Product during the Price Applicability Period (the “**IRA Reduction Event**”), then each royalty rate payable under Section 8.5.1 with respect to such Lead Product in the United States during the Price Applicability Period shall be reduced by a percentage equal to [**]. For clarity, royalties

payable on Net Sales of Lead Products and Back-Up Products outside the U.S. will not be reduced as a result of the IRA.

8.5.4. Royalty Reports and Payments.

(a) **Quarterly Flash Reports.** No later than [**] after the end of each Calendar Quarter during the Term, Gilead will provide to Xilio “flash” reports that will set forth (i) for the first and second month of such Calendar Quarter: (A) the actual gross sales of the Lead Products and Back-Up Products sold by Gilead and its Affiliates and its and their Sublicensees in the Territory in such months; and (B) the actual total aggregate Net Sales of the Lead Products and Back-Up Products sold by Gilead and its Affiliates and its and their Sublicensees in the Territory in such months, and (ii) for the third month of such Calendar Quarter, Gilead’s good faith, non-binding estimate of the amounts set forth in the foregoing clauses (i)(A) and (i)(B) of this Section 8.5.4(a).

(b) **Quarterly Final Reports.** During the Term, for each Calendar Quarter following the First Commercial Sale of a Lead Product or Back-Up Product in the Territory, Gilead shall furnish to Xilio a quarterly written report for such Calendar Quarter showing, on a country-by-country basis, the gross sales of Lead Products and Back-Up Products subject to royalty payments sold by Gilead and its Affiliates and its and their Sublicensees in the Territory during the reporting period, Net Sales during such reporting period and a calculation of the royalties payable under this Agreement. Reports under this Section 8.5.4(b) shall be due [**] following the close of each Calendar Quarter. Royalties shown to have accrued by each report shall, unless otherwise specified under this Agreement, be due and payable concurrent with delivery of such report.

8.6. Apportionment of Compulsory License Consideration. If Gilead receives any cash consideration from any Compulsory Licensee for a Lead Product or Back-Up Product in a given country under any Compulsory License during the Royalty Term for the applicable Lead Product or Back-Up Product in such country, then such amounts [**]. For clarity, no royalties or other amounts shall be payable on such consideration (including non-cash consideration) other than the apportionment set forth in this Section 8.6.

8.7. Offset for Third Party Payments. In the event that Gilead owes upfront payments, milestone payments, royalties or other amounts under an agreement with a Third Party in order to obtain a license or right under a Third Party Right pursuant to Section 9.7 (“**Third Party Payments**”),

Gilead shall be entitled to deduct from any royalties payable under Section 8.5 (including for Back-Up Products as set forth in Section 8.10) [**].

8.8. Mechanics of Adjustments. Any reductions set forth in Section 8.5.3 and offsets set forth in Section 8.7 shall be applied to the royalties payable to Xilio under Section 8.5.1 in the order in which the event triggering such reduction or offset occurs; *provided* that the adjustments made pursuant to Section 8.5.3 and Section 8.7, in the aggregate, [**]. Credits for offsets pursuant to Section 8.7 not exhausted in any Calendar Quarter may be carried into future Calendar Quarters, subject to the preceding sentence. Any adjustments pursuant to Section 8.5.3 shall apply only to the applicable Lead Product in the relevant country and, with respect to royalties under Section 8.5.1, shall be allocated *pro rata* across each of the royalty tiers in the relevant Calendar Quarter.

8.9. Estimated Sales Levels; Diligence. Xilio acknowledges and agrees that (a) the sales levels set forth in Section 8.4 and Section 8.5.1 shall not be construed as representing an estimate or projection of anticipated sales of the IL-12 Products and (b) such sales levels and the development and regulatory milestone events set forth in Section 8.3 shall not be construed as implying any level of diligence or Commercially Reasonable Efforts in the Territory, and that such sales levels and development and

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regulatory milestone events are merely intended to define Gilead's payment obligations in the event such sales levels or such development and regulatory milestone events are achieved.

8.10. Back-Up Products. In the event that Gilead or its Affiliates or its or their Sublicensees [**]:

8.10.1. the Development/Regulatory Milestone Events in Section 8.3.2 shall apply [**] and the corresponding Development/Regulatory Milestone Payments shall be due with respect to [**]; *provided* that [**]. For example, [**];

8.10.2. the Commercial Milestone Events set forth in Section 8.4 shall apply [**] and the Commercial Milestone Payments shall be due with respect to [**]; *provided* that [**]. For clarity, [**]; and

8.10.3. the royalty rates set forth in Section 8.5.1 shall apply [**], and the Royalty Term and related provisions in Section 8.5.2, any reductions set forth in Section 8.5.3, Section 8.7 and Section 8.8 shall be applied [**].

8.11. Mode of Payment. All payments to be made by Gilead to Xilio under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account in the United States designated in writing by Xilio, unless otherwise specified in writing by Xilio. With respect to sales of an IL-12 Product that are invoiced in a currency other than Dollars, such amounts and amounts payable will be converted to Dollars using the exchange rate mechanism generally applied by Gilead or its Affiliates in preparing its financial statements for the applicable Calendar Quarter in which the applicable sales were made.

8.12. Taxes. Except as expressly set forth herein, any amounts payable by Gilead to Xilio hereunder are exclusive of and shall not be reduced on account of any taxes unless required by Applicable Law. Gilead shall deduct and withhold from any such payments due hereunder any taxes that it is required by Applicable Law to withhold, and agrees to then remit the remaining payment (net of tax withheld) to Xilio, pay the amounts of such withheld taxes to the proper governmental authority in a timely manner, promptly notify Xilio of the amount and recipient of the payment, and promptly thereafter transmit to Xilio an official tax certificate, or such other evidence as is available to Gilead and which Xilio may reasonably request, to establish that such taxes have been withheld and paid. If Xilio is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, then it may deliver to Gilead the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Gilead of its obligation to withhold tax. In such case and to the extent a valid claim under Applicable Law is made, Gilead agrees [**]. Notwithstanding the foregoing, if Gilead is required by Applicable Law to withhold taxes in respect of any payment, [**]; *provided, however*, that Gilead will have no obligation to pay any additional amounts pursuant to this Section 8.12 (a) to the extent that Xilio is able to claim a refund of such additional amounts, (b) if Xilio has the ability to offset such withheld amounts against other tax liabilities of Xilio, or (c) if such increased withholding tax would not have been imposed but for (i) the assignment by Xilio of this Agreement as permitted under Section 15.3 of this Agreement or a change in tax residency of Xilio, or (ii) the failure by Xilio to comply with the requirements of this Section 8.12. The Parties agree to cooperate with one another and use reasonable efforts and provide reasonable assistance to mitigate or enable the recovery, as permitted by Applicable Law, of withholding taxes, value added taxes, sales taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such taxes.

8.13. Interest on Late Payments. Payments that are not made when due hereunder shall (except for any portions thereof that are subject to a good faith dispute) accrue interest, from due date until

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paid, at the lower of at an annum-rate of [**] above the prime rate as reported in The Wall Street Journal, Digital Edition or the highest rate permitted under Applicable Law.

8.14. Financial Records. Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Net Sales and any reimbursable FTE Costs or Out-of-Pocket Costs hereunder in sufficient detail to calculate all amounts payable hereunder. Such books and records shall be retained by each Party and its Affiliates until the later of (a) [**] after the end of the period to which such books and records pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

8.15. Audit.

8.15.1. Procedures. Each Party may request that the other Party permit and cause its Affiliates to permit an independent, internationally recognized auditor designated by such first Party

as the auditing Party and reasonably acceptable to the audited Party, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 8.14 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter [**], (b) be conducted [**] (unless a previous audit during such [**] period revealed a material discrepancy with respect to such period) or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be borne by the auditing Party, [**], in each case, from the reported amounts in the auditing Party's favor, in which case the audited Party shall bear the cost of the audit. The auditor shall disclose to the auditing Party only whether the reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the auditing Party in connection with this audit right. Unless disputed pursuant to Section 8.15.2 below, if such audit concludes that (x) additional amounts were owed by the audited Party or excess payments were made by the auditing Party, the audited Party shall pay such additional amounts or refund such excess payments, as applicable or (y) excess payments were made by the audited Party or additional amounts were owed by the auditing Party, the auditing party shall refund such excess payments or pay such additional amounts, as applicable, in either case ((x) or (y)), within [**] after the date on which such audit is completed by the auditing Party and if such additional amounts or excess payments were due to an error in an invoice or report provided by the Party that is required to pay such additional amounts or refund such excess payments, with interest from the date originally due as provided in Section 8.13.

8.15.2. Audit Dispute. In the event of a dispute between the Parties with respect to any audit under Section 8.15.1 (an “**Audit Dispute**”), the Parties shall work in good faith to resolve the Audit Dispute. If the Parties are unable to reach a mutually acceptable resolution of any such Audit Dispute within [**] from the date on which either Party notifies the other in writing of the existence of an Audit Dispute, the Audit Dispute shall be submitted for resolution to a recognized, certified public accounting firm jointly selected by both Parties (the “**Auditor**”). The decision of the Auditor (the “**Audit Decision**”) shall be final and binding on the Parties, and the costs of the Auditor proceeding shall be borne between the Parties in such manner as the Auditor shall determine. If such Audit Decision concludes that (a) additional amounts were owed by the audited Party or excess payments were made by the auditing Party, the audited Party shall pay such additional amounts or refund such excess payments, as applicable or (b) excess payments were made by the audited Party or additional amounts were owed by the auditing Party, the auditing Party shall refund such excess payments or pay such additional amounts, as applicable, in either case ((a) or (b)), within [**] from the date on which the Audit Decision is served on the Parties and if such additional amounts or excess payments were due to an error in an invoice or report provided by the Party that is required to pay such additional amounts or refund such excess payments, with interest from the date originally due as provided in Section 8.13.

8.15.3. Confidentiality. Each Party shall treat all information subject to review under this Article 8 in accordance with the confidentiality provisions of Article 10, and the Parties shall cause the Auditor to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

8.16. Third Party Obligations. Except with respect to obligations under any Product Agreement assigned to Gilead pursuant to Section 4.3.2 that relate to activities conducted after such assignment, Xilio shall be responsible for all payments owed to Third Parties under the Existing Agreements and any other license and other agreements regarding any intellectual property rights licensed, acquired or otherwise obtained by Xilio or its Affiliates, including any agreement pursuant to which Xilio or any of its Affiliates has rights with respect to any IL-12 Molecule or IL-12 Product.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1. Ownership of Intellectual Property.

9.1.1. Ownership of Technology Generally. Subject to Section 7.2.1(b), Section 9.1.2 and Section 9.1.3, as between the Parties, each Party shall own and retain all rights, title and interests in and to any and all: (a) Information and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party (or its Affiliates or its or their respective (sub)licensees/Sublicensees) under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto, except to the extent that any such Information or invention, or any Patent or intellectual property rights with respect thereto, is [**]; and (b) other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants and right of reference set forth in Section 5.1 and Section 5.2) by such Party or any of its Affiliates or its or their respective (sub)licensees/Sublicensees outside of this Agreement.

9.1.2. Ownership of Joint Patents and Joint Know-How.

(a) Subject to Section 7.2.1(b), the last sentence of this Section 9.1.2(a) and Section 9.1.3, as between the Parties, the Parties shall each own an equal, undivided interest in any and all: (i) Information and other inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of Xilio or its Affiliates or its or their (sub)licensees, on the one hand, and Gilead or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement (other than [**]), whether or not patented or patentable (together with the Joint CT Know-How, the “**Joint Know-How**”); and (ii) any Patents (other than [**]) (together with the [**], the “**Joint Patents**”) and other intellectual property rights with respect to the Information and inventions described in clause (i) (together with Joint Know-How and Joint Patents, the “**Joint Intellectual Property Rights**”). In addition, Xilio shall own and retain all right, title and interests in and to any and all [**].

(b) Subject to, with respect to Xilio, the licenses granted under Section 5.1, its exclusivity obligations under Section 5.6 and its obligations with respect to Product Information under Article 10, (i) each Party shall have the right to practice, grant licenses under and transfer any [**], (ii) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any [**] by reason of joint ownership thereof and (iii) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

(c) Notwithstanding any provision to the contrary herein, unless otherwise agreed by the Parties in writing, except as expressly permitted under this Agreement (including as required

for conducting the Combination Arm in accordance with this Agreement and the protocol for the Combination Arm), Xilio shall not, and shall cause its Affiliates not to, use (or grant, or permit its Affiliates to grant, any Third Party any rights to use) (i) any (A) [**] or (B) Combination Sample Analysis Results, in either case ((A) or (B)), for the Restricted Purpose, or (ii) any [**] for the purpose of developing or commercializing [**].

9.1.3. Ownership of Combination Therapy Technology. Subject to Section 7.2.1(b), as between the Parties, (a) Xilio shall own and retain all rights, title and interests in and to any and all [**], (b) Gilead shall own and retain all rights, title and interests in and to any and all [**] and (c) the Parties shall each own an equal, undivided interest in any and all [**]. For clarity, [**].

9.1.4. Disclosures of Inventions. Each Party shall disclose to the other Party in writing, and shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so disclose, the conception, discovery, development or making of any [**], except that the foregoing shall not apply to Gilead with respect to disclosure of [**].

9.1.5. United States Law; Assignment. The determination of whether Information and inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs. Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so assign, to the other Party, without additional compensation, such rights, title and interests in and to any Information and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, (a) the sole ownership provided for in Section 9.1.1, the last sentence of Section 9.1.2(a) and Section 9.1.3 and (b) the joint ownership provided for in Section 9.1.2 and Section 9.1.3.

9.1.6. Product Patents. [**] until the Continuation Date and thereafter during the Term upon Gilead's request, Xilio shall update **Schedule 1.152** to include all Product Patents that exist at the time of such update and shall provide such updated schedule to Gilead for review. Upon Gilead's request, the Parties shall enter into an amendment to this Agreement to include such updated **Schedule 1.152**.

9.2. Control of Intellectual Property.

9.2.1. Xilio shall not enter into or amend any agreement with a Third Party, or include in any such agreement or amendment any restrictive provisions, with an intent to limit its Control of, or to not Control, any Information, Patent or other intellectual property right that would be subject to the license grants in Section 5.1 in the absence of such agreement, amendment or restrictive provisions. Further, when entering into any agreement or amendment with a Third Party relating to any Information, Patents or other intellectual property rights that, if Controlled by Xilio or its Affiliates, would be subject to the license grants in Section 5.1, Xilio shall use good faith efforts to obtain Control of such Information, Patents and other intellectual property rights.

9.2.2. Xilio shall cause all Persons who perform Development, Manufacturing or regulatory activities for Xilio under this Agreement or who conceive, discover, develop or otherwise make any Information by or on behalf of Xilio or its Affiliates or its or their (sub)licensees under or in connection with this Agreement to be under an obligation to assign (or, if Xilio is unable to cause such Person to agree to such assignment obligation despite Xilio using commercially reasonable efforts to negotiate such assignment obligation, provide an exclusive license under) their rights in any Information or other inventions resulting therefrom to Xilio, except where Applicable Law requires otherwise and except in the

case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained).

9.2.3. Gilead shall cause all Persons engaged by Gilead in performance of the Combination Arm or who conceive, discover, develop or otherwise make any Information by or on behalf of Gilead or its Affiliates or its or their Sublicensees under or in connection with the performance of activities in furtherance of the Combination Arm to be under an obligation to assign (or, if Gilead is unable to cause such Person to agree to such assignment obligation despite Gilead using commercially reasonable efforts to negotiate such assignment obligation, provide an exclusive license under) their rights in any Information or other inventions resulting therefrom to Gilead, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained).

9.3. Maintenance and Prosecution of Patents.

9.3.1. Prior to the Continuation Date. As between the Parties, prior to the Continuation Date, (a) Xilio shall have the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain, and to control any opposition, re-issuance, post-grant review, inter-partes review, reexamination request, nullity action, interference or other similar post-grant proceedings and any appeals therefrom (each, a **"Defense Proceeding"**) with respect to, the **[**]** in the Territory, at its sole cost and expense and (b) Gilead shall have the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain, and to control any Defense Proceeding with respect to, the **[**]** in the Territory, at its sole cost and expense. Xilio will prepare and file Patents in a manner that will generate **[**]** and **[**]**, including through filing continuations or divisionals with respect to the Licensed Patents and any other reasonable action as may be available under Applicable Law, with the objective of maximizing patent protection with respect to the IL-12 Molecules and IL-12 Products in the Field in the Territory by filing Patents that claim and Cover IL-12 Molecules and IL-12 Products only, including as Gilead may reasonably request.

9.3.2. After the Continuation Date.

(a) **Product Patents and Joint Patents.** As between the Parties, from and after the Continuation Date, Gilead shall have the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain, and to control any Defense Proceeding with respect to, the [**] and the [**] in the Territory, at its sole cost and expense. For clarity, [**].

(b) **Licensed Patents (other than Product Patents).** As between the Parties, from and after the Continuation Date, Xilio shall have the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain the [**] in the Territory and to control any Defense Proceeding with respect thereto, in each case, at its sole cost and expense.

9.3.3. Procedures; Step-In. With respect to [**] (and any related Defense Proceedings), the prosecuting Party shall periodically inform the other Party of all material steps with regard to the preparation, filing, prosecution and maintenance of such [**] (or the related Defense Proceedings) in the Territory, including by providing the other Party with a copy of material communications to and from any patent authority in the Territory regarding such [**] (or such Defense Proceedings) and by providing the other Party drafts of any material filings or responses to be made to such patent authorities in the Territory in connection therewith sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the other Party to review and comment thereon. The prosecuting Party shall consider in good faith the requests and suggestions of the other Party with respect to such drafts and with

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respect to strategies for filing and prosecuting such [**] (or the conduct of such Defense Proceedings) in the Territory. If, as between the Parties, the prosecuting Party decides not to prepare, file, prosecute or maintain a [**] (or conduct such a Defense Proceeding) in a country in the Territory, then the prosecuting Party shall provide reasonable prior written notice to the other Party of such intention, and the other Party shall thereupon have the option to assume the control and direction of the preparation, filing, prosecution and maintenance of such [**] (or such Defense Proceeding) at its sole cost and expense in such country; *provided* that, with respect to [**] from and after the Continuation Date, Xilio shall not have the right to assume the control and direction of the preparation, filing, prosecution and maintenance of any such [**] (or such Defense Proceeding) if Gilead [**].

9.3.4. Cooperation. The non-prosecuting Party shall, and shall cause its Affiliates and to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the [**] (and any related Defense Proceedings) under this Agreement, including that the non-prosecuting Party shall, and shall cause its Affiliates to, (a) offer its comments, if any, promptly, (b) provide access to relevant documents and other evidence and make its employees available at reasonable business hours and (c) provide the prosecuting Party, upon its request, with copies of any patentability search reports generated by its patent counsel with respect to the [**], including relevant Third Party patents and patent applications located (*provided* that neither Party shall be required to provide legally privileged information with respect to such intellectual property unless and until procedures reasonably acceptable to such Party are in place to protect such privilege); *provided, further*, that the prosecuting

Party shall reimburse the non-prosecuting Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith.

9.3.5. Patent Term Extension and Supplementary Protection Certificate.

(a) **Prior to the Continuation Date.** As between the Parties, prior to the Continuation Date, Xilio shall have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future prior to the Continuation Date, wherever applicable, for the [**].

(b) **After the Continuation Date.** As between the Parties, from and after the Continuation Date:

(i) Gilead shall have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future from and after the Continuation Date, wherever applicable, for the [**], in each case, including whether or not to do so. Xilio shall, and shall cause its Affiliates to, provide prompt and reasonable assistance, as requested by Gilead, including by taking such action as patent holder as is required under any Applicable Law, to obtain such extension or supplementary protection certificate.

(ii) Xilio shall have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future from and after the Continuation Date, wherever applicable, for the [**].

9.3.6. Common Ownership Under Joint Research Agreements. The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in 35 U.S.C. §100(h). Notwithstanding any provision to the contrary in this Agreement, neither Party shall invoke this Agreement under 35 U.S.C. §102(c) to except any patent or patent application as prior art without the prior written consent of the other Party. If such written consent is granted, the Parties shall coordinate their activities with respect to all submissions under 35 U.S.C. §102(c).

9.3.7. Patent Listings. As between the Parties, from and after the Continuation Date, Gilead shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the [**], including as required or allowed (a) in the United States, in the FDA's Orange Book or Purple Book, as applicable and (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. Xilio shall provide prompt and reasonable assistance, as requested by Gilead, with

respect to such filings, including by taking such action as may be required of the Patent holder under any Applicable Law.

9.3.8. UPC Opt-Out and Opt-In. Gilead shall have the sole right to make decisions regarding any UPC Opt-Out or UPC Opt-In with respect to any [**]. Xilio shall provide prompt and reasonable assistance, as requested by Gilead, with respect to such UPC Opt-Out or UPC Opt-In, including by taking such action as may be required of the Patent holder under any Applicable Law. Xilio shall have the sole right to make decisions regarding any UPC Opt-Out or UPC Opt-In with respect to [**].

9.4. Enforcement of Patents.

9.4.1. Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of the [**] in any jurisdiction in the Territory based on the development, commercialization or an application to market a product containing an IL-12 Molecule or any IL-12 Product or Competing Product (including any Biosimilar Product) of which such Party becomes aware (a “**Competitive Infringement**”).

9.4.2. Enforcement of Infringement Actions Prior to the Continuation Date. As between the Parties, prior to the Continuation Date, Xilio shall have the first right, but not the obligation, to prosecute any infringement [**] with respect to the [**], including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Xilio's sole cost and expense, using counsel of its own choice (*provided* that Xilio shall not settle any Competitive Infringement in any manner that would reasonably be expected to have an adverse effect on Gilead's rights under this Agreement). In the event that Xilio prosecutes any infringement with respect to [**], Gilead shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; *provided* that Xilio shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If Xilio or its designee does not take commercially reasonable steps to prosecute or settle an infringement by the earlier of (a) [**] following the first notice of such infringement (or, with respect to Competitive Infringement under 35 USC §271(e)(2), [**]) and (b) [**] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, then Gilead shall have the right to prosecute such infringement with respect to a [**] or [**] with respect to [**], as applicable, at its sole cost and expense, using counsel of its own choice (*provided* that Gilead shall not have the right to prosecute such [**] with respect to [**] prior to the Continuation Date without Xilio's prior written consent). The controlling Party shall promptly notify the other Party if it determines not to prosecute or settle any infringement [**] with respect to [**].

9.4.3. Enforcement of Infringement Actions After the Continuation Date.

(a) **Licensed Patents (other than Product Patents) After the Continuation Date.** As between the Parties, from and after the Continuation Date, Xilio shall have the first right, but not the obligation, to prosecute any infringement [**] with respect to [**], including

as a defense or counterclaim in connection with any Third Party Infringement Claim, at Xilio's sole cost and expense, using counsel of its own choice; *provided* that (i) Xilio shall not institute any action or discussions with respect to a Competitive Infringement without Gilead's prior written consent and (ii) if there is no valid and enforceable [**] that would be infringed by the Exploitation of the IL-12 Molecule, IL-12 Product or Competing Product that is the subject of a Competitive Infringement, Gilead shall have the right to prosecute such Competitive Infringement with respect to [**] at its sole cost and expense. In the event Xilio prosecutes any such Competitive Infringement, Gilead shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; *provided* that Xilio shall retain control of the prosecution of such claim, suit or proceeding to the extent applicable to [**], including the response to any defense or defense of any counterclaim raised in connection therewith. If Xilio or its designee does not take commercially reasonable steps to prosecute or settle a Competitive Infringement with respect to [**] by the earlier of (x) [**] following the first notice of such Competitive Infringement (or, with respect to Competitive Infringement under 35 USC §271(e)(2), [**]) and (y) [**] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, then, unless [**], Gilead shall have the right to prosecute such Competitive Infringement with respect to [**] at its sole cost and expense. Xilio shall promptly notify Gilead if it determines not to prosecute or settle a Competitive Infringement with respect to [**].

(b) **Product Patents and Joint Patents After the Continuation Date.** As between the Parties, from and after the Continuation Date, Gilead shall have the first right, but not the obligation, to prosecute any infringement [**] with respect to [**], including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Gilead's sole cost and expense, using counsel of its own choice. If Gilead or its designee does not take commercially reasonable steps to prosecute or settle a Competitive Infringement with respect to [**] by the earlier of (x) [**] following the first notice provided above with respect to such Competitive Infringement (or, with respect to Competitive Infringement under 35 USC §271(e)(2), [**]) and (y) [**] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, then, unless [**], Xilio may prosecute such Competitive Infringement with respect to [**] at its sole cost and expense. Gilead shall promptly notify Xilio if it determines not to prosecute or settle a Competitive Infringement with respect to [**].

9.4.4. Cooperation; Settlement. Where a Party controls an infringement action under this Section 9.4, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.4, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees available at reasonable business hours; *provided* that, the controlling Party shall reimburse such other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. Unless otherwise set forth herein, the Party entitled to bring any infringement action in accordance with this Section 9.4 shall have the right to settle such claim; *provided* that [**]. The Party that controls any Competitive Infringement claim, suit or proceeding pursuant to this Section 9.4 shall (a) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding, (b) consider in good faith any comments from the other Party and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such claim, suit or proceeding.

9.4.5. Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement and except with respect to costs incurred by a Party that joins and participates in litigation at its sole cost and expense as set forth in this Section 9.4, any recovery realized as a result of such litigation described above in this Section 9.4 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated *pro rata* if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to bring the enforcement action; *provided, however*, that, to the extent that any award or settlement (whether by judgment or otherwise) with respect to [**] is attributable to loss of sales or profits with respect to a Lead Product or Back-Up Product, (a) if Gilead controls such action, Gilead shall pay to Xilio [**] and (b) if Xilio controls such action, Xilio shall pay to Gilead [**].

9.5. Invalidity or Unenforceability Defenses or Actions.

9.5.1. Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of [**] by a Third Party of which such Party becomes aware.

9.5.2. Defense Actions.

(a) **Prior to the Continuation Date.** As between the Parties, prior to the Continuation Date, (i) Xilio shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of [**] and (ii) Gilead shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of [**], in each case ((i) and (ii)), in the Territory, using counsel of its own choice, at its sole cost and expense.

(b) **After the Continuation Date.** As between the Parties, from and after the Continuation Date, (i) Xilio shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of [**] and (ii) Gilead shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of [**], in each case ((i) and (ii)), in the Territory, using counsel of its own choice, at its sole cost and expense; *provided that*, in each case ((i) and (ii)), if the assertion of invalidity or unenforceability of such Patents is brought as a defense or counterclaim in connection with an infringement action initiated pursuant to Section 9.4, the applicable enforcing Party shall have the first right, but not the obligation, to defend and control the validity and enforceability of such Patents at its sole cost and expense. For clarity, this Section 9.5 shall not apply to control of Defense Proceedings, which proceedings shall be governed by Section 9.3. Nothing in this Section 9.5 will limit any indemnification rights or obligations of a Party under Article 12.

