

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

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

For the quarterly period ended June 30, 2023

OR

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

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

Commission File Number: 001-39503

**Athira Pharma, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**45-3368487**

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

**18706 North Creek Parkway, Suite 104**

**Bothell, Washington 98011**

(Address of principal executive offices)

**(425) 620-8501**

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	ATHA	The Nasdaq Stock Market LLC (The 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

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

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

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

As of August 7, 2023, there were 38,054,583 shares of registrant's common stock, \$0.0001 par value per share, outstanding.

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*This report includes our trademarks and registered trademarks, including Athira, Athira Pharma, the Athira logo, and other trademarks or service marks of Athira. Each other trademark, trade name or service mark appearing in this report belongs to its holder.*

## SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this report captioned "Risk Factors." The following is a summary of the principal risks we face:

- We are a late clinical-stage biopharmaceutical company with a limited operating history.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.
- Our development of fosgonimeton may never lead to a marketable product.
- Our approach to targeting brain growth factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from our Phase 1a/1b and Phase 2 clinical trials to date, and we cannot be certain that future trials will yield data in support of the safety, efficacy, and tolerability of our product candidates.
- We have concentrated our research and development efforts on the treatment of central and peripheral nervous system degenerative disorders, a field that has seen very limited success in product development.
- An independent special committee of our board of directors engaged in a review of papers co-authored by our former chief executive officer in connection with her doctoral research at Washington State University, or WSU. The special committee's findings included that (1) our former chief executive officer altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at Washington State University, and published from 2011 to 2014, (2) that we cited challenged research papers in certain communications and applications, and (3) that WSU's dihexa patent, exclusively licensed to us, incorporated certain of these altered images. Washington State University has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at Washington State University. We cannot predict when WSU's investigation will be completed or what conclusions WSU will reach.
- We are and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations and other legal, regulatory and administrative proceedings and face potential liability and expenses related thereto, which could have a material adverse effect on our business, operating results and financial condition.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale preclinical studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale potentially pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.
- If we experience delays or difficulties in the enrollment or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.
- The loss of any of our key personnel could significantly harm our business, results of operations and competitive position.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- 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.
- The potential effects of health epidemics, including the novel coronavirus disease, or COVID-19, pandemic, could adversely impact our business, including our nonclinical studies and clinical trials.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of fosgonimeton, and develop and commercialize other and future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce, or eliminate our product development programs or other operations.

- The regulatory approval processes of the U.S. Food and Drug Administration and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- Intellectual property discovered or developed through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a manufacturing 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, which could adversely affect our ability to successfully develop and commercialize our products.
- We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
- Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- The market price of our common stock has been and may continue to be volatile, which could result in substantial losses for investors.
- We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management’s attention.
- Actions by activist stockholders have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business.

Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements (Unaudited)

**Athira Pharma, Inc.**  
**Condensed Consolidated Balance Sheets**  
(in thousands, except share and per share amounts)

	June 30, 2023 (unaudited)	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 113,628	\$ 95,966
Short-term investments	72,462	104,378
Unbilled grant receivable	—	1,227
Prepaid expenses and other current assets	6,043	5,962
<b>Total current assets</b>	<b>192,133</b>	<b>207,533</b>
Restricted cash	631	420
Property and equipment, net	3,847	4,053
Operating lease right-of-use asset	1,159	1,263
Long-term investments	10,217	44,829
Other long-term assets	61	55
<b>Total assets</b>	<b>\$ 208,048</b>	<b>\$ 258,153</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 612	\$ 2,501
Accrued liabilities	10,703	8,604
Accrued legal settlement (Note 7)	10,000	10,000
Current operating lease liability	347	326
<b>Total current liabilities</b>	<b>21,662</b>	<b>21,431</b>
Operating lease liability, less current portion	1,407	1,585
<b>Total liabilities</b>	<b>23,069</b>	<b>23,016</b>
Stockholders' equity:		
Common stock, \$0.0001 par value; 900,000,000 shares authorized at June 30, 2023 and December 31, 2022, respectively; 38,054,583 and 37,877,387 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	434,865	428,623
Accumulated other comprehensive loss	(939)	(1,956)
Accumulated deficit	(248,951)	(191,534)
<b>Total stockholders' equity</b>	<b>184,979</b>	<b>235,137</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 208,048</b>	<b>\$ 258,153</b>