9.5.3. Step-In; Cooperation. If the controlling Party elects not to defend or control the defense of the [**] in a claim, suit or proceeding arising under this Section 9.5 brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, and, in either case, has not settled and is not actively pursuing settlement of such claim, suit or proceeding, then the other Party may conduct and control the defense of any such claim, suit or proceeding at its own expense; *provided that* [**]. The non-controlling Party may participate in any claim, suit or proceeding regarding the validity and enforceability of such [**] in the Territory with counsel of its choice at its sole cost and expense; *provided that* the controlling Party shall retain control of the defense in such claim, suit or proceeding. Where a Party controls a claim, suit or

proceeding under this Section 9.5, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time in connection with its activities set forth in this Section 9.5, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, the relevant action, providing access to relevant records, documents and other evidence (including

laboratory notebooks) and making inventors and other of its employees available at reasonable business hours; *provided* that, the controlling Party shall reimburse such other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. In connection with any activities with respect to a defense, claim or counterclaim relating to [**] pursuant to this Section 9.5, the controlling Party shall (a) consult with the other Party as to the strategy for such activities, (b) consider in good faith any comments from the other Party and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

9.6. Infringement Claims by Third Parties. If the Exploitation of [**] pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by a Party or any of its Affiliates or its or their (sub)licensees/Sublicensees, distributors or customers (a “**Third Party Infringement Claim**”), including any defense or counterclaim in connection with an enforcement action initiated pursuant to Section 9.4, the Party first becoming aware of such alleged Third Party Infringement Claim shall promptly notify the other Party thereof in writing. As between the Parties, prior to the Continuation Date, Xilio shall have the sole right, but not the obligation, to defend and control the defense of (including to settle) any such Third Party Infringement Claim at its sole cost and expense (but subject to Article 12), using counsel of its own choice; *provided* that Xilio shall obtain the written consent of Gilead prior to settling or compromising any such Third Party Infringement Claim. As between the Parties, from and after the Continuation Date, Gilead shall have the sole right, but not the obligation, to defend and control the defense of (including to settle) any such Third Party Infringement Claim at its sole cost and expense (but subject to Section 8.7 and Article 12), using counsel of its own choice. In each case, the non-controlling Party may participate in any such Third Party Infringement Claim with counsel of its choice at its sole cost and expense; *provided* that the controlling Party shall retain control of such Third Party Infringement Claim. Where a Party controls such an action, after the Continuation Date, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.6, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees available at reasonable business hours; *provided* that the controlling Party shall reimburse such other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. Nothing in this Section 9.6 will limit any indemnification rights or obligations of a Party under Article 12.

9.7. Third Party Rights.

9.7.1. Prior to the Continuation Date.

(a) Subject to Section 9.2, prior to the Continuation Date, if Xilio determines that any Patent, trade secret or other intellectual property right of a Third Party in any country in the Territory is necessary or useful for the Exploitation of an IL-12 Molecule or IL-12 Product (such Patent, trade secret or other intellectual property right, a “Third Party Right”), then, as between the Parties, Xilio shall have the sole right, but not the obligation, to challenge the applicability, patentability, validity or enforceability of, or to enter into a license or other agreement with such Third Party pursuant to which Xilio or its Affiliate would acquire a license or other right under, such Third Party Right as necessary or useful to Exploit IL-12 Molecules and IL-12 Products in such country. Prior to entering into any such license or other agreement with respect to a Third Party Right, Xilio shall notify Gilead of such Third Party Right, including a reasonably detailed explanation of its relevance and Xilio’s plans with respect thereto. Xilio shall ensure that the terms of such license are consistent with this Agreement and such terms as applicable to the IL-12 Molecules and IL-12 Products are no less favorable than the terms applicable to other programs

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and products under such license agreement. Xilio will promptly provide Gilead with notice and a copy of each such agreement entered into by Xilio or any of its Affiliates.

(b) As soon as reasonably practical after the Effective Date, Xilio shall [**]. Without limiting the foregoing, [**], Xilio shall [**].

9.7.2. After the Continuation Date. From and after the Continuation Date [**], if Gilead determines that any Third Party Right is necessary or useful for the Exploitation of an IL-12 Molecule or IL-12 Product by Gilead or any of its Affiliates or any of its or their Sublicensees, distributors or customers, then, as between the Parties, Gilead shall have the sole right, but not the obligation, to challenge the applicability, patentability, validity or enforceability of, or to enter into a license or other agreement with such Third Party pursuant to which Gilead or its Affiliate would acquire a license or other right under, such Third Party Right as necessary or useful for Gilead or its Affiliates or its and their Sublicensees, distributors or customers to Exploit IL-12 Molecules and IL-12 Products in such country. [**].

9.8. Product Trademarks. As between the Parties, Gilead and its Affiliates shall have the sole right to use any Trademark it owns or controls for IL-12 Products in the Territory at its sole discretion. Gilead shall have the sole right to determine, develop, prosecute, enforce and defend one (1) or more Product Trademark(s) for use by Gilead and its Affiliates and its or their Sublicensees in the Territory to Commercialize IL-12 Products in the Field in the Territory. As between the Parties, Gilead and its Affiliates shall own all rights to such Product Trademarks and all goodwill associated therewith, and the rights to any Internet domain names incorporating the applicable Product Trademarks or any variation or part of such Product Trademarks used as its URL address or any part of such address, throughout the Territory. Xilio shall not, and shall cause its Affiliates and its and their

(sub)licensees not to, (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks and (b) do any act that endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. Xilio shall not, and shall cause its Affiliates and its and their (sub)licensees not to, attack, dispute or contest the validity of or ownership of any Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

9.9. [**]. Notwithstanding any provision to the contrary in this Article 9, to the extent that any [**] constitutes a Collaboration Patent under [**], each Party's rights set forth in this Article 9 with respect to such [**] shall be subject to [**] rights and Gilead's obligations with respect thereto under the [**].

ARTICLE 10 CONFIDENTIALITY AND NON-DISCLOSURE

10.1. **Confidentiality Obligations.** At all times during the Term and for a period of [**] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its Affiliates and each of its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. “**Confidential Information**” means any technical, business or other information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic or otherwise) that is disclosed or otherwise provided by or on behalf of one (1) Party to the other Party in connection with this Agreement or that certain Mutual Confidential Disclosure Agreement entered into by the Parties, dated [**], as amended (“**Confidentiality Agreement**”), whether prior to, on or after the Effective Date, including the

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terms of this Agreement (subject to Section 10.5), information relating to any IL-12 Molecule or any IL-12 Product (including the Regulatory Documentation), any Development or Commercialization of any IL-12 Molecule or any IL-12 Product, any Information with respect thereto developed by or on behalf of the disclosing Party or its Affiliates or its or their respective (sub)licensees/Sublicensees (including Licensed Know-How) and the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Confidential Information constituting (a) [**] shall be deemed the Confidential Information of Gilead (and Gilead shall be deemed to be the disclosing Party and Xilio shall be deemed to be the receiving Party with respect thereto), (b) from and after the Continuation Date until termination (but not expiration) of this Agreement, Regulatory Documentation, [**], in each case, specifically relating to any IL-12 Molecule or any IL-12 Product or the Exploitation of any of the foregoing in the Field in the Territory (collectively, “**Product Information**”) shall be deemed the Confidential Information of Gilead (and Gilead shall be deemed to be the disclosing Party and Xilio shall be deemed to be the receiving Party with respect thereto), (c) [**] and, for clarity, [**] and, prior to the Continuation Date, Product Information shall be deemed

the Confidential Information of Xilio (and Xilio shall be deemed to be the disclosing Party and Gilead shall be deemed to be the receiving Party with respect thereto) and (d) any other [**] and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto).

10.2. Exceptions. Notwithstanding the foregoing, information will not be Confidential Information, and the confidentiality and non-use obligations under Section 10.1 shall not apply to any such information, that:

10.2.1. is or hereafter becomes generally available to the public by use, publication, general knowledge or the like other than by breach by the receiving Party or any of its Affiliates of this Agreement or, prior to the Effective Date, the Confidentiality Agreement by the receiving Party;

10.2.2. is subsequently disclosed to the receiving Party or any of its Affiliates, without obligation of confidentiality or non-use, by a Third Party who may lawfully do so and who is not under an obligation of confidentiality to the disclosing Party or any of its Affiliates with respect to such information;

10.2.3. was already in the possession of the receiving Party or any of its Affiliates prior to receipt from the disclosing Party or any of its Affiliates as shown in the written records of the receiving Party or its Affiliates or by other competent evidence; *provided* that the foregoing exception shall not apply with respect to [**] disclosed to Gilead under the Confidentiality Agreement prior to the Effective Date, [**]; or

10.2.4. is or was independently developed by the receiving Party or any of its Affiliates without use or reference to Confidential Information of the disclosing Party, as shown in the written records of the receiving Party or its Affiliates or by other competent evidence; *provided* that the foregoing exception shall not apply with respect to [**].

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

10.3. Permitted Disclosures. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

10.3.1. made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body

of competent jurisdiction or, if in the advice of the receiving Party's legal counsel, such disclosure is otherwise required by law (other than by reason of filing with securities regulators, which shall be governed by Section 10.5); *provided* that to the extent practicable under the circumstances, the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order or required to be disclosed be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by law; and *provided, further*, that the Confidential Information disclosed in response to such court or governmental order or as required by law shall be limited to the information that is legally required to be disclosed in response to such court or governmental order or by such law;

10.3.2. made in order to prosecute or defend litigation;

10.3.3. with respect to Xilio's disclosure of Gilead's Confidential Information related to **[**]**, necessary in connection with (a) the use of any permitted subcontractors for the performance of the Combination Arm; *provided* that such subcontractors shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than **[**]** from the date of disclosure) or (b) any submission to or other communication with any Regulatory Authority, institutional review board or other ethics committee relating to the Combination Arm or the Combination Therapy; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

10.3.4. necessary for the purpose of evaluating or carrying out an actual or potential investment, acquisition, debt transaction or royalty financing transaction, including to existing or potential investors, financing sources, underwriters or acquirers (including in connection with any royalty financing transaction); *provided* that such Persons (including such investors, financing sources, underwriters or acquirers) shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than **[**]** from the date of disclosure);

10.3.5. made by or on behalf of Gilead or its Affiliates or its or their Sublicensees as may be necessary or reasonably useful in connection with the Exploitation of the IL-12 Molecules, the IL-12 Products (including in connection with any filing, application or request for Regulatory Approval by or on behalf of Gilead or any of its Affiliates or its or their Sublicensees) or otherwise in connection with the performance of its obligations or exercise of Gilead's rights as contemplated by this Agreement, including to existing or potential vendors, service providers, contractors, distributors, (sub)licensees or collaboration partners; *provided* that such vendors, service providers, contractors, distributors, (sub)licensees or collaboration partners shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than **[**]** from the date of disclosure);

10.3.6. made by or on behalf of the receiving Party to a patent authority as may be necessary or reasonably useful for purposes of obtaining or enforcing a Patent in accordance with the terms of this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

10.3.7. made by or on behalf of Gilead in accordance with Section 3.4.2(c).

10.4. Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their respective (sub)licensees/Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.4 shall not prohibit either Party from making any disclosure (a) identifying Xilio to the extent required in connection with its exercise of its rights or obligations under this Agreement or (b) identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). If a Party desires to use the other Party's corporate name or logo in presentations, its website, collateral materials or corporate overviews to describe the collaboration relationship, or in taglines of press releases issued pursuant to this Section 10.4 (Use of Names), such Party will make such request to the other Party, and the other Party will promptly consider such request in good faith.

10.5. Public Announcements. The Parties have agreed upon the content of a joint press release, which shall be issued substantially in the form(s) attached hereto as **Schedule 10.5**, the release of which the Parties shall coordinate in order to accomplish such release promptly following the Effective Date. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, consistent with the advice of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, consistent with the advice of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than **[**]** prior to the anticipated date of disclosure unless a shorter timeframe is required by Applicable Law or the circumstances) so as to provide a reasonable opportunity to comment thereon; *provided* that if such required disclosure includes a disclosure of this Agreement, then the disclosing Party shall also submit a redacted form of this Agreement to the other Party and shall submit a confidential treatment request (or equivalent protection in a country other than the U.S.) in connection with such disclosure. The disclosing Party shall incorporate any reasonable comments received from the other Party with respect to such disclosure. Notwithstanding the foregoing, from and after the Continuation Date, Gilead and its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the IL-12 Molecules and IL-12 Products; *provided* that such disclosure is subject to the other provisions of this Article 10 with respect to Xilio's Confidential Information. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 10.5, *provided* that such information remains current and accurate as of such time and provided the frequency and form of such disclosure are reasonable.

10.6. Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of, and information regarding, activities under this Agreement. Accordingly:

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10.6.1. prior to the Continuation Date, Xilio shall have the right to publicly disclose the results of, and information regarding, activities under this Agreement, subject to Gilead's prior written consent, not to be unreasonably withheld, conditioned or delayed. The Parties acknowledge and agree that it shall be reasonable for Gilead to withhold its consent for concerns regarding patent protection, to otherwise address issues of Confidential Information or related competitive harm and to the extent any such publication relates to [**];

10.6.2. from and after the Continuation Date, Gilead shall be free to publicly disclose the results of, and information regarding, activities under this Agreement, subject to prior review by Xilio of any disclosure of Xilio's Confidential Information for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 10.6.2. Accordingly, prior to publishing or disclosing any of Xilio's Confidential Information, Gilead shall provide Xilio with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information. Xilio shall respond promptly through its designated representative and in any event no later than [**] after the receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation. Gilead agrees to allow a reasonable period (not to exceed [**]) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm; and

10.6.3. with respect to the listing of clinical trials or the publication of clinical trial results for the IL-12 Molecules or IL-12 Products, each Party will comply with the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results. The Parties agree that any such listings of clinical trials or publications of clinical trial results will be considered a publication for purposes of this Section 10.6.

10.7. Protection of Personal Data.

10.7.1. The Parties acknowledge and agree that each Party alone determines the purposes and means of its Processing of Personal Data in connection with this Agreement, and thus that each Party is the controller in respect of its own Processing of Personal Data in connection with this Agreement (where such concept is recognized under applicable Data Protection Law) and not a processor which Process Personal Data on behalf of the other Party. Consequently, each Party shall comply with the obligations as a controller under applicable Data Protection Law and Process Personal Data, including pseudonymized raw data, only in accordance with Data Protection Law. Notwithstanding the foregoing, Xilio shall provide a data privacy notice to all Persons participating in clinical trials under the Development Plan that discloses and is consistent with, and, when required by applicable Data Protection Law, obtain appropriate consent or authorization in accordance with applicable Data Protection Law to allow for, the use and other Processing of Personal Data as set forth in this Agreement, including the Processing of data (including the Combination Clinical Data

and Combination Sample Analysis Results) by Gilead as contemplated in this Agreement. Without limitation, Xilio shall ensure that there is no prohibition or restriction that (a) prevents or restricts it from disclosing or transferring data (including the Combination Clinical Data and Combination Sample Analysis Results) to Gilead as contemplated under this Agreement or (b) prevents or restricts Gilead from Processing such data as contemplated under this Agreement. If any Party becomes aware that it has provided Personal Data to the other Party that may not be shared pursuant to such a consent, authorization or notice, or such Person participating in a clinical trial has withdrawn his or her consent or authorization for the Processing of Personal Data, such Party shall promptly notify the other Party so that the affected Personal Data can be removed or anonymized if and to the extent required under applicable Data Protection Law.

10.7.2. The Parties agree to enter any supplemental terms that are or become required under Data Protection Law, including, as necessary, (a) supplemental data processing agreements, (b) joint

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controllership terms or (c) data transfer agreements that may be required with respect to the international transfer of Personal Data.

10.7.3. Upon request, each Party shall provide to the other Party commercially reasonable assistance as is reasonably requested to enable the requesting Party to comply with its obligations under Data Protection Law. Without limitation, Xilio shall provide, and shall ensure that all clinical trial site personnel provide, Gilead with reasonable assistance in addressing data subject rights (e.g., rights to access, correct, delete and object to processing of Personal Data), conducting privacy impact assessments and responding to data subject inquiries, in each case, in accordance with industry practices and Data Protection Laws.

10.7.4. Xilio shall notify Gilead in writing (a) immediately, if Xilio becomes aware of any investigation by or communication from any government authority relating to Personal Data Processed in connection with this Agreement, in which case Xilio shall also inform Gilead of all material information relating to the circumstances giving rise to such claims; and (b) promptly, if Xilio receives any inquiry, notice or complaint from any individual relating to Personal Data about that individual.

10.8. Information Security. Each Party shall implement and maintain reasonable administrative, technical and physical safeguards that comply with Data Protection Law and are designed to (a) maintain the security and confidentiality of Personal Data and the Confidential Information of the other Party and the systems on which such data is Processed; (b) protect against reasonably anticipated threats or hazards to the security or integrity of such data and systems; and (c) protect against unauthorized access to or use of such data and systems.

ARTICLE 11

REPRESENTATIONS AND WARRANTIES

11.1. Mutual Representations and Warranties. Xilio and Gilead each represents and warrants to the other as of the Effective Date that:

11.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

11.1.2. the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

11.1.3. this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

11.1.4. neither it nor any of its Affiliates nor its or their (sub)licensees has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the IL-12 Molecules or IL-12 Products, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section; and

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11.1.5. it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

11.2. Additional Representations and Warranties of Xilio. Xilio further represents and warrants to Gilead that (a) except as set forth in **Schedule 11.2** attached hereto (the "**Initial Disclosure Schedule**") and except with respect to Section 11.2.18, as of the Effective Date, and (b) subject to Section 11.3.2, except as set forth in the Data Package Disclosure Schedule, as of the date Xilio delivers the Data Package to Gilead (the "**Data Package Delivery Date**"), as follows:

11.2.1. All existing Licensed Patents are listed on **Schedule 11.2.1** (the "**Existing Patents**"), and Xilio is the sole and exclusive owner of the entire rights, title and interests in the Existing Patents listed on **Schedule 11.2.1** free of any encumbrance, lien or claim of ownership by any Third Party. All such Existing Patents are subsisting and, to the Knowledge of Xilio, are not invalid or unenforceable, in whole or in part, are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment (taking account of any permitted extensions). With respect to pending applications in the Existing

Patents, Xilio and its Affiliates have presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office. Xilio is entitled to grant the licenses specified herein.

11.2.2. All Existing Agreements are listed on **Schedule 11.2.2.** To the Knowledge of Xilio, the Development, Manufacture and Commercialization of the IL-12 Molecules and the IL-12 Products as contemplated as of the Effective Date and Data Package Delivery Date, as applicable, are not subject to any other license or agreement to which Xilio or any of its Affiliates is a party other than the Existing Agreements. The rights and obligations of the Parties hereunder are fully consistent with, and are not limited in any material respect by, the Existing Agreements. None of Xilio or its Affiliates (a) is, to the Knowledge of Xilio, in material breach of any Existing Agreement or (b) has received any written notice of material breach or termination under any Existing Agreement from the counterparty thereto. To the Knowledge of Xilio, (i) no facts or circumstances exist that would reasonably be expected to give rise to any such material breach or termination and (ii) no counterparty is in material breach of any Existing Agreement.

11.2.3. There are no claims, judgments or settlements against, or amounts with respect thereto owed by, Xilio or any of its Affiliates relating to the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How. Neither Xilio nor any of its Affiliates has received written notice of any actual or threatened claim or litigation, or any notice of any pending claim or litigation, and Xilio has no Knowledge of any such claim, whether or not asserted, that (a) the Existing Patents are invalid or unenforceable or (b) the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How, or the disclosing, copying, making, assigning or licensing of the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How or the Development, Manufacture or Commercialization of the IL-12 Molecules or IL-12 Products as contemplated herein, does or will violate, infringe, misappropriate or otherwise conflict or interfere with, any Patent or other intellectual property or proprietary right of any Person, and to Xilio's Knowledge, no facts or circumstances exist that would reasonably be expected to give rise to any such claims. To Xilio's Knowledge, no Person (i) has infringed, is infringing or threatening to infringe any Existing Patent or (ii) has misappropriated, is misappropriating or threatening to misappropriate the Licensed Know-How.

11.2.4. To the Knowledge of Xilio, the Development, Manufacture or Commercialization of the IL-12 Molecules or IL-12 Products as contemplated herein as of the date of such representation does

not violate, infringe, misappropriate or otherwise conflict or interfere with any Patent or other intellectual property or proprietary right of any Third Party.

11.2.5. Xilio Controls all Information and Patents in its or its Affiliates' ownership or control that are necessary or useful to Develop, Manufacture or Commercialize the IL-12 Molecules and the IL-12 Products as contemplated herein and such Information and Patents are not subject to

any other license or agreement to which Xilio or any of its Affiliates is a party. Xilio Controls all Regulatory Documentation with respect to the IL-12 Molecules and IL-12 Products.

11.2.6. The Existing Patents represent all Patents within Xilio's or its Affiliates' ownership or control that are necessary or useful to Develop, Manufacture or Commercialize the IL-12 Molecules or the IL-12 Products as contemplated herein as of the date of such representation. The Licensed Know-How represent all Information within Xilio's or its Affiliates' ownership or control necessary or useful to Develop, Manufacture or Commercialize the IL-12 Molecules or the IL-12 Products as contemplated herein as of the date of such representation. Neither Xilio nor any of its Affiliates has previously entered into any written agreement with respect to, or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to, any Patent or Information that would be Existing Patents or Licensed Know-How, as applicable, but for such assignment, transfer, license, conveyance or encumbrance, and it will not enter into any such agreements or grant any such right, title, or interest to any Person that is inconsistent with the rights and licenses granted to Gilead under this Agreement.

11.2.7. Each Person who has or has had any rights in or to any Existing Patents or any Licensed Know-How has assigned and has executed an agreement assigning its entire right, title and interest in and to such Existing Patents and Licensed Know-How to Xilio. To Xilio's Knowledge, no current officer, employee, agent or consultant of Xilio or any of its Affiliates is in violation of any term of any assignment or other agreement, including any employment contract, regarding the protection of Patents or other intellectual property or proprietary information of Xilio or such Affiliate.

11.2.8. Xilio or one of its Affiliates has obtained the right (including under any Patents and other intellectual property rights) to use all Information and all other materials (including any formulations and manufacturing processes and procedures) developed or delivered by any Third Party under any Existing Agreements with respect to the IL-12 Molecules and IL-12 Products to the extent necessary to provide Gilead with the rights to Develop, Manufacture and Commercialize the IL-12 Molecules and IL-12 Products as contemplated hereunder, and Xilio or one of its Affiliates has the rights under each such agreement to transfer such Information or other materials to Gilead and its designees and to grant Gilead the right to use such Information or other materials in the Development, Manufacture and Commercialization of the IL-12 Molecules or IL-12 Products as required to enable Gilead to Exploit the IL-12 Molecules or IL-12 Products as contemplated hereunder.

11.2.9. The inventions claimed or covered by the Existing Patents (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e), (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401 and (d) are not the subject of any licenses, options or other rights of any other governmental authority, within or outside the United States, due to such governmental authority's funding of research and development or otherwise (other than the right to receive payments or any law of general application that applies to personal property generally, e.g., takings laws).

11.2.10. With respect to the portions of the Licensed Know-How the confidentiality of which is material to Develop, Manufacture or Commercialize the IL-12 Molecules or the IL-12 Products existing as of the Effective Date or Data Package Delivery Date, as applicable, such portions of the Licensed Know-How have been kept confidential or have been disclosed to Third Parties only under terms of confidentiality or if published or otherwise publicly disclosed, were published or publicly disclosed in a manner that would not reasonably be expected to adversely impact the patentability of such Licensed Know-How. To the Knowledge of Xilio, no breach of such confidentiality has been committed by any Third Party.

11.2.11. Xilio has made available to Gilead copies of (a) the file wrapper and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Existing Patents; (b) all Existing Regulatory Documentation and all Existing Agreements; and (c) Licensed Know-How and other Information in its possession or Control necessary or useful to Develop, Manufacture or Commercialize the IL-12 Molecules or IL-12 Products, including all material adverse information with respect to the safety and efficacy of the IL-12 Molecules known to Xilio or its Affiliates, and in each case ((a) through (c)), all such materials, Existing Regulatory Documentation, Existing Agreements, Licensed Know-How and other Information are true and correct. Neither Xilio nor any of its Affiliates has any Knowledge of any scientific or technical facts or circumstances that would adversely affect the scientific, therapeutic or commercial potential of the IL-12 Molecules or IL-12 Products. Neither Xilio nor any of its Affiliates is aware of anything that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for any IND or Regulatory Approval.

11.2.12. Neither Xilio nor any of its Affiliates or its or their respective officers or employees or, to the Knowledge of Xilio, its or any of its Affiliates' agents or (sub)licensees, nor any of such agents' or sublicensees' respective officers, employees or agents, has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the IL-12 Molecules or IL-12 Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the IL-12 Molecules or IL-12 Products or committed an act, made a statement or failed to make a statement with respect to the Development of the IL-12 Molecules or IL-12 Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

11.2.13. Xilio and its Affiliates and its and their (sub)licensees have conducted, and their respective contractors and consultants have conducted, all Development and Manufacture of the IL-12 Molecules and IL-12 Products (including the generation, preparation, maintenance and retention of all Regulatory Documentation) that they have conducted prior to the Effective Date and the Data Package Delivery Date, as applicable, in accordance with good laboratory and clinical practice and Applicable Law.

11.2.14. There are no amounts that will be required to be paid to a Third Party as a result of the Development, Manufacture or Commercialization of the IL-12 Molecules or IL-12 Products that arise out of any agreement (other than the Existing Agreements) to which Xilio or any of its Affiliates is a party.

11.2.15. Xilio and its Affiliates and its and their (sub)licensees have complied with all Applicable Laws relating to the privacy, Processing of Personal Data, and information security in all countries in connection with the IL-12 Molecules and IL-12 Products (including any transfer of Personal Data across national borders), all privacy related consents, authorizations and notices that apply to the IL-12 Molecules and IL-12 Products and the requirements of any contract or codes of conduct to which it is a party. Xilio, its Affiliates and its and their (sub)licensees has, when required by applicable Data Protection

Law, provided a data privacy notice to all persons participating in clinical trials with respect to the IL-12 Molecules and IL-12 Products and obtained appropriate consent and authorization from such persons. Such notices, consents and authorizations are in accordance with applicable Data Protection Law and allow for the disclosure and use of Personal Data by Gilead, its Affiliates and its and their Sublicensees as set forth in this Agreement. Without limitation, as appropriate, such notices, consents and authorizations have been approved by a cognizant and appropriately qualified institutional review board or research ethics committee.

11.2.16. In connection with this Agreement, the IL-12 Molecules and the IL-12 Products, Xilio, its Affiliates, its and their owners, officers, directors or employees and, to the Knowledge of Xilio, its and their (sub)licensees and other Persons acting on its or their behalf (a) have complied with all Anti-Corruption Laws and (b) have not, directly or indirectly, (i) made, offered, given, promised to give or authorized any bribe, kickback, payment or transfer of anything of value, regardless of form or amount, to any Government Official or any other Person for the purpose of: (A) improperly influencing any act or decision of the Government Official; (B) inducing the Government Official to do or omit to do any act in violation of a lawful or otherwise required duty; or (C) securing any improper advantage, (ii) made or permitted any off-the-books accounts, inadequately identified transactions, recording of non-existent expenditures, entry of liabilities with incorrect identification of their object or the use of false documents, (iii) been (and is not under) administrative, civil or criminal investigation, indictment, information, suspension, debarment or audit by any governmental authority, in connection with alleged or possible violations of any Anti-Corruption Laws and (iv) (A) received written notice or inquiry from, or made a voluntary or involuntary disclosure to, the United States Department of Justice, the Securities and Exchange Commission, the UK Serious Fraud Office or any other governmental authority, (B) received a whistleblower report or (C) conducted any internal investigation or audit regarding alleged or possible violations of any Anti-Corruption Laws.

11.2.17. Neither Xilio nor any of its Affiliates or, to the Knowledge of Xilio, any Third Party has ever requested or caused to be requested any UPC Opt-In or UPC Opt-Out of any Existing Patents.

11.2.18. Solely as of the Data Package Delivery Date, (a) the Data Package is complete and correct in all material respects and (b) if Xilio has entered into any agreement with a Third Party in order to obtain a license or right under a Third Party Right pursuant to Section 9.7, (i) such agreement is valid, enforceable, in full force and effect and, by its terms, is sublicensable to Gilead as contemplated by this Agreement, (ii) the rights and obligations of the Parties hereunder are

fully consistent with, and are not limited in any material respect by, such agreement, including that the rights granted to Gilead hereunder to intellectual property licensed pursuant such agreement are no more restricted under such agreement than the analogous rights granted to Gilead hereunder with respect to intellectual property rights wholly owned by Xilio or its Affiliates and (iii) Xilio has made available to Gilead a copy of any such agreement.

11.2.19. To the Knowledge of Xilio, the representations and warranties of Xilio in this Agreement and the information, documents and materials furnished to Gilead in connection with its period of diligence prior to the Effective Date and the Data Package Delivery Date, as applicable, do not, taken as a whole, (a) contain any untrue statement of a material fact or (b) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading.

11.3. Updated Disclosure Schedules.

11.3.1. On the Data Package Delivery Date, Xilio shall provide to Gilead either (a) an updated **Schedule 11.2.1**, an updated **Schedule 11.2.2** and a list of any exceptions to any of the representations and warranties in Section 11.2 (such list of exceptions, the “**Data Package Disclosure**

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Schedule”); or (b) a written statement that no such updates are required and all such schedules and representations and warranties, as qualified by the Initial Disclosure Schedule, remain true and correct as of the Data Package Delivery Date.

11.3.2. Any update in the Data Package Disclosure Schedule shall not be deemed to amend or supplement the Initial Disclosure Schedule as it exists as of the Effective Date, including for the purposes of the indemnification provisions under Section 12.2 (and therefore shall not cure any prior failure to disclose). For all representations and warranties for which Xilio does not provide an updated schedule pursuant to Section 11.3.1, or if Xilio fails to provide any updated schedules or such statement in clause (b) of Section 11.3.1 as of the Data Package Delivery Date, Xilio shall be deemed to have made the representations and warranties in Section 11.2 to Gilead as of the Data Package Delivery Date without additional qualification. For the avoidance of doubt, an exception made by Xilio in the Data Package Disclosure Schedule shall not cure a deficiency in the Initial Disclosure Schedule. Xilio acknowledges and agrees that any disclosure made in the Data Package Disclosure Schedule cannot cure a breach of any covenant or obligation of Xilio hereunder, including Section 11.5.

11.4. Anti-Bribery and Anti-Corruption Compliance. In connection with this Agreement, the IL-12 Molecules and the IL-12 Products, each Party, its Affiliates and its and their (sub)licensees and its and their owners, employees, officers, directors and other representatives, in each case, will comply with all Anti-Corruption Laws. Each Party and its Affiliates have, and undertake that they shall update and maintain during the Term, an adequate system of internal controls, including anti-corruption policies, procedures and training, that are reasonably designed to ensure compliance with

Anti-Corruption Laws and under which such Party's (and its Affiliates') owners, employees, officers, directors, (sub)licensees and other representatives are required to comply with all Applicable Law, including Anti-Corruption Laws. In connection with this Agreement, the IL-12 Molecules and the IL-12 Products, none of each Party, its Affiliates, its or their (sub)licensees or any of its or their owners, officers, directors or employees, and to the Knowledge of each Party, no other Person acting on its or their behalf, directly or indirectly, (a) will make, offer, give, promise to give or authorize any bribe, kickback, payment or transfer of anything of value, regardless of form or amount, to any Government Official or any other Person for the purpose of: (i) improperly influencing any act or decision of the Government Official; (ii) inducing the Government Official to do or omit to do any act in violation of a lawful or otherwise required duty; or (iii) securing any improper advantage or (b) will make or permit any off-the-books accounts, inadequately identified transactions, recording of non-existent expenditures, entry of liabilities with incorrect identification of their object or the use of false documents.

11.5. Covenants.

11.5.1. Each Party, its Affiliates and its and their (sub)licensees (with respect to Xilio)/Sublicensees (with respect to Gilead) will, in the course of performing its obligations or exercising its rights under this Agreement, comply with all Applicable Law, including, as applicable, cGMP, GCP and GLP standards, and will not employ or engage, and if so employed and engaged, will thereafter terminate such Person's involvement with the IL-12 Molecules and IL-12 Products, any Person who has been debarred pursuant to Section 306 of the FFDCa or who is the subject of a conviction described in such

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section, or is the subject of any proceedings that could result in such Person being debarred pursuant to Section 306 of the FFDCa or the subject of a conviction described in such section.

11.5.2. During the Term, neither Xilio nor any of its Affiliates shall encumber or diminish the rights granted (or to be granted as of the Continuation Date) to Gilead hereunder with respect to the Licensed Patents.

11.5.3. During the Term, Xilio shall not, and shall cause its Affiliates not to (a) misappropriate any Know-How of a Third Party or infringe any published or issued Patent (or, with respect to any Patent application, take any action that would constitute infringement if such application were to issue as a published Patent) or, to the extent known, or reasonably knowable, by Xilio or any of its Affiliates, any other intellectual property rights of a Third Party, in each case, in connection with the Development or Manufacture of the IL-12 Molecules and IL-12 Products and (b) use any funds from the federal government of the United States or any agency thereof to fund, directly or indirectly, any Development or Manufacturing activities hereunder, in whole or in part.

11.5.4. During the Term, Xilio shall inform Gilead in writing promptly if it or any Person who is performing or has performed services with respect to the IL-12 Molecules or IL-12 Products is debarred or is the subject of a conviction described in Section 306 of the FFDCa or if any action,

suit, claim, investigation or legal or administrative proceeding is pending or, to Xilio's Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing (or who has performed) services with respect to the IL-12 Molecules or IL-12 Products.

11.5.5. From the Effective Date until the Continuation Date, Xilio shall, and shall cause its Affiliates to (a) conduct its business with respect to the IL-12 Molecules and IL-12 Products and the intellectual property rights granted hereunder in the ordinary course consistent with past practice and in accordance with all Applicable Law, (b) not commit any act or permit the occurrence of any omission that would cause any of the representations and warranties of Xilio in Section 11.2 to be untrue or misleading in any material respect as of the Continuation Date and (c) promptly notify Gilead if it becomes aware that any of the representations and warranties in Section 11.2 are untrue or misleading in any material respect. During the Term, Xilio shall, and shall cause its Affiliates to, refrain from taking any action or omitting to take any action that would have the effect of restricting or impairing the rights granted or to be granted to Gilead hereunder or preventing either Party's ability to perform its obligations under this Agreement, including (i) licensing, transferring or otherwise disposing of any Licensed Know-How or Licensed Patent or (ii) entering into, modifying, extending, renewing or amending any contract related to the IL-12 Molecules or IL-12 Products or the intellectual property rights granted hereunder, in each case ((i) and (ii)), in a manner that would materially limit or impair Gilead's rights under this Agreement.

11.6. DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 12

INDEMNITY

12.1. Indemnification of Xilio. Gilead shall indemnify Xilio, its Affiliates and its and their respective directors, officers, employees and agents ("**Xilio Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (a) the breach by or on behalf of Gilead or its Affiliates or Sublicensees of this Agreement, including the enforcement of Xilio's rights under this Section 12.1; (b) the gross negligence or willful misconduct on the part of the Gilead Indemnitees in performing Gilead's obligations or exercising its rights under this Agreement; (c) any personal injury or death to any patient in the Combination Arm to the extent resulting from the administration of [**] to such patient in the Combination Arm in accordance with the protocol for the Combination Arm; or

(d) the Exploitation by Gilead or any of its Affiliates of any IL-12 Product or any IL-12 Molecule anywhere in the world, except to the extent that such Loss (x) in the case of Section 12.1(a), (b) and (c), is based upon an action or omission for which Xilio would have an obligation to indemnify a Gilead Indemnatee under Section 12.2(a), (b) or (c) if such Loss were incurred by a Gilead Indemnatee, (y) in the case of Section 12.1(d), is based upon an action or omission for which Xilio would have an obligation to indemnify a Gilead Indemnatee under Section 12.2 if such Loss were incurred by a Gilead Indemnatee, in each case ((x) and (y)), as to which Losses each Party shall indemnify the other to the extent of their respective liability or (z) arises from or occurs as a result of the negligence on the part of any Xilio Indemnatee under this Agreement.

12.2. Indemnification of Gilead. Xilio shall indemnify Gilead, its Affiliates, its and their Sublicensees and distributors and its and their respective directors, officers, employees and agents (“**Gilead Indemnitees**”) and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the breach by or on behalf of Xilio or its Affiliates or (sub)licensees of this Agreement, including the enforcement of Gilead's rights under this Section 12.2; (b) the gross negligence or willful misconduct on the part of the Xilio Indemnitees in performing Xilio's obligations or exercising its rights under this Agreement; (c) the Existing Agreements; and (d) the Exploitation by Xilio or any of its Affiliates of the IL-12 Molecules or IL-12 Products anywhere in the world, except to the extent that such Loss, (x) in the case of Section 12.2(a), (b) and (c), is based upon an action or omission for which Gilead would have an obligation to indemnify an Xilio Indemnatee under Section 12.1(a), (b) or (c) if such Loss were incurred by an Xilio Indemnatee, and (y) in the case of Section 12.2(d), is based upon an action or omission for which Gilead would have an obligation to indemnify an Xilio Indemnatee under Section 12.1 if such Loss were incurred by an Xilio Indemnatee, in each case ((x) and (y)), as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses, or (z) arises from or occurs as a result of the negligence on the part of any Gilead Indemnatee under this Agreement.

12.3. Indemnification Procedures.

12.3.1. Notice of Claim. All indemnification claims in respect of an Xilio Indemnatee or Gilead Indemnatee, as applicable, shall be made solely by such Party to this Agreement (the “**Indemnified Party**”). The Indemnified Party shall give the indemnifying Party prompt written notice (an “**Indemnification Claim Notice**”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish

promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

12.3.2. Control of Defense. Subject to the provisions of Section 9.4, Section 9.5 and Section 9.6, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within **[**]** after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.3.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party.

12.3.3. Right to Participate in Defense. Without limiting Section 12.3.2, any Indemnified Party shall be entitled to participate in, but not control (except as provided in Section 9.4, Section 9.5 and Section 9.6), the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.3.2 (in which case the Indemnified Party shall control the defense) or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles. For clarity, if the Indemnified Party has the right to control the defense of a Third Party Claim pursuant to Section 9.4, Section 9.5 or Section 9.6, the Indemnified Party shall be entitled to control such Third Party Claim, without limiting the indemnifying Party's responsibility for Losses under Section 12.1 or Section 12.2, as applicable.

12.3.4. Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Without limiting the rights and obligations of the Parties under Article 9, regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the indemnifying Party. Except as provided in Article 9, the

indemnifying Party shall not be liable for any settlement, compromise or other disposition of a Loss by an

Indemnified Party that is reached without the written consent of the indemnifying Party. For clarity, if a Third Party Claim, or the events giving rise to or resulting in such Third Party Claim, are subject to Article 9 and Section 12.1 or Section 12.2, then Article 9 shall apply with respect to the defense of such Third Party Claim and Section 12.1 or Section 12.2, as applicable, shall apply with respect to the allocation of financial responsibility for the related Losses.

12.3.5. Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket costs in connection therewith.

12.4. Special, Indirect and Other Losses. EXCEPT (A) FOR THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY, (B) A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10 OR SECTION 5.6, AND (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR ITS OR THEIR SUBLICENSEES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOST PROFITS, LOSS OF OPPORTUNITY, OR LOSS OF REVENUE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF THE IL-12 MOLECULES OR IL-12 PRODUCTS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

12.5. Insurance. Each Party will, at its own expense, procure and maintain during the Term and for a period of [**] thereafter, insurance policies, including product liability insurance when applicable, adequate to cover its obligations hereunder and that are consistent with normal business practices of prudent companies similarly situated. Such insurance will not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this Article 12. Each Party will provide the other Party with written evidence of such insurance upon request from the other Party. Notwithstanding any provision to the contrary set forth in this Agreement, Gilead may self-insure, in whole or in part, the insurance requirements described above.

ARTICLE 13
TERM AND TERMINATION

13.1. Term and Expiration. This Agreement shall commence on the Effective Date and, unless earlier terminated (including pursuant to Section 4.2), shall continue in force and effect until the date of expiration of the last Royalty Term for the last Lead Product or Back-Up Product (such period, the “Term”). Upon the expiration of the Royalty Term as to each Lead Product or Back-Up Product in each country (and upon expiration of the Term of this Agreement in its entirety), the grants in Section 5.1 shall remain exclusive and automatically become fully-paid, royalty-free, perpetual and irrevocable in their entirety; *provided that*, notwithstanding the foregoing, Xilio shall retain the right to terminate such licenses granted to Gilead under this Agreement with respect to such Lead Product or Back-Up Product (or all IL-

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12 Molecules and IL-12 Products if the applicable material breach relates to the Agreement as a whole) and such country to the extent (a) Xilio has brought a claim prior to the expiration of the applicable Term alleging a material breach with respect to such Lead Product or Back-Up Product and such country (or all IL-12 Molecules and IL-12 Products if the applicable material breach relates to the Agreement as a whole), and (b) following expiration of such Term for such Lead Product or Back-Up Product and such country (or in its entirety), it is finally determined in accordance with Article 14 that Gilead was in fact in material breach of this Agreement with respect to such Lead Product or Back-Up Product and such country (or all IL-12 Molecules and IL-12 Products if the applicable material breach relates to the Agreement as a whole).

13.2. Termination.

13.2.1. Termination for Material Breach. In the event that either Party (the “Breaching Party”) materially breaches any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the “Non-Breaching Party”) may have, the Non-Breaching Party may terminate this Agreement by providing [**] or, if such material breach arises from failure to make a payment set forth in this Agreement, [**] (the “Notice Period”) prior written notice (the “Termination Notice”) to the Breaching Party and specifying the breach and its claim of right to terminate; *provided that*:

(a) the termination shall not become effective at the end of the applicable Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period (or, if such breach cannot be cured within the Notice Period, if the Breaching Party commences actions to cure such breach within the Notice Period and diligently continues such actions, such termination shall not become effective for so long as the Breaching Party diligently continues such actions); and

(b) if the Breaching Party initiates a dispute resolution procedure under Article 14 as permitted under this Agreement during the Notice Period regarding whether the Breaching Party materially breached any of its material obligations under this Agreement and is

pursuing such procedure in good faith, the Notice Period set forth in this Section 13.2.1 shall be suspended and the termination shall become effective only if such breach remains uncured for [**] after the final resolution of the dispute through such dispute resolution procedure (or, if the breach cannot be cured within such [**], as applicable, if the Breaching Party commences actions to cure such breach within such period and thereafter diligently continues such actions, such termination shall not become effective for so long as the Breaching Party diligently continues such actions).

13.2.2. Termination for Patent Challenge. Except to the extent unenforceable under the Applicable Law, Xilio may terminate this Agreement by providing [**] prior written notice of termination to Gilead if Gilead or its Affiliates or Sublicensees (directly or indirectly) contests the validity or enforceability of any Licensed Patent [**] (a “**Patent Challenge**”), unless Gilead or its applicable Affiliate or Sublicensee [**] following Xilio’s notice; *provided* that (a) [**] if: (i) [**], or (ii) [**], and (b) Xilio shall not have the right to terminate this Agreement pursuant to this Section 13.2.2 if Gilead or its Affiliate or Sublicensee takes any action described in the definition of Patent Challenge (i) [**], (ii) [**] or (iii) [**]. In addition, notwithstanding the foregoing, Xilio shall not have the right to terminate this Agreement pursuant to this Section 13.2.2 if any Affiliate that first becomes an Affiliate of Gilead after the Effective Date [**] within the later to occur of (x) [**] after the date such Affiliate first becomes an Affiliate of Gilead and (y) [**] after the date Xilio provides Gilead notice regarding such Patent Challenge. As used herein, a Patent Challenge includes: ([**]).

13.2.3. Termination by Gilead. Gilead may terminate this Agreement in its entirety (a) [**], or (b) (i) prior to the first First Commercial Sale, upon [**] prior written notice to Xilio, and (ii) from and after the first First Commercial Sale, upon [**] prior written notice to Xilio, in each case ((i) and (ii)), for any or no reason.

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13.2.4. Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged [**] after such filing, (d) proposes a written agreement of composition, (e) proposes or is a party to any dissolution or liquidation, or (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged [**] of the filing, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

13.3. Termination for Cessation of Development or Commercialization. If [**] Gilead [**] (a) does not conduct any Development or Commercialization activities for any IL-12 Product throughout the Territory, or (b) has instituted and maintained (per Gilead’s internal policies) a hold on conducting all Development activities and Commercialization activities for all IL-12 Products throughout the Territory [**] a “**Cessation Event**”), then Xilio will notify Gilead in writing upon becoming aware of such Cessation Event having occurred. [**] the Parties shall meet (including via teleconference or videoconference) to discuss the nature and circumstances surrounding any such Cessation Event. Gilead shall [**] cure such Cessation Event. If Gilead fails to cure such Cessation Event [**], then Xilio may terminate this Agreement effective immediately upon written notice to Gilead.

13.4. Rights in Bankruptcy. The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted to Gilead under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to “intellectual property” as defined in Section 101 of Title 11 of the U.S. Code (the “**U.S. Bankruptcy Code**”), shall be deemed to be “intellectual property” for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction. All royalties and milestone payments under this Agreement will be deemed “royalties” for purposes of Section 365(n) of the U.S. Bankruptcy Code. For the avoidance of doubt, each Party shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

13.4.1. Xilio will, during the Term, create and maintain current and updated copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed to Gilead under this Agreement. Each Party acknowledges and agrees that “embodiments” of intellectual property within the meaning of Section 365(n) include (a) copies of research data; (b) laboratory samples; (c) product samples and inventory; (d) formulas; (e) laboratory notes and notebooks; (f) data and results related to clinical trials; (g) Regulatory Documentation (including Regulatory Approvals); (h) rights of reference in respect of Regulatory Documentation (including Regulatory Approvals); (i) pre-clinical research data and results; (j) tangible Information (including Licensed Know-How and Joint Know-How); and (k) marketing, advertising and promotional materials that relate to such intellectual property. In the event of a proceeding commenced by or against Xilio pursuant to the U.S. Bankruptcy Code, Gilead shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in Gilead’s possession, shall be promptly delivered to it upon Gilead’s written request (x) upon commencement of a bankruptcy proceeding, unless Xilio continues to perform all of its obligations under this Agreement, or (y) if not delivered pursuant to clause (x) above because Xilio continues to perform, upon the rejection of this Agreement by or on behalf of Xilio. Unless and until Xilio rejects this Agreement, each Party shall perform all of its obligations under this Agreement, and Xilio shall not interfere with the rights of Gilead to intellectual property as set forth in this Section 13.4, including the right to obtain the intellectual property from another entity.

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13.4.2. The Parties intend and agree that any sale of Xilio’s assets under Section 363 of the U.S. Bankruptcy Code shall be subject to Gilead’s rights under Section 365(n) of the U.S. Bankruptcy Code.

13.4.3. All rights, powers and remedies Gilead provided in this Section 13.4 are not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code). The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property rights (including all embodiments thereof) of Xilio, or any Third Party with whom Xilio contracts to perform an obligation of Xilio under this Agreement, and, in the case of any such Third Party, that is necessary or reasonably useful for the Exploitation of any IL-12 Molecules or IL-12 Products or the exercise of any other rights granted to Gilead under this Agreement;

(b) the right to contract directly with any Third Party to complete the contracted work; and

(c) the right to cure any default under any such agreement with a Third Party.

13.5. Consequences of Termination Prior to Continuation Date. In the event of any termination of this Agreement prior to the Continuation Date by a Party pursuant to Section 13.2, (a) all rights and licenses granted by one Party to the other Party shall immediately terminate, (b) Xilio shall promptly return to Gilead or destroy, as requested by Gilead in its sole discretion, any unused [**] in its possession or under its control and (c) if, during the Development Period, Gilead requested that Xilio Manufacture and supply clinical quantities of the IL-12 Molecules and IL-12 Products in accordance with clause (b) of Section 6.1.1, then Gilead shall promptly return to Xilio or destroy, as requested by Xilio in its sole discretion, any unused IL-12 Molecules and IL-12 Products in its possession or under its control; *provided that*, to the extent Xilio requests return of any such supply, Xilio shall reimburse Gilead for the Fully Burdened Manufacturing Costs that Gilead paid to Xilio for any such supply pursuant to Section 6.1.1. If a Party requests that the other Party destroy any unused [**], IL-12 Molecules or IL-12 Products in accordance with the foregoing, then the other Party shall provide such requesting Party written certification of such destruction.

13.6. Consequences of Termination After Continuation Date. In the event of any termination of this Agreement in its entirety after the Continuation Date by a Party pursuant to Section 13.2 (but, for clarity, not if this Agreement expires pursuant to Section 13.1 or if this Agreement is terminated prior to the Continuation Date), the following shall apply:

13.6.1. except to the extent necessary for Gilead to perform activities in accordance with Section 13.6.2 and Section 13.6.4 and subject to Section 13.6.5, all rights and licenses granted by one Party to the other Party shall immediately terminate;

13.6.2. Gilead shall grant, and hereby grants effective as of the effective date of such termination, to Xilio a sublicensable (through multiple tiers), exclusive license under the Gilead Grantback Know-How and Gilead Grantback Patents solely to Exploit the Reversion Product(s) in the Field in the Territory as such Reversion Product(s) exist as of the effective date of termination [**];

13.6.3. [**];

13.6.4. notwithstanding the termination of Gilead's licenses and other rights under this Agreement with respect to a particular IL-12 Product or a particular country, Gilead shall [**]. For the

avoidance of doubt, Gilead shall continue to make payments on such IL-12 Product as provided in Section 8.4, Section 8.5 and Section 8.10 (as if this Agreement had not terminated with respect to such IL-12 Product or country); and

13.6.5. unless otherwise agreed in the termination transition plan pursuant to Section 13.6.2, Xilio shall be responsible for all ongoing costs and expenses with respect to the terminated IL-12 Molecules and IL-12 Products in the terminated country(ies), including regulatory reporting and long-term monitoring (for safety and efficacy) of patients who were or are administered an IL-12 Product before, on or after the effective date of termination.

13.7. Return of Confidential Information. Upon the effective date of any termination of this Agreement for any reason, upon the written request of a Party, the non-requesting Party shall either, at the requesting Party's election: (a) promptly destroy all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party (other than Joint Know-How and the terms of this Agreement) and confirm such destruction in writing to the requesting Party or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party (other than Joint Know-How and the terms of this Agreement). Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain (i) such Confidential Information to the extent necessary or reasonably useful for purposes of performing any continuing obligations or exercising any ongoing rights and, in any event, a single copy of such Confidential Information for archival purposes and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 10.1.

13.8. Modification In Lieu of Termination. If, at any time during the Term, Gilead has the right to terminate this Agreement pursuant and subject to Section 13.2.1 as a result of Xilio's material breach of any material obligation in this Agreement that is finally determined in accordance with Article 14, then Gilead may, as its sole and exclusive remedy for such material breach, by written notice to Xilio, elect to continue this Agreement as modified by this Section 13.8, in which case, effective as of the date Gilead delivers such notice of such election to Xilio:

13.8.1. [**];

13.8.2. [**]; and

13.8.3. all other provisions of this Agreement shall remain in full force and effect without change.

13.9. Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more IL-12 Products or countries) shall not limit remedies that may otherwise be available in law or equity.

13.10. Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from

obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing:

13.10.1. Sections 3.3 (last sentence), 3.4.1(c), 3.4.2(b), 3.4.2(c), 3.4.3, 3.7.2 (as applicable), 3.8 (for the period provided therein), 4.2 (as applicable), 5.4, 7.6 (for the period provided therein), 8.5 through 8.8 (for final accounting), 8.10 through 8.14 (for final accounting), 8.15 (for final accounting, except that Section 8.15.3 shall survive generally for the period set forth in Section 10.1), 8.16, 9.1 (except for 9.1.4 and 9.1.6), 9.3 (solely with respect to Joint Patents and except for 9.3.5, 9.3.7 and 9.3.8), 9.5 (solely with respect to Joint Patents), 9.9, 10.1 (for the period provided therein), 10.2, 10.3 (except for Section 10.3.3 and Section 10.3.5), 10.4, 10.5 (except for the penultimate sentence), 10.7, 10.8, 11.1, 11.2, 11.6, 12.1 through 12.4, 12.5 (for the period provided therein), 13.5 (as applicable), 13.6 (as applicable), 13.7, 13.9 and this Section 13.10.1 and Articles 1 (to the extent required to give effect to the provisions set forth in this Section 13.10.1), 14 and 15 of this Agreement shall survive the termination of this Agreement for any reason; and

13.10.2. Sections 3.3 (last sentence), 3.4.1(c), 3.4.2(c), 3.4.3, 3.8 (for the period provided therein), 4.1.2(b), 4.3.4, 5.1, 5.3 (first sentence), 5.4, 5.5, 6.6, 7.1, 7.2, 7.4, 7.6 (for the period provided therein), 8.5 through 8.8 (for final accounting), 8.10 through 8.14 (for final accounting), 8.15 (for final accounting, except that Section 8.15.3 shall survive generally for the period set forth in Section 10.1), 8.16, 9.1 (except for 9.1.6), 9.3, 9.4 (clause (a) and clause (b) of Section 9.4.5 shall not survive), 9.5, 9.6, 9.7, 9.8, 9.9, 10.1 (for the period provided therein), 10.2, 10.3 (except for Section 10.3.3), 10.4, 10.5, 10.6, 10.7, 10.8, 11.1, 11.2, 11.6, 12.1 through 12.4, 12.5 (for the period provided therein), 13.1, 13.4, 13.9 and this Section 13.10.2 and Articles 1 (to the extent required to give effect to the provisions set forth in this Section 13.10.2), 14 and 15 of this Agreement shall survive the expiration of this Agreement.