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

**Athira Pharma, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share amounts)  
(unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating expenses:				
Research and development	\$ 21,615	\$ 14,803	\$ 42,908	\$ 29,263
General and administrative	10,025	8,766	18,502	17,693
Total operating expenses	<u>31,640</u>	<u>23,569</u>	<u>61,410</u>	<u>46,956</u>
Loss from operations	(31,640)	(23,569)	(61,410)	(46,956)
Grant income	—	(1,259)	157	975
Other income, net	2,043	493	3,836	666
Net loss	<u>\$ (29,597)</u>	<u>\$ (24,335)</u>	<u>\$ (57,417)</u>	<u>\$ (45,315)</u>
Unrealized gain (loss) on available-for-sale securities	90	(469)	1,017	(1,537)
Comprehensive loss attributable to common stockholders	<u>\$ (29,507)</u>	<u>\$ (24,804)</u>	<u>\$ (56,400)</u>	<u>\$ (46,852)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.78)</u>	<u>\$ (0.65)</u>	<u>\$ (1.51)</u>	<u>\$ (1.20)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>37,999,578</u>	<u>37,667,971</u>	<u>37,961,700</u>	<u>37,630,856</u>

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

**Athira Pharma, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**For the Three and Six Months Ended June 30, 2023**  
(in thousands, except share amounts)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of January 1, 2023</b>	37,877,387	\$ 4	\$ 428,623	\$ (1,956)	\$ (191,534)	\$ 235,137
Issuance of common stock upon exercise of common stock options	73,213	—	99	—	—	99
Stock-based compensation	—	—	2,782	—	—	2,782
Unrealized gain on available-for-sale securities	—	—	—	927	—	927
Net loss	—	—	—	—	(27,820)	(27,820)
<b>Balance as of March 31, 2023</b>	<u>37,950,600</u>	<u>\$ 4</u>	<u>\$ 431,504</u>	<u>\$ (1,029)</u>	<u>\$ (219,354)</u>	<u>\$ 211,125</u>
Issuance of common stock upon exercise of common stock options	7,882	—	11	—	—	11
Issuance of common stock under employee stock purchase plan	96,101	—	231	—	—	231
Stock-based compensation	—	—	3,119	—	—	3,119
Unrealized gain on available-for-sale securities	—	—	—	90	—	90
Net loss	—	—	—	—	(29,597)	(29,597)
<b>Balance as of June 30, 2023</b>	<u>38,054,583</u>	<u>\$ 4</u>	<u>\$ 434,865</u>	<u>\$ (939)</u>	<u>\$ (248,951)</u>	<u>\$ 184,979</u>

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

**Athira Pharma, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**For the Three and Six Months Ended June 30, 2022**  
(in thousands, except share amounts)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of January 1, 2022</b>	37,379,077	\$ 4	\$ 417,363	\$ (388)	\$ (95,895)	\$ 321,084
Issuance of common stock upon exercise of common stock options	244,981	—	210	—	—	210
Stock-based compensation	—	—	2,731	—	—	2,731
Unrealized loss on available-for-sale securities	—	—	—	(1,068)	—	(1,068)
Net loss	—	—	—	—	(20,980)	(20,980)
<b>Balance as of March 31, 2022</b>	<u>37,624,058</u>	<u>\$ 4</u>	<u>\$ 420,304</u>	<u>\$ (1,456)</u>	<u>\$ (116,875)</u>	<u>\$ 301,977</u>
Issuance of common stock upon exercise of common stock options	163,387	—	83	—	—	83
Issuance of common stock under employee stock purchase plan	30,279	—	214	—	—	214
Stock-based compensation	—	—	3,095	—	—	3,095
Unrealized loss on available-for-sale securities	—	—	—	(469)	—	(469)
Net loss	—	—	—	—	(24,335)	(24,335)
<b>Balance as of June 30, 2022</b>	<u>37,817,724</u>	<u>\$ 4</u>	<u>\$ 423,696</u>	<u>\$ (1,925)</u>	<u>\$ (141,210)</u>	<u>\$ 280,565</u>

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



**Athira Pharma, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(in thousands)  
(unaudited)

	Six Months Ended June 30,	
	2023	2022
<b>Operating activities</b>		
Net loss	\$ (57,417)	\$ (45,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,901	5,826
Depreciation expense	480	375
Non-cash lease expense	104	92
Amortization of premiums and accretion of discounts on available-for-sale securities, net	(737)	149
Changes in operating assets and liabilities:		
Unbilled grant receivable	1,227	2,336
Prepaid expenses and other current assets	(87)	1,149
Accounts payable and accrued liabilities	210	365
Operating lease liability	(157)	(139)
Net cash used in operating activities	<u>(50,476)</u>	<u>(35,162)</u>
<b>Investing activities</b>		
Purchases of available-for-sale securities	(24,891)	(51,670)
Maturities of available-for-sale securities	93,173	71,951
Purchases of property and equipment	(274)	(896)
Net cash provided by investing activities	<u>68,008</u>	<u>19,385</u>
<b>Financing activities</b>		
Proceeds from exercise of common stock options and issuance of common stock under employee stock purchase plan	341	507
Net cash provided by financing activities	<u>341</u>	<u>507</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	17,873	(15,270)
Cash, cash equivalents and restricted cash, beginning of period	96,386	110,537
Cash, cash equivalents and restricted cash, end of period	<u>\$ 114,259</u>	<u>\$ 95,267</u>