ARTICLE 14 DISPUTE RESOLUTION

14.1. Exclusive Dispute Resolution Mechanism. The Parties agree that the procedures set forth in this Article 14 shall be the exclusive mechanism for resolving any Dispute between the Parties or their respective Affiliates or its or their respective (sub)licensees/Sublicensees that may arise from time to time (except, for clarity, for decisions of the JSC and resolution of matters within the purview of the JSC, which are not “Disputes” and will be resolved in accordance with Section 2.1.3). For the avoidance of doubt, this Article 14 shall not apply to any decision with respect to which a Party has final decision-making authority hereunder, but, for clarity, this Article 14 shall apply to any dispute with respect to *whether* a Party has final decision-making authority hereunder.

14.2. Resolution by Executive Officers. Except as otherwise provided in this Article 14, in the event of any Dispute, the Parties shall refer the Dispute to the Executive Officer of each Party for attempted resolution by good faith negotiation for a period of [**]. Each Party may, in its discretion, seek resolution of any Disputes that are not resolved within such [**] through (a) except as

set forth in clause (b), litigation in accordance with the remainder of this Article 14 or (b) with respect to Disputes described in Section 14.3, arbitration in accordance with Section 14.3.

14.3. Baseball Arbitration. Notwithstanding anything to the contrary in this Article 14, the dispute resolution mechanism set forth in this Section 14.3 shall apply if the Parties' Executive Officers fail to agree on: (a) any unresolved terms pursuant to, and as set forth in, Section 13.6.2 (including financial consideration payable to Gilead) or (b) the fair market value of each component or target, as applicable, of an IL-12 Product for purposes of Net Sales as described in clause (x) or (y) of the last paragraph of Section 1.129, in each case ((a) and (b)), [**]; *provided that*, [**]. Within [**] after the expiration of such [**],

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each Party shall, by written notice to the other Party, nominate an individual arbitrator who (i) has [**], (ii) is not affiliated and has not been affiliated with either Party or with either Party's Affiliates, licensees, sublicensees or business partners (including that such individual has not received compensation or other payments from such Party or its Affiliates) and (iii) does not otherwise have any interest in the resolution of the issue to be submitted by the Parties for resolution (the foregoing requirements, the "**Requirements**"). Within [**] after each Party nominates its individual arbitrator, the two (2) Party-nominated arbitrators shall appoint the third (3rd) arbitrator that satisfies the Requirements, who shall act as chairperson of the tribunal; *provided that* if the two (2) Party-selected individuals are unable to agree upon a third (3rd) individual within [**] the Parties' nominations, then the ICC shall appoint such third individual in accordance with the 2018 Rules of ICC as Appointing Authority in UNCITRAL or Other Arbitration Proceedings (the selected individuals, the "**Industry Experts**"). [**] each Party shall submit to the other Party and to the Industry Experts a detailed written proposal (the "**Proposal**" of such Party) of its proposed reversion terms pursuant to Section 13.6.2 (including financial consideration payable to Gilead) or Net Sales allocation, as applicable, and a memorandum in support thereof. Each Party shall [**] submit a written rebuttal to the other Party's submission to the other Party and to the Industry Experts. The Industry Experts shall have the discretion to interview the Parties' officers and employees to obtain further information relating to the matters in issue and to hear oral argument, on such schedule and following such procedure as the Industry Experts may determine. Each Party shall reasonably cooperate with the Industry Experts. [**] the Industry Experts shall select one (1) of the two (2) Proposals as the resolution of such dispute, consistent with the applicable terms of this Agreement, and *provided that* (x) with respect to the determination of fair market value of each component or target of an IL-12 Product for purposes of Net Sales as described in clause (x) or (y) of the last paragraph of Section 1.129, the Industry Experts shall consider the therapeutic contribution of each such component or target, as applicable, and (y) with respect to the terms of reversion (including financial consideration payable to Gilead) in connection with a license grant to Xilio pursuant to Section 13.6.2, the Industry Experts shall consider the reason for termination of this Agreement, the stage of Development and Commercialization of the terminated products (including each Party's investment in the Development and Commercialization of the terminated IL-12 Products), fairness and equity to the Parties under the circumstances and commercial reasonableness in selecting a Proposal. The Industry Experts' determination shall be final, binding and unappealable, and shall be given retroactive effect. For clarity, the Industry Experts must select, as the only method to resolve such dispute, one (1) of the

two (2) Proposals and may not combine elements of the two (2) Proposals or award any other relief or take any other action to resolve the dispute. The Parties shall share equally all fees and expenses of the Industry Experts.

14.4. Jurisdiction, Venue and Service of Process. Subject to Section 14.6 and Section 14.7, each Party irrevocably submits to the exclusive jurisdiction of (a) the courts of the State of New York located in New York, NY, and (b) the United States District Court for the Southern District of New York, for the purposes of any Dispute arising out of this Agreement. Each Party agrees to commence any Action with respect to a Dispute either in the United States District Court for the Southern District of New York or if such Action may not be brought in such court for jurisdictional reasons, in the courts of the State of New York located in New York, NY. Each Party further agrees that service of any process, summons, notice or document by the U.S. registered mail to such Party's respective address set forth in Section 15.5 shall be effective service of process for any Action in New York with respect to any matters to which it has submitted to jurisdiction in this Section 14.4. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any Action arising out of this Agreement in (i) the courts of the State of New York located in New York, NY and (ii) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead

or claim in any such court that any such Action brought in any such court has been brought in an inconvenient forum.

14.5. Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort, statute or otherwise) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement, or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations, without giving effect to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The provisions of the United Nations Convention on Contracts for the International Sale of Goods are expressly excluded.

14.6. Patent Disputes. As between the Parties, notwithstanding any provision herein to the contrary, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent shall not be subject to such jurisdiction and venue as is set forth in Section 14.4, but shall be submitted to a court of competent jurisdiction in the jurisdiction in which such Patent rights were granted or arose. With respect to any Patent issues related to the enforceability or validity of a Patent, the laws of the jurisdiction in which the applicable Patent is filed or granted shall govern.

14.7. Equitable Relief. Party acknowledges and agrees that the provisions of Section 3.7, Section 4.3, Section 5.6, Section 6.4 and Articles 9 and 10 are reasonable and necessary to protect

the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such provisions and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 14.7 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement, and, notwithstanding anything to the contrary, either Party may at any time seek to obtain preliminary injunctive relief or other applicable provisional relief from any court of competent jurisdiction with respect to an issue arising under this Agreement if the rights of such Party would be prejudiced absent such relief.

ARTICLE 15

MISCELLANEOUS

15.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, pandemics, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (including any Regulatory Authority) (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any

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term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [**] after such occurrence by providing a written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

15.2. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export

requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

15.3. Assignment. Neither Party may assign its rights or, except as provided in Section 3.3 and Section 7.4, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that (a) Gilead shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or its or their Sublicensees or distributors (*provided* that Gilead will be fully responsible and liable for any breach of the terms of this Agreement by any of its Affiliates or its or their Sublicensees or distributors to the same extent as if Gilead itself has committed any such breach) and (ii) to assign any or all of its rights and delegate any or all of its obligations to any of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to one (1) or more IL-12 Products, whether globally or for specific individual markets and (b) Xilio shall have the right, without such consent but subject to Section 5.6.2, to assign any or all of its rights and delegate any or all of its obligations to any successor in interest in connection with a Change of Control. **[**]**. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 15.3 shall be void and of no effect.

15.4. Severability. If, under Applicable Law, any one (1) or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable at law or in equity in any court of competent jurisdiction and the rights of the Parties will not be materially and adversely affected thereby, then (a) such invalid, illegal or unenforceable provision(s) shall be considered severed from this Agreement with respect to such jurisdiction, (b) this Agreement shall be construed and enforced as if such invalid, illegal or unenforceable provision(s) had never comprised a part hereof and (c) the Parties shall make a good faith effort to replace any invalid, illegal or unenforceable provision(s) with a valid, legal and enforceable provision(s) such that the objectives contemplated by the Parties when entering this Agreement may be realized (and, to the extent the Parties agree to a replacement provision, the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the invalid, illegal or unenforceable provision(s) or by its or their severance herefrom). To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof invalid, illegal or unenforceable in any respect.

15.5. Notices.

15.5.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand, sent by electronic mail, sent by

registered or certified mail (postage prepaid, return receipt requested) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 15.5.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 15.5.1. Such notice shall be deemed to have been given as of receipt; *provided* that any notice sent via electronic mail is not deemed received if the sender receives a delivery failure notification. Any notice delivered by email shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 15.5.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

15.5.2. Address for Notice.

If to Gilead, to:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
United States
Email: [**]
Attention: Alliance Manager

with a copy (which shall not constitute notice) to:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
United States
Email: [**]
Attention: General Counsel

If to Xilio, to:

Xilio Development, Inc.
828 Winter Street, Suite 300
Waltham, MA 02451
Email: [**]
Attention: Alliance Manager

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
800 Boylston Street, Prudential Tower
Boston, MA 02199
Email: [**]
Attention: Hannah H. England

and

Xilio Therapeutics, Inc.
828 Winter Street, Suite 300

Waltham, MA 02451
Email: [**]
Attention: Legal Department

15.6. Entire Agreement; Amendments. This Agreement, together with the attached Schedules and the Purchase Agreement and Investor Rights Agreement and any Supply Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter of this Agreement and all prior agreements, understandings and representations, whether written or oral, with respect thereto, including the Confidentiality Agreement, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement and the Purchase Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.7. Parent Guaranty. Xilio Parent hereby unconditionally, absolutely and irrevocably guarantees, as a primary obligor and not merely as surety, the due and punctual payment and performance of all obligations of Xilio under this Agreement (the “Xilio Obligations”). Xilio Parent agrees that the Xilio Obligations may be extended, modified or renewed, in whole or in part, without notice or further assent from it (*provided* that, for clarity, the Xilio Obligations may only be extended, modified or renewed as permitted by this Agreement), and that it will remain bound upon its guarantee notwithstanding any extension, modification or renewal of any Xilio Obligation. The obligations of Xilio Parent under this Section 15.7 shall not be affected by (a) the failure of Gilead to assert any claim or demand or to enforce any right or remedy against Xilio under the provisions of this Agreement or otherwise; or (b) any rescission, waiver, amendment or modification of any of the terms or provisions of this Agreement in accordance with the terms hereof. Xilio Parent further agrees that its guarantee constitutes a guarantee of payment and performance when due and not of collection and waives any right to require that any resort be had by Gilead to Xilio or to any other guarantee for any security held for payment or performance of the Xilio Obligations. This guarantee shall remain in full force and effect until all Xilio Obligations have been paid and performed in full, including obligations that survive termination or expiration hereof.

15.8. English Language. This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.9. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies

provided in this Agreement are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available, except as expressly provided herein.

15.10. No Benefit to Third Parties. The Contracts (Rights of Third Parties) Act 1999 shall not apply to this Agreement except with respect to Article 12. Except as provided in Article 12, subject to the foregoing, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons (including any Third Party beneficiary rights) (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise).

15.11. Further Assurance. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement.

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15.12. Relationship of the Parties. It is expressly agreed that Xilio, on the one hand, and Gilead, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Xilio, on the one hand, nor Gilead, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All Persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

15.13. Right to Offset. Each Party shall have the right to offset any amount owed to it by the other Party under or in connection with this Agreement (as determined in good faith by such Party), including pursuant to Article 12 or in connection with any breach, against any payments owed by it to such other Party under this Agreement. Such offsets shall be in addition to any other rights or remedies available under this Agreement and Applicable Law. [**].

15.14. References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

15.15. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe,

extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include" or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term and will be deemed to be followed by the phrase "without limitation,." All references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. Any reference herein to any Person will be construed to include the Person's successors and assigns. The words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement. Provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging unless otherwise expressly stated). References to any specific law, rule or regulation, or section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

15.16. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

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THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

GILEAD SCIENCES, INC.

By: Consideration and Reimbursement /s/ Andrew Dickinson

Name: Andrew Dickinson

Title: Chief Financial Officer

XILIO DEVELOPMENT, INC.

By: /s/ René Russo

Name: René Russo

Title: Chief Executive Officer

With respect to Section 15.7 only:

XILIO THERAPEUTICS, INC.

By: Equity Awards /s/ René Russo

. In full
consideration
of the
services
performed
by the
Consultant
under
this
Agreement,
and for
so long
as the
Consultant
provides
services
to the
Company
pursuant
to this
Agreement,
each
outstanding
and
unvested
equity
award
granted
to the
Consultant
by the
Company
other
than
that
certain
stock
option
granted
to the
Consultant
by the
Company
on

August
16,
2023
to
purchase
136,500
shares
of the
Company's
common
stock
(the
"Name Excluded Option René Russo

") will
remain
outstanding
and
continue
to vest
and be
exercisable
in
accordance
with,
and
otherwise
be
governed
by, the
applicable
equity
plan
and
award
agreement.
The
Consultant
acknowledges
and
agrees
that in
consideration
of the
Company's
entering

into
this
Agreement
with
the
Consultant,
the
Excluded
Option
shall
not
vest
during
the
Consultation
Period
and
shall
instead
terminate
unvested
on
September
8,
2023,
and
the
Consultant
shall
have
no
further
rights
with
respect
to the
Excluded
Option
(or any
shares
of
Company
common
stock
subject

thereto] Chief Executive Officer

- b. **Expense Reimbursement.** The Company shall reimburse the Consultant for all reasonable out-of-pocket expenses incurred by the Consultant in connection with the performance of the services under this Agreement. The Consultant shall submit to the Company itemized monthly statements, in a form satisfactory to the Company, of such expenses incurred in the previous month. The Company shall pay to the Consultant amounts shown on each such statement within thirty (30) days after receipt thereof. Notwithstanding the foregoing, the Consultant shall not

[Signature Page to License Agreement]

Exhibit 10.2

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential.

Double asterisks denote omissions.

XILIO THERAPEUTICS, INC.

COMMON STOCK PURCHASE AGREEMENT

This Common Stock Purchase Agreement (this “Agreement”) is dated as of March 27, 2024, by and between Xilio Therapeutics, Inc., a Delaware corporation (the “Company”), and Gilead Sciences, Inc., a Delaware corporation (“Gilead”).

WHEREAS, subject to the terms and conditions set forth in this Agreement, the Company desires to issue and sell to Gilead, and Gilead desires to purchase from the Company, shares of common stock of the Company as more fully described in this Agreement; and

WHEREAS, concurrently herewith, Xilio Development, Inc. (“Xilio Development”) and Gilead have entered into a License Agreement (the “License Agreement”), and the Company and Gilead have entered into an Investor Rights Agreement (the “Investor Rights Agreement”).

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and Gilead agree as follows:

ARTICLE 1

DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

1.1.1 “Action” has the meaning set forth in Section 3.1.12 hereof.

1.1.2 “Additional Closing” has the meaning set forth in Section 2.3.2 hereof.

1.1.3 “Additional Closing Date” has the meaning set forth in Section 2.3.2 hereof.

1.1.4 “Additional Shares” means the shares of Common Stock and/or Pre-Funded Warrants, as applicable, subject to an Additional Shares Purchase Exercise Notice.

1.1.5 “Additional Share Purchase Details” has the meaning set forth in Section 2.3.2.

1.1.6 “Additional Shares Purchase Exercise Confirmation” has the meaning set forth in Section 2.3.2 hereof.

incur total expenses

1.1.7 “Additional Shares Purchase Exercise Notice” has the meaning set forth in excess Section 2.3.2 hereof.

1.1.8 “Additional Shares Purchase Price” means, with respect to an Additional Closing, a price per share and/or a price per Pre-Funded Warrant to purchase a share of \$500.00 Common Stock, as applicable, equal to (a) the price per month without share of Common Stock and/or per pre-funded warrant to purchase Common Stock, as applicable, paid by investors in an Equity Financing or (b) if no such Equity Financing has occurred within the prior written approval five (5) days preceding the delivery of the Additional Shares Purchase Exercise Notice (such period, the “Recent Financing Period”), the Nasdaq Official Closing Price of the Common Stock (as reflected on Nasdaq.com) on the Trading Day immediately preceding the date the Company delivers the Additional Shares Purchase Exercise Notice; provided that if the purchase price per share of Common Stock determined pursuant to the foregoing clause (a) is less than the lower of (i) the Nasdaq Official Closing Price of the Common Stock (as reflected on Nasdaq.com) immediately preceding the date on which the Company delivers the Additional Shares Purchase Exercise Notice or (ii) the

average Nasdaq Official Closing Price of the Common Stock (as reflected on Nasdaq.com) for the five (5) Trading Days immediately preceding the date on which the Company delivers the Additional Shares Purchase Exercise Notice, the Additional Shares Purchase Price shall instead be the lower of the amounts set forth in clauses (i) and (ii).

1.1.9 “Adjusted Company Capitalization” means, as of any date of measurement, the total number of outstanding shares of voting capital stock of the Company after giving effect to the exercise of any outstanding pre-funded warrants to purchase shares of the Company’s voting capital stock.

1.1.10 “Affiliate” means any Person that, directly or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with a Person.

1.1.11 “Aggregate Additional Purchase Price” means the dollar amount obtained by multiplying the number of Additional Shares to be purchased at an Additional Closing by the applicable Additional Shares Purchase Price.

1.1.12 “Aggregate Equity Investment” means the sum of the Aggregate Initial Purchase Price, the Aggregate Additional Purchase Price from any prior Additional Closing and any amounts invested pursuant to Section 4.3 of the Investor Rights Agreement.

1.1.13 “Aggregate Initial Purchase Price” means the dollar amount obtained by multiplying the number of shares of Common Stock constituting the Initial Shares by the Initial Shares Purchase Price.

1.1.14 “Anti-Corruption Laws” has the meaning set forth in Section 3.1.17 hereof.

1.1.15 “Bankruptcy Law” means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

1.1.16 “Beneficial Ownership” or “Beneficial Owner” or “Beneficially Own” or “Beneficially Owned” shall have the meaning set forth in Rule 13d-3 under the Exchange Act.

1.1.17 “Business Day” means any day on which Nasdaq and commercial banks in the City of New York are open for business.

1.1.18 “Closing” means, as applicable, the Initial Closing or the Additional Closing.

1.1.19 “Closing Date” means, as applicable, the Initial Closing Date or each Additional Closing Date.

1.1.20 “Commission” means the United States Securities and Exchange Commission.

1.1.21 “Common Stock” means the Company’s common stock, par value \$0.0001 per share.

1.1.22 “Company Capitalization” means, as of any date of measurement, the total number of outstanding shares of voting capital stock of the Company.

1.1.23 “Control,” including the terms “Controlling,” “Controlled by” and “under common Control with,” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

1.1.24 “Cross-Receipt” means a cross-receipt substantially in the form of Exhibit A hereto.

1.1.25 “Custodian” means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

1.1.26 “Disclosure Schedule” means the confidential Disclosure Schedule referred to in Section 3.1 hereof, if any, delivered by the Company concurrently with the execution and delivery of this Agreement and, with respect to any Additional Closing, as such Disclosure Schedule may be updated and delivered by the Company prior to the applicable Additional Closing Date.

1.1.27 “Disqualification Event” has the meaning set forth in Section 3.1.20 hereof.

1.1.28 “Entity” has the meaning set forth in Section 3.1.18(a) hereof.

1.1.29 “Equity Financing” means a registered public offering, private placement, registered direct offering or similar transaction, or series of transactions, in which the Company sells shares of its Common Stock and/or pre-funded warrants to purchase Common Stock to investors.

1.1.30 “Evaluation Date” has the meaning set forth in Section 3.1.10 hereof.

1.1.31 “Event of Default” has the meaning set forth in Section 4.7 hereof.

1.1.32 “Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.1.33 “Exercise Period” means the period beginning on the date of this Agreement and continuing through the date that is the first anniversary of the Initial Closing Date.

1.1.34 “FDA” has the meaning set forth in Section 3.1.13 hereof.

1.1.35 “GAAP” has the meaning set forth in Section 3.1.9 hereof.

1.1.36 “Governmental Authority” means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal, as well as any securities exchange or securities exchange authority, including Nasdaq).

1.1.37 “Individual” has the meaning set forth in Section 3.1.18(a) hereof.

1.1.38 “Initial Closing” means the closing of the sale of the Initial Shares pursuant to Section 2.3.1 hereof.

1.1.39 “Initial Closing Date” has the meaning set forth in Section 2.3.1 hereof.

1.1.40 “Initial Shares” means 6,860,223 shares of Common Stock.

1.1.41 “Initial Shares Purchase Price” means a purchase price per share of Common Stock equal to the lower of (i) \$1.97 per share and (ii) [**] of the average daily volume-weighted average per share price of the Common Stock on Nasdaq as reported by Bloomberg L.P. over the [**] Trading Day period ending on and including the last Trading Day prior to the date of this Agreement, rounded to the nearest cent; provided that if the purchase price per share of Common Stock calculated pursuant to the foregoing clause is less than the lower of (A) the Nasdaq Official Closing Price of the Common Stock (as reflected on Nasdaq.com) immediately preceding the signing of this Agreement or (B) the average Nasdaq Official Closing Price of the Common Stock (as reflected on Nasdaq.com) for the five (5) Trading Days immediately preceding the signing of this Agreement, the Initial Shares Purchase Price shall instead be the lower of the amounts set forth in clauses (A) and (B).

1.1.42 “Intellectual Property Rights” has the meaning set forth in Section 3.1.15 hereof.

1.1.43 “Investor Rights Agreement” has the meaning set forth in the recitals.

1.1.44 “Issuer Covered Person” has the meaning set forth in Section 3.1.20 hereof.

1.1.45 “Law” or “law” means any supranational, national, federal, state, regional, provincial, local or municipal constitution, treaty, law, statute, ordinance, code, determination, principle of common law or any other requirement having the effect of law of any Governmental

Authority (including any rule, regulation, plan, injunction, judgment, order, award, decree, ruling, requirement, guidance, policy or charge thereunder or related thereto), in each case as amended, whether in the United States or a foreign jurisdiction.

1.1.46 “License Agreement” has the meaning set forth in the recitals.

1.1.47 “Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, mortgage, claim, easement, right-of-way, option, title retention agreement, preemptive right or other restriction.

1.1.48 “Material Adverse Effect” means a material adverse effect on the condition (financial or otherwise), results of operations, business, management, properties or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement.

1.1.49 “Maximum Equity Investment” means \$25,000,000.

1.1.50 “Nasdaq” means the Nasdaq Stock Market.

1.1.51 “OFAC” has the meaning set forth in Section 3.1.18(a) hereof.

1.1.52 “Other Investor Documentation” has the meaning set forth in Section 2.6.1(m) hereof.

1.1.53 “Permits” has the meaning set forth in Section 3.1.13 hereof.

1.1.54 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.1.55 “Pre-Funded Warrant” means a pre-funded warrant issued pursuant to Section 2.3.2 hereof, which shall be in substantially the same form as the pre-funded warrants offered and sold to investors in the most recent Equity Financing in which pre-funded warrants were offered and sold to investors, and which shall include a provision that

prevents the holder from exercising such pre-funded warrant to the extent the exercise thereof would cause such holder to Beneficially Own more than 19.9% of the Company Capitalization.

1.1.56 “Principal Market” means the NASDAQ Global Select Market; provided however, that in the event the Company’s Common Stock is ever listed or traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Market or the NASDAQ Capital Market, then the “Principal Market” shall mean such other market or exchange on which the Company’s Common Stock is then listed or traded.

1.1.57 “Recent Financing Period” has the meaning set forth in Section 1.1.8 hereof.

1.1.58 “[**]” has the meaning set forth in Section [**].

1.1.59 “Required Approvals” has the meaning set forth in Section 3.1.4 hereof.

1.1.60 “Rule 144” means Rule 144 promulgated by the Commission under the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

1.1.61 “Sanctions” has the meaning set forth in Section 3.1.18(a) hereof.

1.1.62 “SEC Report” means any report filed or furnished by the Company with the Commission under the Exchange Act or the Securities Act.

1.1.63 “Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.1.64 “Shares” means the Initial Shares and the Additional Shares collectively.

1.1.65 “Trading Day” means a day on which Nasdaq is open for trading.

1.1.66 “Transfer Agent” means Computershare Trust Company, N.A., with a mailing address of 150 Royall Street, Canton, Massachusetts 02021, or any successor transfer agent of the Common Stock.

1.1.67 “Valid Account Details” means, with respect to any bank account, the valid (a) name of bank, (b) bank address, (c) account number and (d) ABA routing number.

ARTICLE 2

PURCHASE AND SALE OF SHARES

2.1 Purchase of Shares. Subject to the terms and conditions of this Agreement, at the Initial Closing, the Company will issue and sell to Gilead, and Gilead will purchase from the Company, the Initial Shares, at a price per share equal to the Initial Shares Purchase Price, for an aggregate purchase price equal to the Aggregate Initial Purchase Price. Subject to the terms and conditions of this Agreement, at each Additional Closing, if any, the Company will issue and sell to Gilead, and Gilead will purchase from the Company, the number of Additional Shares specified in the applicable Additional Shares Purchase Exercise Notice, at a price per share equal to the applicable Additional Shares Purchase Price, for an aggregate purchase price equal to the applicable Aggregate Additional Purchase Price.

2.2 Payment.

2.2.1 At the Initial Closing, Gilead will pay the Aggregate Initial Purchase Price to the Company by wire transfer of immediately available funds in accordance with the Valid Account Details, together with a Form W-9, which Valid Account Details will have been provided by the Company to Gilead at least two (2) Business Days prior to the Initial Closing Date.

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2.2.2 At each Additional Closing, if any, Gilead will pay the applicable Aggregate Additional Purchase Price, in each case by wire transfer of immediately available funds in accordance with the Valid Account Details, together with a Form W-9, which Valid Account Details will have been provided by the Company to Gilead at least two (2) Business Days prior to the Additional Closing Date.

2.2.3 The Company shall cause delivery of the applicable Shares at each Closing to be made in book-entry form to an account of Gilead specified in writing by Gilead at the Transfer Agent.

2.3 Closings.

2.3.1 The Initial Closing shall occur at 12:00 pm (New York City time) on such date as the parties may select, not later than the second (2nd) Business Day after satisfaction or (to the extent permitted by law) waiver of the conditions set forth in Section 2.6 (other than those conditions that by their terms are to be satisfied at the Initial Closing, but subject to the satisfaction or (to the extent permitted by law) waiver of those conditions),

unless such other place, time and date shall be agreed in writing between the Company and Gilead (such date, the “Initial Closing Date”).

2.3.2 Subject to the conditions set forth in Section 2.7, the Company may, on no more than three separate occasions, during the Exercise Period elect to cause Gilead to purchase from the Company a number of Additional Shares specified by the Company in writing to Gilead (an “Additional Shares Purchase Exercise Notice”) at the applicable Additional Shares Purchase Price, [**]; *provided further* that the number of Additional Shares indicated by the Company in such Additional Shares Purchase Exercise Notice shall not cause the Aggregate Equity Investment following issuance and sale of such Additional Shares to exceed the Maximum Equity Investment; and *provided further* that the issuance and sale of such Additional Shares to Gilead shall not cause Gilead to Beneficially Own a number of shares of Common Stock equal to greater than 19.9% of the Adjusted Company Capitalization as of the applicable Additional Closing Date, and that any Additional Shares issued and sold to Gilead in such Additional Closing that would cause Gilead to Beneficially Own a number of shares of Common Stock equal to greater than 19.9% of the Company Capitalization as of the applicable Additional Closing Date shall be allocated to Pre-Funded Warrants (provided that Gilead shall not be required to purchase any such allocation of Pre-Funded Warrants, in whole or in part). The Additional Shares Purchase Exercise Notice shall also include the Company’s calculation of the (i) Aggregate Equity Investment, (ii) allocation of the shares of Common Stock and, if applicable, Pre-Funded Warrants constituting the Additional Shares subject to the Additional Shares Purchase Exercise Notice (provided that Gilead shall not be required to purchase any allocation of Pre-Funded Warrants, in whole or in part) and (iii) percentage of the Adjusted Company Capitalization Beneficially Owned by Gilead after giving effect to the Additional Closing (such information, the “Additional Share Purchase Details”). Gilead shall (a) confirm its agreement with the information set forth in the Additional Shares Purchase Exercise Notice (including whether Gilead will, in its sole discretion, elect to purchase all, none or some its allocation of Pre-Funded Warrants, if applicable), (b) notify the Company of any [**] and (c) select an anticipated closing date for the purchase of the Additional Shares subject to the Additional Shares Purchase Exercise Notice, which date shall be no later than the date that is five

(5) Business Days after the date that Gilead receives such Additional Shares Purchase Exercise Notice, in a written notice delivered to the Company within two (2) Business Days of receiving such Additional Shares Purchase Exercise Notice specifying such anticipated closing date (each an “Additional Shares Purchase Exercise Confirmation”). Each Closing of the sale of Additional Shares (each such closing, an “Additional Closing”) shall occur at 11:00 am (New York City time) on the date specified in such Additional Shares Purchase

Exercise Confirmation; *provided*, that if any of the conditions set forth in Section 2.7 have not been satisfied or (to the extent permitted by law) waived by such date and time (other than those conditions that by their terms are to be satisfied at an Additional Closing), the Additional Closing shall occur on the second (2nd) Business Day after satisfaction or (to the extent permitted by law) waiver of the conditions set forth in Section 2.7 (other than those conditions that by their terms are to be satisfied at an Additional Closing, but subject to the satisfaction or (to the extent permitted by law) waiver of those conditions), unless such other place, time and date shall be agreed in writing between the Company and Gilead (each such date, an “Additional Closing Date”).

2.4 Initial Closing Deliverables.

2.4.1 At the Initial Closing, the Company will deliver to Gilead:

- c. **No Employee Benefits.** The Consultant's relationship a duly executed Cross-Receipt with respect to the Company will be that of an independent contractor, and the Consultant shall not, in connection with this relationship, be entitled to any benefits, coverages or privileges, including, without limitation, health insurance, social security, unemployment, workers compensation, or pension payments, made available to employees of the Company. Initial Shares;
- 4. **Termination.** This Agreement may be terminated prior to the Expiration Date in the following manner: (a) by the Company at any time immediately upon written notice if the Consultant has materially breached this Agreement or the Restrictive Covenants Agreement by and between the Consultant and the Company (as defined in the September 30, 2021 Employment Agreement by and between the Consultant and the Company) of any confidentiality, non-disclosure, inventions assignment, non-competition, and/or non-solicitation obligations in any other agreement by and between the Consultant and the Company; (b) by the Consultant at any time immediately upon written notice if the Company has materially breached this a duly executed Investor Rights Agreement; (c) by either the Company or the Consultant upon not less than thirty (30) days' prior written notice; or (d) at any time upon the mutual written consent of the parties hereto. In the event of any termination, the Consultant shall be entitled only to reimbursements for expenses incurred in accordance with Section 3(b) prior to termination, and no further payments of any kind will be due.

5. Cooperation. The Consultant shall perform the services hereunder a certificate in a professional manner form and consistent with the highest industry standards. The Company shall provide such access substance reasonably satisfactory to its information Gilead and property as may be reasonably required in order to permit the Consultant to perform the Consultant's obligations hereunder. The Consultant shall cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business, and shall observe all rules, regulations and security requirements duly executed on behalf of the Company concerning by an authorized officer of the safety Company, certifying that the conditions to the Initial Closing set forth in Sections 2.6.1(a) and (b) of persons and property. this Agreement have been fulfilled

6. Proprietary Information evidence that the Company has delivered to the Transfer Agent irrevocable written instructions to issue the Initial Shares to Gilead in a form and Inventions. substance acceptable to the Transfer Agent; and

a. Proprietary Information.

(e) a certificate of the secretary of the Company dated as of the Initial Closing Date certifying that attached thereto is a true and complete copy of all resolutions adopted by the Company's board of directors authorizing the execution, delivery and performance of this Agreement and the transactions contemplated herein and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Initial Closing Date.

2.4.2 At the Initial Closing, Gilead will deliver to the Company:

(a) a duly executed Cross-Receipt with respect to the Initial Shares;

- i. The Consultant acknowledges that the Consultant's relationship with the Company is one of high trust and duly executed Investor Rights Agreement; and confidence and that in the course of the Consultant's service to the Company, Consultant will have access to and contact with Proprietary Information (as defined below). The Consultant will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of the services) without written approval by an officer of the Company, either during or after the Consultation Period, unless and until such Proprietary Information has become public knowledge without fault by the Consultant.
- (b)

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- ii. For purposes a certificate in form and substance reasonably satisfactory to the Company and duly executed on behalf of Gilead by an authorized officer of Gilead, certifying that the conditions to the Closing set forth in Sections 2.6.2(a) and (b) of this Agreement Proprietary Information shall mean, by way of illustration and not limitation, all information, whether or not in writing, whether or not patentable and whether or not copyrightable, of have been fulfilled.
- (c)

2.5 Additional Closing Deliverables.

2.5.1 At each Additional Closing, if any, the Company will deliver to Gilead:

- (a) a private, secret or confidential nature, owned, possessed or used by the Company, concerning the Company's business, business relationships or financial affairs, including, without limitation, any Invention (as defined below), formula, vendor information, customer information, apparatus, equipment, trade secret, process, research, report, technical or research data, clinical data, know-how, computer program, software, software documentation, hardware design, technology, product, processes, methods, techniques, formulas, compounds, projects, developments, marketing or business plan, forecast, unpublished financial statement, budget, license, price, cost, customer, supplier or personnel information or employee list that is communicated to, learned of, developed or otherwise acquired by the Consultant in the course of the Consultant's service as a consultant duly executed Cross-Receipt with respect to the Company.
- applicable Additional Shares;

- iii. The Consultant agrees that all files, documents, letters, memoranda, reports, records, data sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible material containing Proprietary Information, whether created by the Consultant or others, which shall come into Consultant's custody or possession, shall be a certificate in form and are the exclusive property substance reasonably satisfactory to Gilead and duly executed on behalf of the Company to be used by the Consultant only in the performance of the Consultant's duties for the Company and shall not be copied or removed from the Company premises except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property an authorized officer of the Company, certifying that the conditions to such Additional Closing set forth in the custody or possession of the Consultant shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) the termination Sections 2.7.1(a) and (b) of this Agreement. After such delivery, the Consultant shall not retain any such materials or copies thereof or any such tangible property.

Agreement have been fulfilled;

- iv. The Consultant agrees evidence that Consultant's obligation not to disclose or to use information and materials of the types set forth in paragraphs (b) and (c) above, and Consultant's obligation to return materials and tangible property set forth in paragraph (c) above extends to such types of information, materials and tangible property of customers of the Company or suppliers has delivered to the Company Transfer Agent irrevocable written instructions to issue the applicable Additional Shares to Gilead and/or other third parties who may have disclosed or entrusted establish a reserve account for the same shares of Common Stock issuable upon the exercise of any Pre-Funded Warrants issued at such Additional Closing in a form and substance acceptable to the Company or to the Consultant.

Transfer Agent;

- v. The Consultant acknowledges a certificate of the secretary of the Company dated as of such Additional Closing Date certifying that attached thereto is a true and complete copy of all resolutions adopted by the Company's board of directors authorizing the execution, delivery and performance of this Agreement and the transactions contemplated herein and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of such Additional Closing Date; and
- (e) a duly executed Pre-Funded Warrant exercisable for the number of shares of Common Stock indicated in the Additional Shares Purchase Exercise Notice, if applicable.

2.5.2 At each Additional Closing, if any, Gilead will deliver to the Company:

- (a) a duly executed Cross-Receipt with respect to the applicable Additional Shares; and
- (b) a certificate in form and substance reasonably satisfactory to the Company and duly executed on behalf of Gilead by an authorized officer of Gilead, certifying that the Company from time conditions to time may have agreements with other persons or with the United States government, or agencies thereof, that impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Consultant agrees to be bound by all such obligations and restrictions that

Additional

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are known Closing set forth in Sections 2.7.2(a) and (b) of this Agreement have been fulfilled.

2.6 Conditions to the Consultant and to take all action necessary to discharge the Initial Closing.

2.6.1 The obligations of Gilead hereunder in connection with the Company under such agreements.

Initial Closing are subject to the following conditions being satisfied or waived:

- vi. The Consultant's obligations under this
- (a) Section 6.1 shall not apply to any information that (i) is or becomes known to the general public under circumstances involving no breach by the Consultant or others representations and warranties of the terms Company set forth in Section 3.1 hereof that are not qualified by materiality shall be true and correct in all material respects as of this Section 6.1, (ii) is generally disclosed to third parties by the Initial Closing Date and the representations and warranties of the Company without restriction on such third parties, or (iii) is approved for release set forth in Section 3.1 that are qualified by written authorization of an officer materiality shall be true and correct in all respects as of the Company. Further, nothing herein prohibits the Consultant from communicating with government agencies about possible violations of federal, state, or local

laws or otherwise providing information to government agencies or participating in government agency investigations or proceedings. In addition, notwithstanding the Consultant's confidentiality and nondisclosure obligations, the Consultant is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the

trade secret under seal;
and (B) does not disclose
the trade secret, except
pursuant to court order."

Initial Closing Date.

b. Inventions.

(b) The Company shall have
complied in all material
respects with its
covenants hereunder as
of the Initial Closing Date.

i. Xilio Development shall
have duly executed and
(c) delivered the License
Agreement, and such
agreement shall be in full
force and effect.

(d) The Consultant will
make Company shall have
duly executed and
delivered the Investor
Rights Agreement, and
such agreement shall be
in full force and prompt
disclosure effect.

(e) The Company shall have
obtained any and all
consents, permits,
approvals, registrations
and waivers necessary for
the consummation of the
purchase and sale of the
Initial Shares, all of which
shall be in full force and
effect.

- (f) All closing deliverables as required under Section 2.4.1 shall have been delivered by the Company to Gilead.
- (g) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Initial Closing, shall have been instituted or be pending before any Governmental Authority.
- (h) The Company shall have delivered to the Transfer Agent irrevocable written instructions to issue the Initial Shares to Gilead in a form and substance acceptable to the Transfer Agent.
- (i) The Company shall have filed with Nasdaq a Listing of all inventions, creations, improvements, enhancements, designs, innovations, discoveries, processes, methods, techniques, developments, software, computer programs, and works of authorship, whether or not patentable and whether or not copyrightable, that are created, made, conceived or reduced to practice by Additional Shares Notification Form for the Consultant or under the

Consultant's direction or jointly with others during the Consultation Period, whether or not during normal working hours or on the premises listing of the Company (all of which are collectively referred to in this Agreement as "Inventions"). The Consultant agrees to assign Initial Shares, if required, and does hereby assign Nasdaq shall not have raised an objection to the Company (or any person or entity designated by the Company) all consummation of the Consultant's right, title and interest in and to all Inventions and all related patents, patent applications, copyrights created in the work(s) of authorship, trademarks, trade names, and other industrial and intellectual property rights and applications therefor in the United States and elsewhere. However, the previous sentence shall not apply to Inventions transactions contemplated by this Agreement,

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that do not relate to the present or planned business or research and development of the Company and that are made and conceived by the Consultant not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. The Consultant understands that, to the extent this Agreement shall be construed in accordance with the laws of any state that precludes a requirement

that an individual assign certain classes of inventions, this Section 6.2(a) shall be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. The Consultant further acknowledges that each original work of authorship that is made by the Consultant (solely or jointly with others) within the scope of the Investor Rights Agreement and which is protectable by copyright is a "work made for hire," as that term is defined the License Agreement in the United States Copyright Act. The

Consultant
hereby
waives all
claims to
moral rights in
any
Inventions. absence
of stockholder
approval of
such
transactions.

- ii. The
Consultant
(j) agrees that
if, Company
shall have
delivered
Valid Account
Details,
together with
a Form W-9,
to Gilead at
least two (2)
Business
Days prior to
the Initial
Closing Date
in the course
of performing
the services,
the
Consultant
incorporates
into any
Invention
developed
under this
Agreement
any
preexisting
invention,
improvement,
development,

concept,
discovery or
other
proprietary
information
owned by the
Consultant or
in which the
Consultant
has an
interest
("Prior
Inventions"),
(i) the
Consultant
will inform the
Company, in
writing before
incorporating
such Prior
Inventions
into any
Invention, a
form and (ii)
the Company
is hereby
granted a
nonexclusive,
royalty-free,
perpetual,
irrevocable,
transferable,
worldwide
license with
the
right substance
acceptable to
grant and
authorize
 sublicenses,
to make,
have made,
modify, use,

import, offer
for sale, sell,
reproduce,
distribute,
modify,
adapt,
prepare
derivative
works of,
display,
perform, and
otherwise
exploit such
Prior
Inventions,
without
restriction,
including,
without
limitation, as
part of or in
connection
with such
Invention,
and to
practice any
method
related
thereto. The
Consultant
will not
incorporate
any invention,
improvement,
development,
concept,
discovery or
other
proprietary
information
owned by any
third party
into any

Invention
without the
Company's
prior written
permission. Gilead.

iii. The
(k) Consultant
agrees to
cooperate
fully with the
Company,
both during
and after the
Consultation
Period, No
Material
Adverse
Effect with
respect to the
procurement,
maintenance,
and
enforcement
of copyrights,
patents and
other
intellectual
property
rights (both in
the United
States and
foreign
countries)
relating to
Inventions.
The
Consultant Company
or its
subsidiaries
shall sign all
papers,
including,
without

limitation,
copyright
applications,
patent
applications,
declarations,
oaths, formal
assignments,
assignments
of priority
rights, and
powers of
attorney,
which the
Company
may deem
necessary have
occurred or
desirable in
order to
protect its
rights and
interests in
any
Invention.
The
Consultant
further
agrees that if
the Company
is unable,
after
reasonable
effort, to
secure the
signature be
existing as of
the
Consultant on
any such
papers, any
executive
officer of the
Company
shall be

entitled to
execute any
such papers
as the agent
and the
attorney-in-
fact of the
Consultant,
and the
Consultant
hereby
irrevocably
designates

- 5 -

and appoints each
executive officer of the
Company as the
Consultant's agent and
attorney-in-fact to execute
any such papers on the
Consultant's behalf, and to
take any and all actions as
the Company may deem
necessary or desirable in
order to protect its rights
and interests in any
Invention, under the
conditions described in this
sentence.

- iv. The Consultant shall maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records shall be available to and remain the sole property of the Company at all times.

Initial Closing Date.

7. Non-Exclusivity.
The Company
(l) retains Principal
Market shall not
have commenced
any final delisting
proceedings against
the right to contract
with other
companies and/or
individuals for
consulting services
without restriction.
Similarly, except as
and to the extent
set forth in the
Restrictive
Covenants
Agreement, the
Consultant retains
the right to contract
with other
companies or
entities for the
Consultant's
consulting services.

Company.

8. [**].

(m)

2.6.2 The obligations of the
Company hereunder in connection with the
Initial Closing are subject to the following
conditions being satisfied or waived:

(a) The representations and warranties of Gilead set forth in Other Agreements; Warranty Section 3.2 hereof that are not qualified by materiality shall be true and correct in all material respects as of the Initial Closing Date and the representations and warranties of Gilead set forth in Section 3.2 hereof that are qualified by materiality shall be true and correct in all respects as of the Initial Closing Date.

a. The Consultant hereby represents
(b) that, except Gilead shall have complied in all material respects with its covenants hereunder as the Consultant has disclosed in writing to the Company, the Consultant is not bound by the terms of any agreement with any third party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of

Consultant's consultancy with the Company, to refrain from competing, directly or indirectly, with the business of such third party or to refrain from soliciting employees, customers or suppliers of such third party. The Consultant further represents that Consultant's performance of all the terms of this Agreement and the performance of the services as a consultant of the Company do not and will not breach any agreement with any third party to which the Consultant is a party (including, without limitation, any nondisclosure or non-competition agreement), and that the Consultant will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or

previous employer
or others.

Initial Closing Date.

- b. The Consultant
hereby represents,
(c) warrants Gilead
shall have duly
executed and
covenants that
Consultant
has delivered the
skills and
experience
necessary to
perform the
services, that
Consultant will
perform said
services in a
professional,
competent and
timely manner, that
Consultant has the
power to enter into
this License
Agreement, and
that Consultant's
performance
hereunder will not
infringe upon or
violate the rights of
any third party or
violate any federal,
state or municipal
laws.
- such agreement
shall be in full force
and effect.

9. Independent Contractor Status.
- (d) Gilead shall have duly executed and delivered the Investor Rights Agreement, and such agreement shall be in full force and effect.
- a. The ConsultantAll closing deliverables required under Section 2.4.2 shall perform all services under this Agreement as an “independent contractor” and not as an employee or agent of have been delivered by Gilead to the Company. The Consultant is not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the

Company in any manner. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties.

- b. The Consultant shall have the right to control and determine the time, place, methods, manner and means of performing the services. In performing the services, the amount of time devoted by the Consultant on any given day will be entirely within the Consultant's control, and the Company will rely on the Consultant to put in the amount of time necessary to fulfill the requirements of this Agreement. The Consultant will provide all equipment and supplies required to perform the services. The Consultant is not required to attend regular meetings at the Company. However, upon reasonable notice, the Consultant shall meet with representatives of the Company at a location to be designated by the parties to this Agreement.

c. In the performance of the services, the
(f) Consultant has the authority to control and direct the performance of the details of the services, the Company being interested only in the results obtained. However, the services contemplated by the Agreement must meet the Company's standards and approval and shall be subject to the Company's general right of inspection and supervision to secure their satisfactory completion.

d. The Consultant shall not use the Company's trade names, trademarks, service names or service marks without the prior approval of the Company.

e. The Consultant shall be solely responsible for all state and federal income taxes, unemployment insurance and social security taxes in connection with No proceeding challenging this Agreement and for maintaining adequate workers' compensation insurance coverage.

or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Initial Closing, shall have been instituted or be pending before any Governmental Authority.

10. Remedies. The Consultant acknowledges that any breach of the provisions of Section 6 of this Agreement shall result in serious and irreparable injury to the Company for which the Company cannot be adequately compensated by monetary damages alone. The Consultant agrees, therefore, that, in addition to any other remedy the Company may have, the Company shall be entitled to enforce the specific performance of this Agreement by the Consultant and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without the necessity of proving actual damages or posting a bond.

11. Indemnification. The Consultant shall be solely liable for, and shall indemnify, defend and hold harmless the Company and its successors and assigns from any claims, suits, judgments or causes of action initiated by any third party against the Company where such actions result from or arise out of the services performed by the Consultant under this Agreement. The Consultant shall further be solely liable for, and shall indemnify, defend and hold harmless the Company and its successors and assigns from and against any claim or liability of any kind (including penalties, fees or charges) resulting from the Consultant's failure to pay the taxes, penalties, and payments referenced in Section 9 of this Agreement. The Consultant shall further indemnify, defend and hold harmless the

2.7 Conditions to each Additional Closing.

- 7 -

2.7.1 The obligations of Gilead hereunder in connection with each Additional Closing, if any, are subject to the following conditions being satisfied or waived:

11	Company and its successors and assigns from and against any and all loss or damage resulting from any misrepresentation, or any non-

fulfillment of any representation, responsibility, covenant or agreement on Consultant's part, as well as any and all acts, suits, proceedings, demands, assessments, penalties, judgments of or against the Company relating to or arising out of the activities of the Consultant and the Consultant shall pay reasonable attorneys' fees, costs and expenses incident thereto.

12. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party at the address shown above, or at such other address or addresses as either party shall designate to the other in accordance with this Section 12.

13. Pronouns.

Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

14. Entire

Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement; provided, however, for the avoidance of doubt, that nothing herein supersedes the Restrictive Covenants Agreement into

which the Consultant entered in connection with his prior employment by the Company, which remains in full force and effect (including without limitation Sections 3(d) and 3(e) of the Restrictive Covenants Agreement). For clarification, but not limitation, this means that if there is a conflict between Sections 6 or 7 of this Agreement and the Restricted Covenant Agreement, such conflict will be resolved in the manner most protective of the Company.

15. Amendment.

This Agreement may be amended or modified only by a written instrument executed by both the Company and the Consultant.

16. Non-Assignability of Contract. This Agreement is personal to the Consultant and the Consultant shall not have the right to assign any of Consultant's rights or delegate any of Consultant's duties without the express written consent of the Company. Any non-consented-to assignment or delegation, whether express or implied or by operation of law, shall be void and shall constitute a breach and a default by the Consultant.

17. Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without giving effect to any choice or conflict of law provision or rule that would cause the application of laws of any other jurisdiction.

18. Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business, provided, however, that the obligations of the Consultant are personal and shall not be assigned by Consultant.

- 8 -

19. Interpretation.
(a) If any restriction
The

representations
and
warranties
of the
Company
set forth
in
Section
6 is
found 3.1
that are
not
qualified
by any
court of
competent
jurisdiction
to be
unenforceable
because
it
extends
for too
long a
period of
time or
over too
great a
range of
activities
or in too
broad a
geographic
area,
it materiality
shall be
interpreted
to
extend
only
over true
and
correct

in all
material
respects
as of
such
Closing
Date
and the
maximum
period representations
and
warranties
of time,
range the
Company
set forth
in
Section
3.1 that
are
qualified
by
materiality
shall be
true and
correct
in all
respects
as of
activities
or
geographic
area as
to which
it may
be
enforceable. such
Closing
Date.

20. Survival.
Sections
(b) 4
through
20The
Company
shall
survive
the
expiration
or
termination have
complied
in all
material
respects
with its
covenants
hereunder
as of
this
Agreement. such
Closing
Date.

21. Miscellaneous.

(c) Each of the License Agreement (without regard to any partial termination thereunder) and the Investor Rights Agreement shall continue to be in full force and effect.

a. No delay or

(d) omission by The Company shall have obtained any and all consents, permits, approvals, registrations and waivers necessary for the Company in exercising any right under

this
Agreement
shall
operate
as a
waiver consummation
of that or
any
other
right. A
waiver
or
consent
given by
the
Company
on any
one
occasion purchase
and sale
of the
applicable
Additional
Shares,
all of
which
shall be
effective
only in
that
instance full
force
and
shall not
be
construed
as a bar
or
waiver of
any right
on any
other
occasion.
effect.

b. The captions
(e) of All closing deliverables as required under Section 2.5.1 shall have been delivered by the sections of this Agreement are for convenience of reference only and in no way define, limit, or affect the scope or substance of any section of this Agreement.

Company to Gilead.

(f) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay such Additional Closing, shall have been instituted or be pending before any Governmental Authority.

(g) The Company shall have delivered to the Transfer Agent irrevocable written instructions to issue the

Additional
Shares
to
Gilead
and/or
establish
a
reserve
account
for the
shares
of
Common
Stock
issuable
upon the
exercise
of any
Pre-
Funded
Warrants
issued
at such
Additional
Closing
in a form
and
substance
acceptable
to the
Transfer
Agent.

(h) The
Company
shall
have
filed with
Nasdaq
a Listing
of
Additional
Shares
Notification
Form for

the
listing of
the
applicable
Additional
Shares,
if
required,
and
Nasdaq
shall not
have
raised
an
objection
to the
consummation
of the
transactions
contemplated
by this
Agreement,
the
Investor
Rights
Agreement
and the
License
Agreement
in the
absence
of
stockholder
approval
of such
transactions.

(i) The Company shall have delivered Valid Account Details, together with a Form W-9, to Gilead at least two (2) Business Days prior to such Additional Closing Date in a form and substance acceptable to Gilead.

(j) No Material Adverse Effect with respect to the Company or its subsidiaries shall have occurred or be existing as of such Closing Date.

(k) The Principal Market shall not have commenced any final delisting proceedings against the Company.

2.7.2 The obligations of the Company hereunder in connection with each Additional Closing, if any, are subject to the following conditions being satisfied or waived:

(a) The representations and warranties of Gilead

set forth
in
Section
3.2
hereof
that are
not
qualified
by
materiality
shall be
true and
correct
in all
material
respects
as of
such
Closing
Date
and the
representations
and
warranties
of
Gilead
set forth
in
Section
3.2
hereof
that are
qualified
by
materiality
shall be
true and
correct
in all
respects
as of
such
Closing
Date.

(b) Gilead
shall
have
complied
in all
material
respects
with its
covenants
hereunder
as of
such
Closing
Date.

(c) Each of
the
License
Agreement
(without
regard
to any
partial
termination
thereunder)
and the
Investor
Rights
Agreement
shall
continue
to be in
full force
and
effect.

(d) All
closing
deliverables
required
under
Section
2.5.2
shall
have
been
delivered
by
Gilead
to the
Company.

(e) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay such Additional Closing, shall have been instituted or be pending before any Governmental Authority.

2.8 Taxes. The Company shall pay any and all transfer, stamp or similar taxes that may be payable with respect to the issuance and delivery of any shares of Common Stock to Gilead made under this Agreement.

2.9 Beneficial Ownership Cap; Commercially Reasonable Efforts. During the period beginning on the date of this Agreement and ending on the later of (A) the first day following the Exercise Period

and (B) the first day following the Lock-up Period (as defined in the Investor Rights Agreement), the Company shall not repurchase or redeem any shares of Common Stock or other securities of the Company (or take any other action) if such repurchase or redemption or other action would cause Gilead to Beneficially Own a number of shares of Common Stock equal to greater than 19.9% of the Company Capitalization immediately following such repurchase or redemption or other action, [**].

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company hereby makes the following representations and warranties to Gilead as of the date hereof, as of the Initial Closing Date and as of any Additional Closing Date (except, in each case, (i) for the representations and warranties that speak as of a specific earlier date, which shall be made as of such date, and (ii) as otherwise set forth in the Disclosure Schedule, if any, delivered herewith or at such Additional Closing). Each such date

is referred to as a Representation Date.

3.1.1 Organization and Good Standing. The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its subsidiaries are duly licensed or qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

3.1.2 Subsidiaries. All of the outstanding shares of capital stock or equivalent equity interests of each subsidiary listed in Exhibit 21 to the Company's most recent Annual Report on Form 10-K filed with the Commission are owned of record and beneficially, directly or indirectly, by the Company free and clear of all material Liens, pledges, security interests or other encumbrances.

3.1.3 Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to

consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by the Company and the consummation by it of the transactions contemplated hereby (including the issuance and sale of the Shares by the Company) have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Company's board of directors or the Company's stockholders in connection herewith other than the Required Approvals (as defined below). This Agreement has been duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (a) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (b) insofar as indemnification and contribution provisions may be limited by applicable law.

3.1.4 No Conflicts; Filings, Consents and Approvals.
The execution, delivery and performance of this Agreement by the Company and the consummation by the Company of the transactions contemplated hereby (including the issuance of the Shares) will not (i) conflict with

or result in a violation of any provision of the Company's Restated Certificate of

Incorporation or Amended and Restated Bylaws, each as in effect on the date hereof, (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default under, any agreement, indenture, or instrument to which the Company is a party, or (iii) result in a violation of any law applicable to the Company, except in the case of clauses (ii) and (iii) only, for such conflicts, breaches, defaults, and violations as would not reasonably be expected to have, a Material Adverse Effect on the Company. The Company is not required to obtain any consent, waiver, approval, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other Governmental Authority or other Person in the United States in connection with the execution, delivery and performance by the Company of this Agreement (including the offer, sale or issuance of the Shares by the Company), other than the listing of the Shares on Nasdaq, filing a Form D with the Commission or as may be required under applicable state securities laws or the by-laws and rules of the Financial Industry Regulatory

Authority (collectively, the “Required Approvals”).

3.1.5 Issuance of Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be validly issued, fully paid and nonassessable, free and clear of all Liens, other than restrictions on transferability under the Investor Rights Agreement and applicable federal securities laws. The Shares are not and will not be subject to any preemptive rights held by any holders of any security of the Company or any similar contractual rights granted by the Company to any Person.

3.1.6 Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the audited financial statements included within the Company’s Annual Report on Form 10-K, originally filed with the Commission on March 2, 2023, except as specifically disclosed in a subsequent SEC Report, there has been no event, occurrence or development that has had or that could reasonably be expected to, either individually or in the aggregate, have a Material Adverse Effect on the business, condition (financial or other), assets, liabilities or results of operations of the Company, taken as a whole.

3.1.7 No General Solicitation. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf, has engaged in any form of general solicitation or general advertising

(within the meaning of Regulation D under the Securities Act) in connection with the offer or sale of the Shares.

3.1.8 Private

Placement. Neither the Company nor any Person acting on its behalf, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares under the Securities Act. Subject to the accuracy of the representations made by Gilead in Section 3.2 the Shares will be issued and sold to Gilead in compliance with applicable exemptions from the registration and prospectus delivery requirements of the Securities Act and the registration and qualification requirements of all applicable securities laws of the states of the United States. The Company has not engaged any brokers, finders or agents, or incurred, or will incur, directly or indirectly, any liability for brokerage or finder's fees or agents' commissions or any similar charges in connection with this Agreement and the transactions contemplated hereby, other than brokerage or finder's fees or agent's commissions or similar charges for which the Company is wholly responsible.

3.1.9 SEC Reports,
Financial Statements.

(a) The
Common
Stock is
registered
|
pursuant
to
Section
12(b) or
12(g) of
the
Exchange
Act. The
Company
has
delivered
or made
available
(by filing
on the
Commission's
|
electronic
data
gathering
and
retrieval
system
(EDGAR))
to
Gilead
complete
copies
of its
SEC
Reports
since
January
1, 2023.
As of its
date,
each

SEC
Report
complied
in all
material
respects
with the
requirements
of the
Exchange
Act, and
other
Laws
applicable
to it,
and, as
of its
date,
such
SEC
Report
did not
contain
any
untrue
statement
of a
material
fact or
omit to
state a
material
fact
required
to be
stated
therein
or
necessary
in order
to make
the
statements
therein,
in light

of the
circumstances
under
which
they
were
made,
not
misleading.

(b) The
financial
statements,
together
with the
related
notes
and
schedules,
of the
Company
included
in the
SEC
Reports
comply
as to
form in
all
material
respects
with all
applicable
accounting
requirements
and the
published
rules
and
regulations
of the
Commission
and all
other
applicable

rules
and
regulations
with
respect
thereto.
Such
financial
statements,
together
with the
related
notes
and
schedules,
have
been
prepared
in
accordance
with U.S.
Generally
Accepted
Accounting
Principles
("GAAP")
applied
on a
consistent
basis
during
the
periods
involved
(except
(i) as
may be
otherwise
indicated
in such
financial
statements
or the
notes
thereto

or (ii) in
the case
of
unaudited
interim
statements,
to the
extent
they
may not
include
footnotes
or may
be
condensed
or
summary
statements),
and
fairly
present
in all
material
respects
the
financial
condition
of the
Company
and its
consolidated
subsidiaries
as of the
dates
thereof
and the
results
of
operations
and
cash
flows for
the
periods
then

ended
(subject,
in the
case of
unaudited
statements,
to
normal
year-end
audit
adjustments).

(c) The
Common
Stock is
listed on
Nasdaq,
and the
Company
has
taken no
action
designed
to, or
that to
its
knowledge
is likely
to have
the
effect of,
terminating
the
registration
of the
Common
Stock
under
the
Exchange
Act or
delisting
the
Common
Stock

from
Nasdaq.
Except
for that
certain
notice
from
Nasdaq
received
on or
about
January
19, 2024
related
to the
minimum
bid
price
requirement,
the
Company
has not
received
any
notification
that,
and has
no
knowledge
that, the
Commission
or
Nasdaq
is
contemplating
terminating
such
registration
or
listing.

3.1.10 Disclosure
Controls; Accounting Controls. The
Company's internal control over

financial reporting was effective as of the most recent date on which the Company completed an evaluation of the effectiveness of its internal control over financial reporting and the Company is not currently aware of any material weaknesses in its internal control over

financial reporting. Except as may be disclosed in the SEC Reports, since the date of the latest audited financial statements of the Company, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company and each of its subsidiaries maintains disclosure controls and procedures (as such is defined in Rule 13a-15(e) under the Exchange Act) that are designed to comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated

and communicated to the Company's management to allow timely decisions regarding disclosures. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of a date within 90 days prior to the filing date of the Company's most recently filed Form 10-K (such date, the "Evaluation Date"). Except as may be disclosed in the SEC Reports, since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly affect the Company's internal controls.

3.1.11 Capitalization and Voting Rights.

- (a) The authorized capital of the Company consists of:
- (i) 200,000,000 shares of Common Stock of which, as of February 29, 2024, (A) 27,613,263 shares were issued

and
outstanding,
(B) 2,357,532
shares
were
reserved
for
future
grants
pursuant
to the
Company's
equity
incentive
plans
(including
its
stockholder
approved
equity
compensation
plans
and
outstanding
equity
compensation
arrangements
that
have not
been
approved
by the
Company's
stockholders)
described
in the
SEC
Reports,
(C) 7,997,201
shares
were
issuable
upon the
exercise
of stock

options
outstanding,
(D) 481,500
shares
issuable
upon the
vesting
of
restricted
stock
units,
and
(E) 701,244
shares
reserved
for
future
purchase
pursuant
to the
Company's
employee
stock
purchase
plan,
and
(ii) 5,000,000
shares
of
designated
|
preferred
stock,
none of
which
shares
of
preferred
stock
are
issued
and
outstanding.
All of
the

issued
and
outstanding
shares
of
Common
Stock
(1) have
been
duly
authorized
and
validly
issued,
(2) are
fully paid
and non-
assessable
and
(3) were
issued in
compliance
with all
applicable
federal
and
state
securities
Laws
and not
in
violation
of any
preemptive
rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(c) Except as described or referred to in the SEC Reports, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements

pursuant
to which
the
Company
is or may
become
obligated
to issue,
sell or
repurchase
any
shares of
its capital
stock or
any other
securities
of the
Company
other
than
equity
securities
that may
have
been
granted
pursuant
to its
equity
incentive
plans,
which
plans are
described
in the
SEC
Reports;
or (ii) any
restrictions
on the
transfer
of capital
stock of
the
Company

other
than
pursuant
to federal
or state
securities
Laws or
as set
forth in
this
Agreement.

(d) The
Company
is not a
party to
or
subject
to any
agreement
or
understanding
relating
to the
voting of
shares
of
capital
stock of
the
Company
or the
giving of
written
consents
by a
stockholder
or
director
of the
Company.

3.1.12 Litigation. There
is no action, charge, suit,
proceeding, suit, litigation,
arbitration, settlement or

complaint(each an “Action”) by or before any Governmental Authority pending, nor, to the Company’s knowledge, any audits or investigations by or before any Governmental Authority to which the Company or any of its subsidiaries is a party or to which any property of the Company or any of its subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have a Material Adverse Effect and, to the Company’s knowledge, no such actions, suits, proceedings, audits or investigations are threatened or contemplated by any Governmental Authority or threatened by others; and (a) there are no current or pending audits or investigations, actions, suits or proceedings by or before any Governmental Authority that are required under the Securities Act to be described in the SEC Reports that are not so described; and (b) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the SEC Reports that are not so filed.

3.1.13 Licenses and Permits. The Company and its subsidiaries have made all filings, applications and submissions required by, possesses and is operating in compliance with, all approvals, licenses, certificates, certifications, clearances, consents, grants, exemptions, marks, notifications, orders, permits and other authorizations issued by, the

appropriate federal, state or foreign Governmental Authority (including, without limitation, the United States Food and Drug Administration (the “FDA”), the United States Drug Enforcement Administration or any other foreign, federal, state, provincial, court or local government or regulatory authorities including self-regulatory organizations engaged in the regulation of clinical trials, pharmaceuticals, biologics or biohazardous substances or materials) necessary for the ownership or lease of their respective properties or to conduct its businesses as described in the SEC Reports (collectively, “Permits”), except for such Permits the failure of which to possess, obtain or make the same would not reasonably be expected to have a Material Adverse Effect; the Company and its subsidiaries are in compliance with the terms and conditions of all such Permits, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect; all of the Permits are valid and in full force and effect, except where any invalidity, individually or in the aggregate, would not be reasonably expected to have a Material Adverse Effect; and neither the Company nor any of its subsidiaries has received any written notice relating to the limitation, revocation, cancellation, suspension, modification or non-renewal of any such Permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material

Adverse Effect, or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course due to non-compliance with any applicable Law. To the extent required by applicable laws and regulations of the FDA, the Company or the applicable subsidiary has submitted to the FDA an Investigational New Drug Application or amendment or supplement thereto for each clinical trial it has conducted or sponsored or is conducting or sponsoring; all such submissions were in material compliance with applicable laws and rules and regulations when submitted and no material deficiencies have been asserted by the FDA with respect to any such submissions.

3.1.14 Clinical Data
and Regulatory Compliance.

- (a) Neither the Company nor any of its subsidiaries has failed to file with the applicable Governmental

Authorities
(including,
without
limitation,
the FDA,
or any
foreign,
federal,
state,
provincial
or local
Governmental
Authority
performing
functions
similar to
those
performed
by the
FDA)
any
required
filing,
declaration,
listing,
registration,
report or
submission,
except
for such
failures
that,
individually
or in the
aggregate,
would
not have
a
Material
Adverse
Effect;
all such
filings,
declarations,
listings,

registrations,
reports
or
submissions
were in
compliance
with
applicable
laws
when
filed and
no
deficiencies
have
been
asserted
by any
applicable
regulatory
authority
with
respect
to any
such
filings,
declarations,
listings,
registrations,
reports
or
submissions,
except
for any
deficiencies
that,
individually
or in the
aggregate,
would
not
reasonably
be
expected
to have
a

Material
Adverse
Effect.
The
Company
has
operated
and
currently
is, in all
material
respects,
in
compliance
with the
United
States
Federal
Food,
Drug,
and
Cosmetic
Act, all
applicable
rules
and
regulations
of the
FDA and
other
federal,
state,
local
and
foreign
Governmental
Authority
exercising
comparable
authority.

(b) The
preclinical
studies
and

tests
and
clinical
trials
described
in the
SEC
Reports
were,
and, if
still
pending,
are
being
conducted
in all
material
respects
in
accordance
with the
experimental
protocols,
procedures
and
controls
pursuant
to,
where
applicable,
accepted
professional
and
scientific
standards
for
products
or
product
candidates
comparable
to those
being
developed
by the

Company;
the
descriptions
of such
studies,
tests
and
trials,
and the
results
thereof,
contained
in the
SEC
Reports
are
accurate
and
complete
in all
material
respects;
the
Company
is not
aware of
any
tests,
studies
or trials
not
described
in the
SEC
Reports,
the
results
of which
reasonably
call into
question
the
results
of the
tests,

studies
and
trials
described
in the
SEC
Reports;
and the
Company
has not
received
any
written
notice or
correspondence
from the
FDA or
any
foreign,
state or
local
Governmental
Authority
exercising
comparable
authority
or any
institutional
review
board or

comparable
authority
requiring
the
termination,
suspension,
clinical

hold or
material
modification
of any
tests,
studies
or trials.

3.1.15 Intellectual

Property. (i) The Company and its subsidiaries own or have a valid license to all pending patent applications and issued patents, inventions, copyrights, know how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks and trade names (collectively, “Intellectual Property Rights”) used in or reasonably necessary to the conduct of their businesses in the manner described in the SEC Reports; (ii) the Intellectual Property Rights owned by the Company and its subsidiaries and, to the Company’s knowledge, the Intellectual Property Rights licensed to the Company and its subsidiaries, are valid, subsisting and enforceable, and there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity, scope or enforceability of any such Intellectual Property Rights; (iii) neither the Company nor any of its subsidiaries has received any notice alleging any infringement, misappropriation or other violation of Intellectual Property Rights which, singly or in the aggregate, if the subject of an unfavorable decision,

ruling or finding, would have a Material Adverse Effect on the Company and its subsidiaries, taken as a whole, and, to the Company's knowledge, none of the licensors, in relation to the Intellectual Property Rights licensed to the Company and its subsidiaries, have received any notice alleging any infringement, misappropriation or other violation of Intellectual Property Rights licensed to the Company and its subsidiaries which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect on the Company and its subsidiaries, taken as a whole; (iv) to the Company's knowledge, no third party is infringing, misappropriating or otherwise violating, or has infringed, misappropriated or otherwise violated, any Intellectual Property Rights owned by the Company or any of its subsidiaries, and any Intellectual Property Rights licensed to the Company and its subsidiaries, that would materially adversely affect the Company and its subsidiaries, taken as a whole; (v) neither the Company nor any of its subsidiaries infringes, misappropriates or otherwise violates, or has infringed, misappropriated or otherwise violated, any Intellectual Property Rights of a third party in any material respect; (vi) all employees or contractors engaged in the development of material Intellectual Property Rights on behalf of the Company or any subsidiary of the Company have executed an invention assignment agreement whereby such employees or

contractors presently assign all of their right, title and interest in and to such Intellectual Property Rights to the Company or the applicable subsidiary, and to the Company's knowledge no such agreement has been breached or violated; (vii) the Company and its subsidiaries use, and have used, commercially reasonable efforts to appropriately maintain all information intended to be maintained as a trade secret; and (viii) all employees or contractors engaged in the development of material trade secrets on behalf of the Company or any subsidiary of the Company have executed a confidentiality agreement with the Company or any subsidiary of the Company.

3.1.16 Sarbanes-Oxley. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all

reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, “principal executive officer” and “principal financial officer” shall have the meanings as such terms are used in the Sarbanes-Oxley Act.

3.1.17 No Improper Practices. (a) Neither the Company nor and of its subsidiaries, nor any director, officer, or employee of the Company or any subsidiary nor, to the Company’s knowledge, any agent, Affiliate or other Person acting on behalf of the Company or any subsidiary has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of applicable law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any applicable law or of the character required to be disclosed in the SEC Reports; (b) no relationship, direct or indirect, exists between or among the Company or any subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or any subsidiary, on the other hand, that is required by the Securities Act to be described in the SEC Reports that is not so described; (c) no relationship, direct or indirect, exists between or

among the Company or any
Subsidiary or any affiliate of them,
on the one hand, and the directors,
officers, or stockholders of the
Company or any subsidiary, on the
other hand, that is required by the
rules of the Financial Industry
Regulatory Authority to be
described in the SEC Reports that is
not so described; (d) there are no
material outstanding loans or
advances or material guarantees of
indebtedness by the Company or
any subsidiary to or for the benefit
of any of their respective officers or
directors or any of the members of
the families of any of them; and (e)
the Company has not offered, or
caused any placement agent to
offer, Common Stock to any person
with the intent to influence
unlawfully (i) a customer or supplier
of the Company or any subsidiary to
alter the customer's or supplier's
level or type of business with the
Company or any subsidiary or (ii) a
trade journalist or publication to
write or publish favorable
information about the Company or
any subsidiary or any of their
respective products or services,
and, (f) neither the Company nor
any subsidiary nor any director,
officer or employee of the Company
or any subsidiary nor, to the
Company's knowledge, any agent,
affiliate or other person acting on
behalf of the Company or any
subsidiary has (i) violated or is in
violation of any applicable provision
of the U.S. Foreign Corrupt
Practices Act of 1977, as amended,
or any other applicable anti-bribery
or anti-corruption law (collectively,
"Anti-Corruption Laws"), (ii) illegally

promised, offered, provided, attempted to provide or authorized the provision of anything of value, directly or indirectly, to any person for the purpose of obtaining or retaining business, influencing any act or decision of the recipient, or securing any improper advantage; or (iii) made any payment of funds of the Company or any subsidiary or received or retained any funds in violation of any Anti-Corruption Laws.

3.1.18 Sanctions.

- (a) The Company represents that, neither the Company nor any of its subsidiaries (collectively, the “Entity”), nor any director or officer of the Entity, nor, to the Company’s knowledge after reasonable due inquiry, any employee, agent, affiliate

or
representative
of the
Entity, is
a
government,
individual
or entity
(an
"Individual")
that is,
or is
owned
or
controlled
by an
Individual
that:

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(1) is
the
subject
of
any
applicable
sanctions
administered
or
enforced
by
the
U.S.
Department
of
Treasury's
Office
of
Foreign

Assets
Control
("OFAC"),
the
United
Nations
Security
Council,
the
European
Union,
His
Majesty's
Treasury,
or
other
relevant
sanctions
authorities,
including,
without
limitation,
designation
on
OFAC's
Specially
Designated
Nationals
and
Blocked
Persons
List
or
OFAC's
Foreign
Sanctions
Evaders
List
and
the
U.S.
Entity
List,
all
administered

by
the
U.S.
Department
of
Commerce;
the
consolidated
list
of
Persons,
Groups
and
Entities
subject
to
EU
Financial
Sanctions,
as
implemented
by
the
EU
Common
Foreign
&
Security
Policy;
and
similar
lists
of
restricted
parties
maintained
by
other
applicable
governmental
entity
or
Governmental
Authority
(as

amended,
collectively,
"Sanctions"),
nor

(2) is
located,
organized
or
resident
in
a
country
or
territory
that
is
the
subject
of
Sanctions
that
broadly
prohibit
dealings
with
that
country
or
territory
(including,
without
limitation,
Cuba,
Iran,
North
Korea,
Syria
and
the
Crimea,
Donetsk
People's
Republic
and

Luhansk
People's
Republic
regions
of
Ukraine).

(b) The
Entity
represents
and
covenants
that it
will not,
directly
or
indirectly,
use the
proceeds
of the
offering,
or lend,
contribute
or
otherwise
make
available
such
proceeds
to any
subsidiary,
joint
venture
partner
or other
Individual:

(1) to
fund
or
facilitate
any
activities
or
business
of
or
with
any
Individual
that,
at
the
time
of
such
funding
or
facilitation,
is
the
subject
of
Sanctions
or
in
any
country
or
territory
that
is
a
Sanctioned
Country
in
violation
of
Sanctions;
or

(2) in any other manner that will result in a violation of Sanctions by any Individual (including any Individual participating in the offer and sale of the Shares, whether as underwriter, advisor, investor or otherwise).

(c) The Entity represents and covenants that for the past five (5) years, it has not

engaged
in, is not
now
engaging
in, and
will not
engage
in, any
dealings
or
transactions
with any
Individual
that at
the time
of the
dealing
or
transaction
is or was
the
subject
of
Sanctions
or in any
country
or
territory
that is or
was a
Sanctioned
Country
in
violation
of
Sanctions.

3.1.19 Not an
Investment Company. Neither the
Company nor any of its subsidiaries
is or, after giving effect to the
offering and sale of the Shares, will
be, an

“investment company” or an entity “controlled” by an “investment company,” as such terms are defined in the Investment Company Act of 1940, as amended.

3.1.20 No

Disqualification Events. None of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering of the Shares contemplated by this Agreement, or to the Company's knowledge, any Beneficial Owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an “Issuer Covered Person”) is subject to any of the “Bad Actor” disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a “Disqualification Event”), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event.

3.1.21 No Integration.

The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the

Securities Act) that is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

3.1.22 Tax Matters.

Since January 1, 2019, the Company and each of its subsidiaries have timely prepared and filed all income and other material tax returns required to have been filed by them with all appropriate Governmental Authorities and timely paid all taxes shown thereon, except as currently being contested in good faith and for which adequate reserves have been created in the financial statements of the Company, if such reserves are determined to be necessary or advisable by the Company. The charges, accruals and reserves on the books of the Company in respect of taxes for all fiscal periods have been and are adequate, and there are no unpaid assessments against the Company or any of its subsidiaries nor any basis for the assessment of any additional taxes, penalties or interest for any fiscal period or audits by any federal, state or local taxing authority, except as would not, individually or in the aggregate, have a Material Adverse Effect. All taxes and other assessments and levies that the Company or any of its subsidiaries is required to withhold or to collect for payment have been duly withheld and collected and paid to the proper Governmental Authority or third party when due, except as would not, individually or

in the aggregate, have a Material Adverse Effect. There are no tax liens or claims pending or, to the Company's knowledge, threatened, against the Company or its of its subsidiaries or any of their assets or properties, except as would not, individually or in the aggregate, have a Material Adverse Effect.

3.2 Representations and Warranties of Gilead. Gilead hereby makes the following representations and warranties to the Company as of the date hereof, as of the Initial Closing Date and as of any Additional Closing Date (except, in each case, for the representations and warranties that speak as of a specific earlier date, which shall be made as of such date).

3.2.1 Organization; Authority; Enforcement. Gilead is duly incorporated, validly existing and in good standing under the laws of the State of Delaware, with all requisite power and authority to own, lease, operate and use its properties and assets and to carry on its business as currently conducted and as it is presently proposed to be conducted. Gilead has the

requisite corporate power and authority to enter into and to consummate the transactions

contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by Gilead and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of Gilead and no further action is required by Gilead, Gilead's board of directors or Gilead's stockholders in connection herewith. This Agreement has been duly executed by Gilead and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of Gilead enforceable against Gilead in accordance with its terms, except (a) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (b) insofar as indemnification and contribution provisions may be limited by applicable law.

3.2.2 No Conflicts; Filings, Consents and Approvals.
The execution, delivery and performance of this Agreement by Gilead and the consummation by Gilead of the transactions contemplated hereby will not (i) conflict with or result in a violation of any provision of the Gilead's Restated Certificate of Incorporation or Amended and Restated Bylaws, each as in effect on the date hereof, (ii) violate or conflict with, or result in a breach of any provision of, or

constitute a default under, any agreement, indenture, or instrument to which the Gilead is a party, or (iii) result in a violation of any law applicable to Gilead, except in the case of clauses (ii) and (iii) only, for such conflicts, breaches, defaults, and violations as would not reasonably be expected to result in a liability for the Company or prevent the consummation of this Agreement. Gilead is not required to obtain any consent, waiver, approval, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other Governmental Authority or other Person in the United States in connection with the execution, delivery and performance by Gilead of this Agreement.

3.2.3 Gilead Status.

At the time Gilead was offered the Shares, it was, and as of the date hereof it is either: (a) an “accredited investor” as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (b) a “qualified institutional buyer” as defined in Rule 144A(a) under the Securities Act. Gilead is acting alone in its determination as to whether to invest in the Shares.

3.2.4 Experience of Gilead.

Gilead, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such

investment. Gilead is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

3.2.5 Access to Information. Gilead acknowledges that it has had the opportunity to review the SEC Reports and has been afforded, (a) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (b) access to information (other than material non-public information) about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (c)

the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

3.2.6 Certain Transactions and Confidentiality. Other than consummating the transactions contemplated

hereunder, Gilead has not, nor has any Person acting on behalf of or pursuant to any understanding with Gilead, directly or indirectly executed any purchases or sales, including any “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock) of the securities of the Company during the period commencing as of the time that Gilead first received any materials setting forth the material pricing terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof.

3.2.7 Legends.

Gilead understands and agrees that the Shares will bear a restrictive legend in substantially the following form (and a stop-transfer order may be placed against transfer of the Shares):

THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”) OR WITH THE SECURITIES COMMISSION OF ANY STATE, AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH

APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY AND THE COMPANY'S TRANSFER AGENT.

THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE, INCLUDING A LOCK-UP PERIOD, AS SET FORTH IN AN INVESTOR RIGHTS AGREEMENT, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE COMPANY.

3.2.8 Reliance on Exemptions. Gilead understands that the Shares are being offered and sold to it in reliance upon specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying upon the truth and accuracy of the representations and warranties of Gilead set forth in this **Section 3.2** in order to determine the availability of such exemptions and the eligibility of Gilead to acquire the Shares.

3.2.9 No Disqualification Events. Gilead is not subject to any Disqualification Event, except for Disqualification Events covered by Rule 506(d)(2) or (d)(3) under the Securities Act and disclosed reasonably in advance of the Closing in writing in reasonable detail to the Company.

ARTICLE 4**OTHER AGREEMENTS OF THE
PARTIES**

4.1 Survival. The representations, warranties, covenants and agreements contained in this Agreement shall survive the Closings and the delivery of the Shares and any termination of this Agreement for the applicable statute of limitations.

4.2 Legend Removal. The Company shall direct its transfer agent to remove the transfer restriction set forth in Section 3.2.7 applicable to any portion of the Shares that are restricted securities, upon the written request of Gilead, within two (2) Business Days of the Company's receipt of such request, at such time as such portion of the Shares (a) are being sold by Gilead pursuant to Rule 144 or (b) may be transferred without the requirement that the Company be in compliance with the public information requirements and volume or manner-of-sale restrictions under Rule 144. Gilead, or if the Company's transfer agent requires, the Company, shall provide such opinions of counsel reasonably requested by the Company's transfer agent in

connection with the removal of legends pursuant to this Section 4.2.

4.3 Book Entry

Statement. The Company hereby agrees to cause the Company's transfer agent to deliver to Gilead a book entry share position for the applicable Shares registered in the name of Gilead within three (3) Business Days following each Closing.

4.4 Capitalization Table.

At any time prior to the expiration of the Exercise Period, as promptly as reasonably practicable following Gilead's written request and in any event within five (5) Business Days after any such request, the Company shall provide Gilead with a summary capitalization table setting forth the then-current Company Capitalization.

4.5 Confidentiality.

Gilead covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company, Gilead will maintain the confidentiality of the existence and terms of this transaction.

4.6 Due Diligence. With

respect to each proposed purchase of Additional Shares, upon Gilead's request, including any such request made prior to delivery of an Additional Shares Purchase Exercise Notice, the Company shall expend commercially reasonable efforts cooperating with any due diligence review conducted by Gilead or its representatives in

connection with such proposed purchase of Additional Shares, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Gilead may request.

4.7 Events of Default. An

"Event of Default" shall be deemed to have occurred and be occurring at any time as any of the following events occurs and has not been cured:

4.7.1 any final notice of institution of delisting proceedings with respect to the Common Stock from the Principal Market until such time as Company has moved its listing to another market or exchange constituting a Principal Market;

4.7.2 the material breach of any representation or warranty on a Representation Date or any covenant under this Agreement, except, in the case of a breach of a covenant which

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is reasonably curable, only if such breach continues uncured for a period of at least twenty (20) Business Days;

4.7.3 if any Person commences an Action against the Company pursuant to or within the meaning of any Bankruptcy Law and such Action is not dismissed or stayed within 45 calendar days;

4.7.4 if the Company pursuant to or within the meaning of any Bankruptcy Law;
(A) commences a voluntary case,
(B) consents to the entry of an order for relief against it in an involuntary case, (C) consents to the appointment of a Custodian of it or for all or substantially all of its property or (D) makes a general assignment for the benefit of its creditors;

4.7.5 a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (A) is for relief against the Company in an involuntary case, (B) appoints a Custodian of the Company or for all or substantially all of its property, or (C) orders the liquidation of the Company or any subsidiary; or

4.7.6 the License Agreement is terminated early for any reason.

In addition to any other rights and remedies under applicable law and this Agreement, including the Gilead termination rights under Section 5.5 hereof, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, the Company may not require and

Gilead shall not be obligated to purchase any Additional Shares. If pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company which is not dismissed or stayed within 45 days, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under Section 5.5.1(a) hereof shall affect the Company's or Gilead's obligations under this Agreement with respect to pending purchases and the Company and Gilead shall complete their respective obligations with respect to any pending purchases under this Agreement.

ARTICLE 5

MISCELLANEOUS

5.1 Fees and Expenses.

Each party shall pay all fees and expenses that it incurs (including on account of any of their respective advisers, counsel, accountants and other experts) in connection with the negotiation, preparation, execution and delivery of this Agreement, including all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company), stamp taxes and other taxes and duties

levied in connection with the delivery of any Shares to Gilead.

5.2 Entire Agreement.

This Agreement, the License Agreement, including the appendices and schedules attached thereto, and the Investor Rights Agreement contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede

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all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.3 Notices. Any notice or other communication required or permitted to be given under this Agreement shall be in writing (whether or not specifically stated), shall specifically refer to this Agreement, and shall be addressed to the appropriate party at the address specified below or such other address as may be specified by such party in writing in accordance with this Section 5.3, and shall be deemed to have been given for all purposes (i) when received, if hand-delivered or sent by a reputable international expedited delivery service (with receipt confirmed), (ii) if given by e-mail, upon receipt of confirmation of

receipt of an e-mail transmission (including automated confirmation of delivery) and (iii) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 5.3 is not intended to govern the day-to-day business communications necessary between the parties in performing their obligations under the terms of this Agreement (for which e-mail or other methods of communications shall suffice).

If to the Company: In the event that any provision of this Agreement Xilio Therapeutics, Inc. Attention: Chief Operating Officer 828 Winter Street, Suite 300 Waltham, MA 02451 Email: [**]

With a copy to Wilmer Cutler (which shall be Pickering Hale invalid, illegal or enforceability otherwise of the remaining unenforceable, the provisions Dorr validity, legality not LLP Attention: constitute notice): Cynthia T. Mazareas 60 State Street Boston, MA 02109 Email: [**]

If to Gilead: Gilead Sciences,
Inc.
333 Lakeside
Drive
Foster City, CA
94404
Attention:
Alliance
Management
Email: [**]

With a copy to Gilead Sciences,
(which shall in no
way be affected or
impaired
thereby, not
constitute notice): 333 Lakeside
Drive
Foster City, CA
94404
Attention:
General Counsel
Email: [**]

Hogan Lovells
US LLP
8350 Broad St.
17th Floor
Tysons, VA
22102
Attention: [**]
Email: [**]

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5.4 Amendments;

Waivers. No subsequent alteration,
amendment, change or addition to
this Agreement shall be binding
upon the parties hereto unless

reduced to writing and signed by an authorized officer of each party. Any delay in enforcing a party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

5.5 Termination. This Agreement shall [**] terminate in the event that (a) the License Agreement terminates in its entirety for any reason or (b) the Company consummates any merger, consolidation or similar transaction, unless immediately following the consummation of such transaction, the stockholders of the Company immediately prior to the consummation of such transaction continue to hold, as a result of their holding of outstanding Common Stock and other securities entitled to vote for the election of directors of the Company immediately prior to the consummation of such transaction, in aggregate more than 50% of the outstanding Common Stock and other securities entitled to vote for the election of directors of the surviving or resulting entity in such transaction.

5.5.1 This Agreement may also be terminated as follows:

- (a) By Gilead [**].

(b) By
Gilead
[**].

5.5.2 Any termination of this Agreement pursuant to Section 5.5.1(a) (except as otherwise set forth in Section 4.7) shall be effected by written notice from Gilead to the Company setting forth the basis for the termination hereof. No termination of this Agreement shall affect the Company's or Gilead's rights or obligations under this Agreement with respect to pending purchases and the Company and Gilead shall complete their respective obligations with respect to any pending purchases under this Agreement.

5.5.3 If not earlier terminated, this Agreement shall automatically terminate upon the later of (A) the expiration of the Exercise Period and (B) the occurrence of all Additional Closings with respect to sales of Additional Shares under any Additional Shares Purchase Exercise Notice(s) made and duly given on or prior to the expiration of the Exercise Period.

5.6 Construction; Headings. The terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation" (regardless of whether it is actually written (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)) and the term "or" has the inclusive meaning represented by the phrase "and/or" (regardless of whether it is

actually written (and drawing no implication from the actual use of the phrase “and/or” in some instances but not in others)). Unless specified to the contrary, references to Articles or Sections shall refer to the particular Articles or Sections of or to this Agreement. The word “day,” “quarter” or “year” (and derivatives thereof, e.g., “quarterly”) shall mean a calendar day, calendar quarter or calendar year unless otherwise specified. The word “hereof,” “herein,” “hereby” and derivative or similar

word refers to this Agreement. The words “will” and “shall” shall have the same obligatory meaning. Provisions that require that a party or parties hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise. Words of any gender include the other gender. Words using the singular or plural number also include the plural or singular number, respectively. References to any specific law or article, section or other division thereof shall be deemed to include the then-current amendments or any replacement law thereto, and any rules and regulations promulgated thereunder. All dollar-denominated amounts

herein are in United States dollars. This Agreement has been prepared jointly and shall not be strictly construed against either party. Ambiguities, if any, in this Agreement shall not be construed against either party, irrespective of which party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

5.7 Adjustments. In the event of any stock split, subdivision, dividend or distribution payable in shares of Common Stock (or other securities or rights convertible into, or entitling the holder thereof to receive directly or indirectly shares of Common Stock), combination or other similar recapitalization or event occurring after the date of this Agreement, each reference in this Agreement shall be deemed to be amended to appropriately account for such event.

5.8 Further Assurances. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

5.9 Successors and Assigns. This Agreement may not be assigned by a party hereto without the prior written consent of the other party, provided, however,

that Gilead may assign its rights and delegate its duties hereunder in whole or in part to an Affiliate without the prior written consent of the Company, *provided* such assignee agrees in writing to be bound by the provisions hereof that apply to Gilead. The provisions of this Agreement shall inure to the benefit of and be binding upon the respective permitted successors and assigns of the parties.

5.10 Third Party

Beneficiaries. This Agreement is not intended to and shall not be construed to give any third party any interest, rights (including any third party beneficiary rights), remedies, obligations, or liabilities with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except as expressly provided in this Agreement.

5.11 Publicity. Gilead shall

have the right to provide comment on and approve before issuance any press release, filing with the Commission or any other public disclosure made by or on behalf of the Company whatsoever with respect to, in any manner, Gilead or the purchase and sale of the Shares contemplated by this Agreement; *provided, however*, that the Company shall be entitled, without the prior approval of Gilead, to make any press release or other public disclosure (including any filings with the Commission) with respect to such transactions as is required by applicable law and regulations so long as the Company provides Gilead with a copy thereof as far in

advance as reasonably practicable
(and in no event less than [**] prior
to the

anticipated date of disclosure,
unless a shorter timeframe is
required by applicable law or the
circumstances) so as to provide a
reasonable opportunity to comment
thereon. Notwithstanding the
foregoing, the Company shall not be
obligated to deliver Gilead a copy of
any release or other public
disclosure that contains information
that is substantially similar to
disclosure previously provided to
Gilead pursuant to this Section 5.11.

5.12 Governing Law. This
Agreement shall be governed by
and construed under the
substantive laws of the State of New
York, excluding any conflicts or
choice of law rule or principle that
might otherwise refer construction or
interpretation of this Agreement to
the substantive law of another
jurisdiction.

5.13 Remedies. In addition
to being entitled to exercise all
rights provided herein or granted by
law, including recovery of damages,
each of Gilead and the Company
will be entitled to seek specific
performance under this Agreement.
The parties agree that monetary
damages may not be adequate
compensation for any loss incurred

by reason of any breach of obligations contained in this Agreement and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.14 WAIVER OF JURY

TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

5.15 Attorneys' Fees.

In the event that any action is instituted under or in relation to this Agreement, including without limitation to enforce any provision in this Agreement, each party shall bear its own fees, costs and expenses of enforcing any right of such party under or with respect to this Agreement.

5.16 Counterparts;

Electronic Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties

need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file (including any “.pdf” including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., a signature applied with DocuSign), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

5.17 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one

such that the objectives contemplated by the parties when

entering into this Agreement may be realized.

5.18 Investor Rights

Agreement. For clarity, the parties agree and acknowledge that this Agreement is the “Purchase Agreement” under and as defined in the Investor Rights Agreement.

[Remainder of Page Intentionally Left Blank]

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- 9 - IN WITNESS WHEREOF,
the parties hereto have caused this Common Stock Purchase Agreement to be duly executed by their respective authorized signatories as of March 27, 2024.

**Xilio
Therapeutics,
Inc.**

By:

/s/

**René
Russo**

Name:

René

**Russo
Title:**

President

and

Chief

Executive

Officer

**Gilead
Sciences,
Inc.**

By:

/s/

Andrew

Dickinson

Name:

Andrew

Dickinson

Title:

Chief

Financial

Officer

*Signature Page to Common Stock
Purchase Agreement*

Exhibit 10.3

Certain identified information has
been excluded from the exhibit
because it is both (i) not material
and (ii) is the type of information that
the registrant treats as private or

confidential. Double asterisks
denote omissions.

XILIO THERAPEUTICS, INC.

INVESTOR RIGHTS AGREEMENT

This Investor Rights Agreement (this “Agreement”) is made as of March 27, 2024, by and between Xilio Therapeutics, Inc., a Delaware corporation (the “Company”), and Gilead Sciences, Inc., a Delaware corporation (“Gilead”).

WHEREAS, concurrently herewith, the Xilio Development, Inc. (“Xilio Development”) and Gilead have entered into a License Agreement (the “License Agreement”) pursuant to which they have established a collaboration with respect to certain of the Company’s product development programs;

WHEREAS, concurrently herewith, the Company and Gilead have entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) pursuant to which Gilead has agreed to purchase from the Company shares of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and may have the obligation to purchase additional shares of Common Stock in the future; and

WHEREAS, the Company and Gilead wish to set forth in this Agreement certain terms and conditions regarding Gilead’s

ownership of Common Stock and certain other matters as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

ARTICLE 1

DEFINITIONS

1.1 Definitions. For purposes of this Agreement:

1.1.1 “Affiliate” means any Person that, directly or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with a Person.

1.1.2 “Beneficially Own” has the meaning specified in Rule 13d-3 promulgated under the Exchange Act.

1.1.3 “Board” means the Board of Directors of the Company.

1.1.4 “Business Day” means any day on which Nasdaq and commercial banks in the City of New York are open for business.

1.1.5 “Change of Control” has the meaning set forth in Section 2.3.

1.1.6 “Closing Date” means the Initial Closing Date as defined in the Purchase Agreement.

1.1.7 “Commission” means the United States Securities and Exchange Commission.

1.1.8 “Commission Rule 144” means Rule 144 promulgated by the Commission under the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

1.1.9 “Commission Rule 415” means Rule 415 promulgated by the Commission under the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

1.1.10 “Common Stock” has the meaning set forth in the recitals.

1.1.11 “Company Capitalization” means, as of any date of measurement, the total number of outstanding shares of voting capital stock of the Company.

1.1.12 “Control,” including the terms “Controlling,” “Controlled by” and “under common Control with,” means the possession, directly or indirectly, of the power to

direct or cause the direction of the management and policies of a Person, whether through the ownership of voting shares, by contract or otherwise.

1.1.13 “Entity” means any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any limited liability company or joint stock company), branch office, firm or other enterprise, association, organization or entity.

1.1.14 “Equity Securities” means (a) any shares of Common Stock or preferred stock of the Company, and (b) any other security, financial instrument, certificate and other right (including options, futures, swaps and other derivatives) issued or, with respect to options, futures, swaps and other derivatives, contracted by the Company and representing, being exercisable, convertible or exchangeable into or for, or otherwise providing a right to acquire, directly or indirectly, any of the Equity Securities referred to in clause (a).

1.1.15 “Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.1.16 “Final Closing Date” means the latest occurring Additional Closing Date (as defined in the Purchase Agreement) or, if no Additional Closing (as defined in the

Purchase Agreement) has occurred,
the Initial Closing Date.

IN WITNESS WHEREOF, 2

1.1.17 “Final Prospectus”
has the meaning set forth in Section 6.1.1.

1.1.18 “Gilead
Foundation” means the Gilead
Foundation, a 501(c)(3) non-profit
organization organized in the state
of California.

1.1.19 “Holder” means
Gilead or its permitted successors
and assigns pursuant to Section 8.8
of this Agreement.

1.1.20 “Indemnified Party”
has the meaning set forth in Section 6.1.3.

1.1.21 “Indemnifying
Party” has the meaning set forth in
Section 6.1.3.

1.1.22 “Inspectors” has
the meaning set forth in Section 7.1.

1.1.23 “License
Agreement” has the meaning set
forth in the recitals.

1.1.24 “Lock-up Period”
has the meaning set forth in Section 3.1.

1.1.25 “Nasdaq” means
the Nasdaq Stock Market.

1.1.26 “Person” means any individual, Entity or governmental authority.

1.1.27 “Principal Market” means the Nasdaq Global Select Market; provided however, that in the event the Company’s Common Stock is ever listed or traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Market or the Nasdaq Capital Market, then the “Principal Market” shall mean such other market or exchange on which the Company’s Common Stock is then listed or traded.

1.1.28 “Purchase Agreement” has the meaning set forth in the recitals.

1.1.29 “Records” has the meaning set forth in Section 7.1.

1.1.30 “Registrable Securities” means the shares of Common Stock purchased by Gilead under the Purchase Agreement and any shares of Common Stock issued as a dividend or other distribution with respect to, in exchange for or in replacement of such shares; *provided, however*, that securities shall cease to be Registrable Securities if they (a) have been disposed of pursuant to a registration statement declared effective by the Commission, (b) have been sold in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act so that all transfer restrictions and restrictive legends with respect thereto are removed upon the consummation of such

sale or (c) may be sold or transferred by non-affiliates without any volume limitations pursuant to Commission Rule 144.

1.1.31 “Registration Expenses” means all expenses incurred by the Company in performing or complying with Article 5, including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of the Company’s counsel and one counsel for Gilead (which amount may not exceed \$[**]), blue sky fees and accounting fees.

1.1.32 “Registration Period” has the meaning set forth in Section 5.1.3.

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1.1.33 “Registration Statement” has the meaning set forth in Section 5.1.1.

1.1.34 “Restricted Securities” means shares of Common Stock held by Gilead or any of its Affiliates, or by any person to whom such shares are transferred by Gilead, any of its Affiliates or any of their respective transferees, that are “restricted securities” as defined in Commission Rule 144.

1.1.35 “Securities Act” means the Securities Act of 1933,

as amended, and the rules and regulations promulgated thereunder.

1.1.36 “Selling Expenses” means all underwriting discounts and selling commissions applicable to an offering involving Registrable Securities registered pursuant to Article 5.

1.1.37 “Shares” means the Shares as defined in the Purchase Agreement.

1.1.38 “Standstill” has the meaning set forth in Section 2.2.

1.1.39 “Standstill Fall-Away” has the meaning set forth in Section 2.3.

1.1.40 “Standstill Fall-Away Notice” has the meaning set forth in Section 2.3.

1.1.41 “Standstill Period” has the meaning set forth in Section 2.1.

1.1.42 “Underwritten Offering” has the meaning set forth in Section 5.3.2.

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

ARTICLE 2

STANDSTILL

2.1 Standstill Obligation. The standstill obligation, as set out in this Article 2, will be in effect for the period (the “Standstill Period”) beginning on the Closing Date and

ending [**] from the Final Closing Date.

2.2 Standstill Limitations.

During the Standstill Period, Gilead shall not and shall cause its Controlled Affiliates to not, without the prior express written consent of the Company, directly or indirectly:

2.2.1 acquire any Equity Securities of the Company other than pursuant to (a) the Purchase Agreement, (b) Section 4.3, or (c) Section 4.4, or in any other transaction with the Company;

2.2.2 knowingly encourage or support a tender, exchange or other offer or proposal by a third party for an extraordinary transaction or series of related transactions resulting in an extraordinary transaction involving the Company;

2.2.3 propose any (a) merger, consolidation, business combination, tender or exchange offer, purchase of substantially all of the Company's consolidated assets or businesses, or similar extraordinary transaction or series of related transactions resulting in an extraordinary transaction involving the Company or (b) recapitalization, restructuring, liquidation or other extraordinary transaction with respect to the

Company (it being understood that Gilead's Chief Executive Officer, Chief Financial Officer or Head of Corporate Development may contact the Company's Chief Executive Officer and/or the Board on a non-public and non-committal basis in such a way that would not be reasonably likely to require the Company to disclose publicly any such matter described in clause (a) or (b));

2.2.4 (a) publicly submit matters to, publicly request that matters be submitted to, or publicly request the convening of, a meeting of the stockholders of the Company, or (b) solicit proxies or consents, or become a participant in a solicitation in relation to matters submitted to a meeting of the stockholders of the Company, in each case of (a) and (b) without or against the recommendation or support by the Board; or

2.2.5 (a) make public statements with respect to (unless legally obliged to do so) or (b) with the actual knowledge of Gilead's executive officers, provide assistance to, commit to, or discuss or enter into any agreement or arrangement with any party to do, any of the foregoing prohibited actions.

(this Section 2.2, the "Standstill"). The foregoing standstill provisions shall not prohibit passive investments by a pension or employee benefit plan or trust for Gilead's employees.

2.3 Standstill Fall-Away. The foregoing standstill provisions shall terminate automatically in the event that (a) the Company enters into, or publicly announces its intention to enter into, a definitive agreement to effect a business combination, merger or other extraordinary transaction that would, if consummated, result in more than 50% of the Company's outstanding voting securities being owned by persons other than the current holders of such voting securities, or which would result in more than 50% of the Company's consolidated assets being sold (such transaction, a "Change of Control"), (b) any third party commences, or publicly announces its intention to commence, a tender or exchange offer for more than 50% of the outstanding voting securities of the Company and (i) the Board fails to recommend prior to the date that is **[**]** after such commencement that the Company's stockholders not tender their shares in such tender or exchange offer or (ii) such proposal has been publicly supported or recommended by the Board or (c) the Board publicly announces its intention to commence a process to seek a potential sale of the Company or all or substantially all of its assets (the "Standstill Fall-Away") and the Company shall notify Gilead of such Standstill Fall-Away event as promptly as practicable and in any event no later than **[**]** after such Standstill Fall-Away event (the "Standstill Fall-Away Notice"). Upon the Standstill Fall-Away, the Standstill obligations of Gilead shall terminate. The Company shall not

be required to specify in the Standstill Fall-Away Notice any information regarding any proposed transaction that has not been publicly disclosed.

2.4 Material Non-Public

Information. Gilead acknowledges that the information contained in the Standstill Fall-Away Notice may, prior to the public announcement of such information, constitute material, non-public information of the Company. When receiving the Standstill Fall-Away Notice, Gilead shall take all appropriate measures to ensure the confidentiality of such information.

ARTICLE 3

LOCK-UP

3.1 Lock-Up Obligation. During the period beginning on the Closing Date and ending on the earliest of (a) [**] of the Final Closing Date, (b) the date the Company delivers a Standstill Fall-Away Notice, (c) the termination of the License Agreement in its entirety and (d) the termination of this Agreement pursuant to Section 8.5 (the “Lock-up Period”), Gilead shall not, and shall cause its Affiliates not to, without the prior consent of the Company, transfer, sell or otherwise dispose of any Equity Securities held by Gilead or any of its Affiliates,

other than transfers, sales or dispositions permitted pursuant to Section 3.3.

3.2 Limitation on Dispositions.

During the period beginning with the expiration of the Lock-up Period and ending on the date that is the earlier of (a) [**] from the expiration date of the Lock-up Period and (b) the date the Company delivers a Standstill Fall-Away Notice, Gilead and any of its Affiliates may, after notifying the Company of their intent to do so, transfer, sell or otherwise dispose of the Equity Securities held by Gilead or any of its Affiliates, *provided that:*

3.2.1 when selling the shares of Common Stock on the open market or in a block trade, Gilead and its Affiliates collectively shall be permitted to sell shares in an amount that, together with all sales of Common Stock sold for the account of Gilead and its Affiliates within the preceding [**], does not exceed the greatest of: (i) [**]% of the Common Stock outstanding as shown by the most recent report or statement published by the Company or (ii) [**] of trading in the Common Stock on the Principal Market during the [**] preceding the date of execution of the transaction; and

3.2.2 when selling the shares of Common Stock through a privately negotiated transaction, the transaction shall not be subject to the limitations in this Section 3.2 if it is not and will not be required to be reported on the Nasdaq consolidated tape.

For the avoidance of doubt, after the date that is the earlier of (i) [**] from the expiration date of the Lock-up Period and (ii) the date the Company delivers a Standstill Fall-Away Notice, (i) Gilead and its Affiliates may freely transfer, sell or otherwise dispose of the Equity Securities held by Gilead and its Affiliates without limitation (other than as imposed by applicable securities laws) and (ii) the restrictions contained in Section 3.1 and Section 3.2 shall terminate and be of no further force and effect. The foregoing limitations set forth in this Section 3.2 shall cease to apply to Gilead's Affiliates if such Person ceases to be an Affiliate of Gilead.

3.3 Permitted Transfers. A transfer, sale or other divestment of Equity Securities by Gilead or any of its Affiliates or the Gilead Foundation to any of their Affiliates or the Gilead Foundation shall be permitted and not be subject to the restrictions set out in Section 3.1 or Section 3.2, *provided* that (a) the obligations of Gilead pursuant to this Agreement remain

unaffected by the proposed transfer, sale or divestment, (b) the transferee agrees in writing to be bound by the restrictions set out in Section 3.1 and Section 3.2 in relation to the Equity Securities it

received and the other obligations of Gilead in relation to the Equity Securities under this Agreement, and (c) the relevant Equity Securities will be re-transferred to Gilead immediately prior to the transferee ceasing to be an Affiliate of Gilead or any winding up of the Gilead Foundation.

ARTICLE 4

ADDITIONAL COVENANTS

4.1 “Market Stand-off” Agreement. Gilead hereby agrees that it and its Controlled Affiliates will not, without the prior written consent of any managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other Equity Securities under the Securities Act on a registration statement in an underwritten public offering of Common Stock, and ending on the date specified by the Company and the managing underwriter, *provided* that such date shall not be later than [**] following the date of such final prospectus, (a) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock (whether such shares or any such securities are then owned by Gilead or its Affiliates

or are thereafter acquired) or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Section 4.1 shall be applicable to Gilead and its Affiliates only if all executive officers and directors of the Company are subject to the same restrictions. If any other Person who has agreed to similar restrictions is released by the Company or the underwriters from such restrictions, then Gilead and its Affiliates shall be released from such restrictions applicable to Gilead and its Affiliates to the same extent as such other Person is released. The underwriters in connection with such registration are intended third party beneficiaries of this Section 4.1 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Gilead further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 4.1 or that are necessary to give further effect thereto. The provisions of this Section 4.1 shall automatically terminate upon the date upon which Gilead, together with its Affiliates, collectively, do not, directly or indirectly, own outstanding shares of

Common Stock representing at least 5% of the Company Capitalization.

4.2 Restrictions on Transfer.

4.2.1 Subject to Article 5, the Shares will not be sold, pledged, or otherwise transferred, and the Company will not recognize and will issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except such sales, pledges or transfers as are executed in accordance with Article 5 or upon the conditions specified in this Section 4.2, which conditions are intended to ensure compliance with the provisions of the

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Securities Act. Gilead, if effecting a transfer of Shares other than a sale pursuant to Commission Rule 144 or sale pursuant to a registration statement under the Securities Act, will cause any proposed purchaser, pledgee, or transferee of the Shares to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Section 4.2.

4.2.2 Gilead consents to the Company making a notation in its records and giving instructions to any transfer agent of the Common Stock in order to implement the restrictions on transfer set forth in this Section 4.2.

4.2.3 Gilead agrees that before any proposed sale, pledge, or transfer of any Restricted Securities that is not effected pursuant to Commission Rule 144, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, Gilead will give notice to the Company of its intention to effect such sale, pledge, or transfer. Each such notice will describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, will be accompanied at Gilead's expense by either: (a) a written opinion of legal counsel who will, and whose legal opinion will, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (b) a "no action" letter from the Commission to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the Commission that action be taken with respect thereto; or (c) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon Gilead will be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by Gilead to the Company and such

securities will no longer constitute Restricted Securities for purposes of this Agreement. The Company will not require such a legal opinion or “no action” letter in any transaction in which Gilead distributes Restricted Securities to an Affiliate of Gilead for no consideration; *provided* that each such transferee agrees in writing to be subject to the terms of this Section 4.2. Each certificate or instrument evidencing the Restricted Securities transferred as above provided will bear, except if such transfer is made pursuant to Commission Rule 144, the appropriate restrictive legend set forth in Section 3.2.7 of the Purchase Agreement, except that such certificate will not bear such restrictive legend if, in the opinion of counsel for Gilead and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act. The Company will take all actions necessary to have the lock-up legend set forth in Section 3.2.7 of the Purchase Agreement removed from all Restricted Securities on the day the Lock-up Period expires.

4.3 **[]**.**

4.4 **Open Market Purchases.**

Notwithstanding Article 2 of this Agreement, at any time during the term of this Agreement, Gilead shall be permitted to acquire shares of Common Stock through open market purchases so long as, after giving effect to such acquisition, Gilead and its Controlled Affiliates, and any other party acting in concert with Gilead or any of its

Controlled Affiliates, would, together in the aggregate, not directly or indirectly Beneficially Own a number of shares of Common Stock greater than the percentage ownership of the Company

Capitalization that Gilead held immediately following the most recent Closing Date (as defined in the Purchase Agreement).

ARTICLE 5

REGISTRATION RIGHTS

5.1 Registration Statements.

5.1.1 If following the termination of the Lock-up Period Gilead or any Holder holds any Registrable Securities, the Company shall upon Gilead's written request (a) within [**] after the date of such request, file a registration statement on Form S-3, or (b) [**] after the date of such request, file a registration statement on Form S-1 if the Company is not eligible to register such Registrable Securities on Form S-3, in each case covering the resale of the Registrable Securities for an offering to be made on a continuous basis pursuant to Commission Rule 415, or if Commission Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of

Registrable Securities as Gilead may reasonably specify, and will use commercially reasonable efforts to have such registration statement on Form S-1 or S-3 (either such registration statement, the “Registration Statement”) promptly declared effective by the Commission (a “Registration Request”). Gilead may deliver one Registration Request during the term of this Agreement. For purposes of clarification, any failure by the Company to file the Registration Statement by the applicable deadline set forth in this Section 5.1.1 shall not otherwise relieve the Company of its obligations to file or effect the Registration Statement as set forth above in this Section 5.1.1.

5.1.2 Notwithstanding the foregoing, if the Company furnishes to Gilead a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board it would be materially detrimental to the Company and its stockholders for such Registration Statement to either become effective, because such action would (a) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (b) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (c) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the

Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, [**]; provided, however, that the Company may not invoke this right [**]; and provided further that the Company shall not register any securities for its own account or that of any other stockholder [**] (other than (a) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (b) a registration relating to a Rule 145 transaction; or (c) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered).

5.1.3 **Registration**

Period. The Company will use commercially reasonable efforts to keep the Registration Statement continuously effective under the Securities Act for one hundred eighty (180) days following the initial effectiveness of such Registration Statement (such period, the “Registration Period”).

5.2 Company Obligations. In the case of the registration, qualification, exemption or

compliance effected by the Company pursuant to this Agreement, the Company shall, upon reasonable request, inform each Holder as to the status of such registration, qualification, exemption and compliance.

5.2.1 At its expense the Company shall:

(a) advise the Holders [**]:

(A) when a Registration Statement or any amendment thereto has been filed with the Commission and when such Registration Statement or any post-effective amendment thereto has become effective;

(B) of any request by the Commission for amendments or supplements to the Registration Statement or the prospectus included therein or for additional information;

(C) of the issuance
by the
Commission of
any stop order
suspending the
effectiveness of
the
Registration
Statement or
the initiation of
any
proceedings for
such purpose;

(D) of the receipt
by the
Company of
any notification
with respect to
the suspension
of the
qualification of
the Registrable
Securities
included
therein for sale
in any
jurisdiction or
the initiation or
threatening of
any proceeding
for such
purpose; and

(E) of the occurrence of any event that requires the making of any changes in the Registration Statement or prospectus so that, as of such date, the statements therein are not misleading and do not omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of a prospectus, in the light of the circumstances under which they were made) not misleading;

(b) use its commercially reasonable efforts to obtain the withdrawal of any order suspending the effectiveness of the Registration Statement as soon as reasonably practicable;

(c) during the Registration Period, promptly deliver to each such Holder, without charge, as many copies of each prospectus included in a Registration Statement and any amendment or supplement thereto as such Holder may reasonably request in writing; and the Company consents to the use, consistent with the provisions hereof, of the prospectus or any amendment or supplement thereto by each of the selling Holders of Registrable Securities in connection with the offering and sale of the Registrable Securities covered by a prospectus or any amendment or supplement thereto;

(d) prior to any public offering of Registrable Securities pursuant to the Registration Statement, promptly take such actions as may be necessary to register or qualify

or obtain an exemption for offer and sale under the securities or blue sky laws of such United States jurisdictions as any such Holders reasonably request in writing, provided that the Company shall not for any such purpose be required to qualify generally to transact business as a foreign corporation in any jurisdiction where it is not so qualified or to consent to general service of process in any such jurisdiction, and do any and all other acts or things reasonably necessary or advisable to enable the offer and sale in such jurisdictions of the Registrable Securities covered by any such Registration Statement;

(e) upon the occurrence of any event contemplated by Section 5.2.1(a)(E) above, except for such times as the Company is permitted hereunder to suspend the use of a prospectus forming part of a Registration Statement, the Company shall use its commercially reasonable efforts to as soon as reasonably practicable prepare a post-effective amendment to such Registration Statement or a supplement to the related prospectus, or file any other required document so that, as thereafter delivered to purchasers of the Registrable Securities included therein, such prospectus will not include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading;

- (f) otherwise use its commercially reasonable efforts to comply in all material respects with all applicable rules and regulations of the Commission which could affect the sale of the Registrable Securities;
- (g) use its commercially reasonable efforts to cause all Registrable Securities to be listed on each securities exchange or market, if any, on which equity securities issued by the Company have been listed;
- (h) use its commercially reasonable efforts to take all other steps necessary to effect the registration of the Registrable Securities contemplated hereby and to enable the Holders to sell Registrable Securities under Commission Rule 144;

(i) permit counsel for Gilead to review the Registration Statement and all amendments and supplements thereto (other than any supplements to a Registration Statement on Form S-1 solely for the purpose of incorporating other filings with the Commission into such Registration Statement and other than any amendment to a Registration Statement on Form S-1 on Form S-3 for the purpose of converting such Registration Statement into a Registration Statement on Form S-3), within two (2) Business Days prior to the filing thereof with the Commission; and

(j) provided that, in the case of clause (i) above, the Company shall not be required (a) to delay the filing of the Registration Statement or any amendment or supplement thereto as a result of any ongoing diligence inquiry by or on behalf of a Holder or to incorporate any comments to the Registration Statement or any amendment or supplement thereto by or on behalf of a Holder if such inquiry or comments would require a delay in the filing of such Registration Statement,

amendment or supplement, as the case may be, or (b) to provide, and shall not provide, Gilead or its representatives with material, non-public information unless Gilead agrees in writing to receive such information and enters into a written confidentiality agreement with the Company in a form reasonably acceptable to the Company.

5.3 Investor Obligations.

5.3.1 Gilead shall furnish to the Company such information regarding Gilead, and the distribution proposed by Gilead, as the Company may reasonably request in writing and as shall be required in connection with the Registration Statement.

5.3.2 In the event Gilead intends to dispose of the Registrable Securities registered on the Registration Statement through an underwritten public offering (an “Underwritten Offering”), (a) the Company shall select the underwriter(s) of the Underwritten Offering that are reasonably acceptable to Gilead and (b) each of the Company and Gilead shall enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter(s) of such offering; provided, that Gilead shall

not be required to make any representations and warranties to, or agreements with, any underwriter in a registration other than customary representations, warranties and agreements. Notwithstanding the foregoing, the Company shall not be obligated to effect, or to take any action to effect, any registration or Underwritten Offering pursuant to this Section 5.3.2 (a) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (b) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (c) if the Company has previously effected one Underwritten Offering pursuant to this Section 5.3.2.

5.4 Registration Expenses. The Company shall pay all Registration Expenses incident to the performance of or compliance with Article 5 by the Company. Gilead will bear any Selling Expenses based upon the sale of Registrable Securities.

ARTICLE 6

INDEMNIFICATION.

6.1.1 To the extent permitted by law, the Company shall

indemnify Gilead, each Holder, and each Person controlling Gilead within the meaning of Section 15 of the Securities Act, with respect to which any registration that has been effected pursuant to this Agreement, against all claims, losses, damages and liabilities (or action in respect thereof), including any of the foregoing incurred in settlement of any litigation, commenced or threatened (subject to Section 6.1.3 below), arising out of or based on any untrue statement (or alleged untrue statement) of a material fact contained in the Registration Statement, or other document incident to any such registration, qualification or compliance or based on any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the

statements therein not misleading, in light of the circumstances in which they were made, or any violation by the Company of any rule or regulation promulgated by the Securities Act applicable to the Company and relating to any action or inaction required of the Company in connection with any such registration, qualification or compliance, and will reimburse Gilead, each Holder, and each Person controlling Gilead, for reasonable and documented legal

and other out-of-pocket expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability or action as incurred; *provided* that the Company will not be liable in any such case to the extent that any untrue statement or omission or allegation thereof is made in reliance upon and in conformity with written information furnished to the Company by Gilead for use in preparation of any registration statement, prospectus, amendment or supplement; *provided further*, that the Company will not be liable in any such case where the claim, loss, damage or liability arises out of or is related to the failure of Gilead to comply with the covenants and agreements contained in this Agreement respecting sales of Registrable Securities, and except that the foregoing indemnity agreement is subject to the condition that, insofar as it relates to any such untrue statement or alleged untrue statement or omission or alleged omission made in any preliminary prospectus but eliminated or remedied in the amended prospectus on file with the Commission at the time the Registration Statement becomes effective or in an amended prospectus filed with the Commission pursuant to Rule 424(b) which meets the requirements of Section 10(a) of the Securities Act (each, a “Final Prospectus”), such indemnity shall not inure to the benefit of Gilead or any such controlling Person, if a copy of a Final Prospectus furnished by the Company to Gilead for

delivery was not furnished to the Person asserting the loss, liability, claim or damage at or prior to the time such furnishing is required by the Securities Act and a Final Prospectus would have cured the defect giving rise to such loss, liability, claim or damage.

6.1.2 Gilead will indemnify the Company, each of its directors and officers, and each Person who controls the Company within the meaning of Section 15 of the Securities Act, against all claims, losses, damages and liabilities (or actions in respect thereof), including any of the foregoing incurred in settlement of any litigation, commenced or threatened (subject to Section 6.1.3 below), arising out of or based on any untrue statement (or alleged untrue statement) of a material fact contained in the Registration Statement, incident to any such registration, or based on any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in light of the circumstances in which they were made, and will reimburse the Company, such directors and officers, and each other Person controlling the Company for reasonable and documented legal and other out-of-pocket expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability or action as incurred, in each case to the extent, but only to the extent, that such untrue statement or

omission is made in reliance upon and in conformity with written information furnished to the Company by Gilead expressly for use in any registration statement, prospectus, amendment or supplement.

6.1.3 Each party entitled to indemnification under this Article 6 (the “Indemnified Party”) shall give notice to the party required to provide indemnification (the “Indemnifying Party”) promptly after such Indemnified Party has actual knowledge of any claim as to which indemnity may be sought, and shall permit the Indemnifying Party (at its expense) to assume the defense of any such claim or any litigation resulting therefrom, *provided* that counsel for the Indemnifying Party, who shall conduct the defense of such claim or litigation, shall be approved by the Indemnified Party (whose approval shall not unreasonably be withheld), and the

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Indemnified Party may participate in such defense at such Indemnified Party’s expense, and *provided further* that the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Agreement, unless such failure is materially

prejudicial to the Indemnifying Party in defending such claim or litigation. An Indemnifying Party shall not be liable for any settlement of an action or claim effected without its written consent (which consent will not be unreasonably withheld). No Indemnifying Party, in its defense of any such claim or litigation, shall, except with the consent of each Indemnified Party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect to such claim or litigation.

6.1.4 If the indemnification provided for in this Article 6 is held by a court of competent jurisdiction to be unavailable to an Indemnified Party with respect to any loss, liability, claim, damage or expense referred to therein, then the Indemnifying Party, in lieu of indemnifying such Indemnified Party thereunder, shall, to the extent permitted by applicable law, contribute to the amount paid or payable by such Indemnified Party as a result of such loss, liability, claim, damage or expense in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party on the one hand and of the Indemnified Party on the other in connection with the statements or omissions which resulted in such loss, liability, claim, damage or expense as well as any other relevant equitable considerations. The relative fault of the Indemnifying Party and of the

Indemnified Party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the Indemnifying Party or by the Indemnified Party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

ARTICLE 7

INFORMATION AND ACCESS RIGHTS

7.1 Information. So long as Gilead and its Affiliates, directly or indirectly, Beneficially Own ^[**] of the Company's outstanding Common Stock, the Company shall make available upon reasonable prior notice during normal business hours and for reasonable periods for inspection by Gilead and by any attorney, accountant or other agent retained by Gilead and who is reasonably acceptable to the Company (collectively, the "Inspectors") all reasonably pertinent financial and other records and pertinent corporate documents and properties of the Company (collectively, the "Records"), including with respect to each of the Company's subsidiaries, and cause the Company's officers, directors and, as deemed appropriate by the Company's officers, other Company employees, and the independent public accountants who have certified its financial statements to make themselves reasonably available to discuss the business of

the Company and to supply all information reasonably requested by Gilead and the Inspectors, in each case as is reasonably necessary for the purpose of conducting due diligence with respect to the Company (including as related to the License Agreement); provided, however, that Gilead shall agree to, and direct its Inspectors to, hold in strict confidence and shall not make any disclosure of any Record or other information which the Company determines in good faith to be confidential, and of which determination Gilead and the Inspectors are so notified, unless (a) the disclosure of such Records is required under applicable Law, (b) the release of such Records is

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ordered pursuant to a final, non-appealable subpoena or order from a court or government body of competent jurisdiction, (c) the information in such Records has been previously disclosed other than by disclosure in violation of this Section 7.1, or (d) the release or disclosure of such Records is required by applicable regulations or to a self-regulatory agency, and, to the extent permitted by applicable law and regulations, Gilead provides the Company with notice of such disclosure, which notice shall be in advance to the extent practicable.

Notwithstanding the foregoing, the Company shall not disclose material nonpublic information to Gilead, or to advisors to or representatives of Gilead, unless prior to disclosure of such information the Company identifies such information as being material nonpublic information and provides Gilead, such advisors and such representatives with the opportunity to accept or refuse to accept such material nonpublic information for review and Gilead enters into an appropriate confidentiality agreement with the Company with respect thereto.

ARTICLE 8

MISCELLANEOUS

8.1 Fees and Expenses. Each party shall pay all fees and expenses that it incurs (including on account of any of their respective advisers, counsel, accountants and other experts) in connection with the negotiation, preparation, execution and delivery of this Agreement and its performance under or compliance with the terms of this Agreement.

8.2 Entire Agreement. This Agreement, the License Agreement, including the appendices and schedules attached thereto, and the Purchase Agreement contain the entire understanding of the parties hereto with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have

executed been merged into such documents, exhibits and schedules.

8.3 Notices. Any notice or other communication required or permitted to be given under this Consulting Agreement shall be in writing (whether or not specifically stated), shall specifically refer to this Agreement, and shall be addressed to the appropriate party at the address specified below or such other address as may be specified by such party in writing in accordance with this Section 8.3, and shall be deemed to have been given for all purposes (i) when received, if hand-delivered or sent by a reputable international expedited delivery service (with receipt confirmed), (ii) if given by e-mail, upon receipt of confirmation of receipt of an e-mail transmission (including automated confirmation of delivery) and (iii) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 8.3 is not intended to govern the Effective Date.

day-to-day business communications necessary between the parties in performing their obligations under the terms of this Agreement (for which e-mail or other methods of communications shall suffice).

If to the Xilio
Company: Therapeutics, Inc.
Attention: Chief
Operating Officer
828 Winter Street,
Suite 300
Waltham, MA
02451
Email: [**]

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With a Wilmer
copy to Cutler
(which Pickering
shall not Hale and
constitute Dorr LLP
notice): Attention:
Cynthia T.
Mazareas
60 State
Street
Boston, MA
02109
Email: [**]

If to Gilead
Gilead: Sciences,
Inc.
333
Lakeside
Drive
Foster City,
CA 94404
Attention:
Alliance
Management
Email: [**]

With a By: Gilead
copy to Sciences,
(which Inc. /s/ René
shall not Russo 333
constitute Lakeside
notice): Drive
Foster City,
CA 94404
Attention:
General
Counsel
Email: [**] Name: Hogan René
Lovells US Russo 8350
LLP Broad St.
Chief
Title: Tysons, Executive
VA 22102 Officer Email:
17th Floor Attention: [**] [**]

CONSULTANT

/s/ Martin Huber
Martin Huber,
M.D.

8.4 Amendments and Waivers.

No subsequent alteration,
amendment, change or addition to
this Agreement shall be binding
upon the parties hereto unless
reduced to writing and signed by an
authorized officer of each party. Any
delay in enforcing a party's rights
under this Agreement or any waiver
as to a particular default or other
matter shall not constitute a waiver
of such party's rights to the future
enforcement of its rights under this
Agreement, except with respect to
an express written and signed
waiver relating to a particular matter
for a particular period of time.

8.5 Termination. This Agreement shall simultaneously and automatically terminate in the event that (a) the License Agreement terminates in its entirety for any reason, (b) the Purchase Agreement is terminated if such termination occurs before the Closing Date, or (c) the Company consummates any merger, consolidation or similar transaction unless immediately following the consummation of such transaction the stockholders of the Company immediately prior to the consummation of such transaction continue to hold, as a result of their holding of outstanding Common Stock and other securities entitled to vote for the election of directors of the Company immediately prior to the consummation of such transaction, in aggregate more than 50% of the outstanding Common Stock and other securities entitled to vote for the election of directors of the surviving or resulting entity in such transaction. If not earlier terminated, this Agreement shall automatically terminate upon the tenth anniversary of the Closing Date. Notwithstanding anything to the contrary set forth herein, (A) the Company's obligations under Article 5 of this Agreement shall survive until the earlier of (i) an event set forth in (c) above or (ii) such obligations are fully performed and discharged; and (B) if this Agreement has terminated as a

result of Gilead having terminated the License Agreement for convenience or the Company having terminated the License Agreement as a result of Gilead's material breach of the License Agreement, and an event set forth in (c) above has not occurred, Gilead's obligations in Article 3 shall survive until terminated as set forth in Article 3, and Gilead's obligations in Article 4 shall survive until terminated as set forth in Article 4.

8.6 Construction; Headings.

The terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation" (regardless of whether it is actually written (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)) and the term "or" has the inclusive meaning represented by the phrase "and/or" (regardless of whether it is actually written (and drawing no implication from the actual use of the phrase "and/or" in some instances but not in others)). Unless specified to the contrary, references to Articles or Sections shall refer to the particular Articles or Sections of or to this Agreement. The word "day," "quarter" or "year" (and derivatives thereof, e.g., "quarterly") shall mean a calendar day, calendar quarter or calendar year unless otherwise specified. The word "hereof," "herein," "hereby" and derivative or similar word refers to this Agreement. The words "will" and "shall" shall have the same

obligatory meaning. Provisions that require that a party or parties hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise. Words of any gender include the other gender. Words using the singular or plural number also include the plural or singular number, respectively. References to any specific law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement law thereto, and any rules and regulations promulgated thereunder. All dollar-denominated amounts herein are in United States dollars. This Agreement has been prepared jointly and shall not be strictly construed against either party. Ambiguities, if any, in this Agreement shall not be construed against either party, irrespective of which party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

8.7 Further Assurances. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

8.8 Successors and Assigns.

This Agreement may not be assigned by a party hereto without the prior written consent of the other party, *provided, however*, that Gilead may assign its rights and delegate its duties hereunder in whole or in part to an Affiliate or to the Gilead Foundation without the prior written consent of the Company, provided such assignee agrees in writing to be bound by the provisions hereof that apply to Gilead. The provisions of this Agreement shall inure to the benefit of and be binding upon the respective permitted successors and assigns of the parties.

8.9 Third Party Beneficiaries.

This Agreement is not intended to and shall not be construed to give any third party any interest, rights (including any third party beneficiary rights) remedies, obligations, or liabilities with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except as expressly provided in this Agreement.

8.10 Governing Law. This Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that

might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

8.11 WAIVER OF JURY TRIAL.

IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

8.12 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of Gilead and the Company will be entitled to seek specific performance under this Agreement. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in this Agreement and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

8.13 Attorneys' Fees. In the event that any action is instituted under or in relation to this Agreement, including without limitation to enforce any provision in this Agreement, each party shall bear its own fees, costs and

expenses of enforcing any right of such party under or with respect to this Agreement.

8.14 Counterparts; Electronic Execution. This Agreement may be executed in one or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file (including any “.pdf” including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., a signature applied with DocuSign), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof.

8.15 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The parties shall make a good faith effort to replace any

invalid or unenforceable provision
with a valid and enforceable one
such that the objectives
contemplated by the parties when
entering into this Agreement may be
realized.

**[Remainder of Page Intentionally
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SCHEDULE A IN WITNESS
WHEREOF, the parties hereto have
caused this Investor Rights
Agreement to be duly executed by
their respective authorized
signatories as of March 27, 2024.

**Xilio
Therapeutics,
Inc.**

By:
/s/
René
Russo

Name:

René

Russo

Title:

President

and

Chief

Executive

Officer

Gilead
Sciences,
Inc.

By:
/s/
Andrew
Dickinson

Name:

Andrew

Dickinson
Title:

Chief

Financial

Officer

Signature Page to Investor Rights
Agreement

Exhibit 10.6

XILIO THERAPEUTICS, INC.
AMENDED AND RESTATED
DIRECTOR COMPENSATION
POLICY

DESCRIPTION OF
SERVICES Effective: April 16, 2024

The non-employee directors
of Xilio Therapeutics, Inc. (the

“Company”) shall receive the following compensation for their service as members of the Board of Directors (the “Board”) of the Company.

Director Compensation

Our goal is to provide compensation for our non-employee directors in a manner that enables us to attract and retain outstanding director candidates and reflects the substantial time commitment necessary to oversee the Company’s affairs. We also seek to align the interests of our directors and our stockholders, and we have chosen to do so by compensating our non-employee directors with a mix of cash and equity-based compensation.

Cash Compensation

The annual cash retainer that will be paid to each of our non-employee directors for service on the Board, and for service on each committee of the Board on which the director is then a member, and the annual cash retainer that will be paid to the chair of the Board, if one is then appointed, and the chair of each committee of the Board will be as follows:

	Member Annual Fee	Additional Fee for Chair
Board of Directors	\$35,000	\$30,000
Audit Committee	\$7,500	\$7,500
Compensation Committee	\$5,000	\$5,000

Nominating and Corporate Governance Committee	\$4,000	\$4,000	

The **Consultant** foregoing annual cash retainers will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our Board or the applicable committee of the Board or, if applicable, as chair of the Board or the applicable committee.

Equity Compensation

Initial Equity Awards. Upon initial election to our Board, with respect to each non-employee director, such non-employee director will be granted, automatically and without the need for any further action by the Board, an initial equity award of an option to purchase 50,000 shares of our common stock. The initial award shall have a term of ten years from the date of grant of the award, and shall vest and become exercisable as to 33.3333% of the shares underlying such award on each of the first, second and third anniversaries of the date of grant of the award, subject the director's continued service to the Company or its subsidiaries through each applicable vesting date. The vesting shall accelerate as to 100% of the shares upon a

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director's death or disability or a change in control of the Company (with disability and change in control each as defined in the form of Nonstatutory Stock Option Agreement for Non-Employee Directors). The exercise price shall be the closing price of our common stock on the date of grant (provided that, for any date that is not a trading day, the exercise price shall be determined in accordance with the applicable stock incentive plan then in effect).

Annual Equity Awards. Each non-employee director who is serving as a member of our Board will be granted, automatically and without the need for any further action by the Board, an option to purchase 25,000 shares of our common stock on the first business day following the date of each annual meeting of stockholders. The annual award shall have a term of ten years from the date of the award, and shall vest on the earlier of (i) the first anniversary of the date of grant of the award and (ii) the Company's next annual meeting of stockholders following the grant date, subject to the director's continued service to the Company or its subsidiaries through the vesting date. The vesting shall accelerate as to 100% of the shares upon a director's death or disability or a change in control of the Company (with disability and change in control each as defined in the form of Non-Employee Director Stock Option Agreement). The

exercise price shall be the closing price of our common stock on the date of grant (provided that, for any date that is not a trading day, the exercise price shall be determined in accordance with the applicable stock incentive plan then in effect).

Adjustments to Share Amounts. The foregoing share amounts shall be automatically adjusted in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event affecting our common stock, or any distribution to holders of our common stock other than an ordinary cash dividend.

Other Terms and Conditions. The initial awards and the annual awards shall be subject to the terms and conditions of our 2021 Stock Incentive Plan, or any successor plan (including, but not limited to, any limits on compensation payable to non-employee directors contained in the 2021 Stock Incentive Plan or any successor plan), and the terms of the option agreements entered into with each director in connection with such awards.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each non-employee director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in

connection with attending meetings of the Board and committees thereof or in connection with other business related to the Board, and each non-employee director shall also be reimbursed for his or her reasonable out-of-pocket business expenses authorized by the Board or a committee of the Board that are incurred in connection with attendance at various conferences or meetings with management of the Company, in accordance with the Company's travel policy, as it may be in effect from time to time, and upon the Company's request, provide the Company (including its executive management team, board of directors or a subset of the foregoing) with consulting and advisory services related to clinical, scientific and other research and development matters. It is anticipated that the Consultant shall perform such services for the Company no more than 10 hours per month on average. time.

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EXHIBIT 31.1

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

I, René Russo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xilio Therapeutics, Inc.;

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

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 14, 2024

/s/ René Russo

Name: René Russo

Title: President and Chief
Executive Officer
(Principal Executive
Officer)

EXHIBIT 31.2

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

I, Kevin Brennan, certify that:

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

- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 14, 2024

/s/ Kevin Brennan

Name: Kevin Brennan

Title: Senior Vice
President, Finance
and Accounting
(Principal Financial
and Accounting
Officer)

EXHIBIT 32.1

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

In connection with this Quarterly Report on Form 10-Q of Xilio Therapeutics, Inc. (the "Company") for the three months ended **September 30, 2023** **March 31, 2024**, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, René Russo, President and Chief Executive Officer of the Company, and Kevin Brennan, Senior Vice President, Finance and Accounting, of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

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

/s/ René Russo

Name: René Russo

Title: President and
Chief Executive
Officer

/s/ Kevin Brennan

Name: Kevin Brennan

Title: Senior Vice
President, Finance and
Accounting

(Principal Executive Officer) (Principal Financial and Accounting Officer)

Date: November 9, 2023 May 14, 2024 Date: November 9, 2023 May 14, 2024

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