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

## **1. Description of Business**

### ***Organization***

Athira Pharma, Inc. (the "Company") was incorporated as M3 Biotechnology, Inc. in the state of Washington on March 31, 2011 and reincorporated in the state of Delaware on October 27, 2015. In April 2019, the Company changed its name to Athira Pharma, Inc. The Company currently has office and laboratory space in Bothell, Washington. The Company is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration.

### ***At The Market Common Stock Offering***

In January 2023, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), and BTIG, LLC ("BTIG"), to sell shares of our common stock having aggregate sales proceeds of up to \$75.0 million, from time to time, through an "at the market" ("ATM") equity offering program under which Cantor Fitzgerald and BTIG are acting as sales agents. The Company has not sold any securities pursuant to this ATM offering.

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

Since the Company's inception, it has funded its operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From the Company's inception through June 30, 2023, it has raised aggregate net cash proceeds of \$407.4 million primarily from the issuance of its common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes. As of June 30, 2023, the Company had \$196.3 million in cash, cash equivalents and investments and had not generated positive cash flows from operations. Since the Company's inception, it has devoted substantially all of its resources to its research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining the Company's intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Based upon the Company's current operating plan, it estimates that its \$196.3 million of cash, cash equivalents and investments at June 30, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements through at least the 12 months following the date of this report.

## **2. Significant Accounting Policies**

### ***Basis of Presentation***

The unaudited condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). The unaudited condensed consolidated financial statements include the operations of Athira Pharma, Inc., and its wholly owned Australian subsidiary. All intercompany balances and transactions have been eliminated upon consolidation.

### ***Unaudited Interim Condensed Consolidated Financial Statements***

The accompanying unaudited condensed consolidated balance sheet as of June 30, 2023, and unaudited condensed consolidated statements of operations and comprehensive loss, and stockholders' equity for the three and six months ended June 30, 2023 and 2022, and the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022, are unaudited. The balance sheet as of December 31, 2022 was derived from the audited consolidated financial statements as of and for the year ended December 31, 2022. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2022, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023, and the unaudited

condensed consolidated results of its operations for the three and six months ended June 30, 2023 and 2022 and the unaudited condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2023 and 2022 are also unaudited. The unaudited condensed consolidated results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the full year ending December 31, 2023 or any other period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements as of and for the year ended December 31, 2022 included in its Annual Report on Form 10-K filed with the SEC on March 23, 2023.

### **Fair Value Measurements**

The carrying amounts of certain financial instruments, including cash, cash equivalents, restricted cash, investments, accounts payable and accrued expenses approximate their fair values due to the short-term nature of those amounts.

### **Restricted Cash**

Restricted cash consists of collateral pledged in connection with the Company's corporate credit cards. The table below reconciles the balances of cash and cash equivalents and restricted cash reported on the unaudited condensed consolidated balance sheets to the balances of cash, cash equivalents and restricted cash reported on the unaudited condensed consolidated statements of cash flows.

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Cash and cash equivalents	\$ 113,628	\$ 95,966
Restricted cash	631	420
Cash, cash equivalents and restricted cash	<u>\$ 114,259</u>	<u>\$ 96,386</u>

### **Grant Income**

In December 2020, the Company accepted a grant from the National Institute on Aging ("NIA") of the National Institutes of Health ("NIH") to support its ACT-AD Phase 2 clinical trial for fosgonimeton (then-named ATH-1017), the Company's lead therapeutic candidate being developed for the treatment of individuals with mild-to-moderate Alzheimer's disease. The Company recognizes income related to the NIH grant in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss as qualifying expenses under the grant agreement are incurred. As of June 30, 2023, the Company has recognized aggregate grant income of \$15.2 million in connection with the NIH grant, equal to the total grant amount approved and the Company will not recognize any additional grant income in connection with the NIH grant.

During the three months ended June 30, 2023, the Company did not recognize any grant income. During the three months ended June 30, 2022, the Company recognized a reversal of \$1.3 million of grant income previously recorded in the three months ended March 31, 2022. During the six months ended June 30, 2023 and 2022, the Company recognized grant income of \$0.2 million and \$1.0 million, respectively, in connection with the NIH grant. As of December 31, 2022, the Company incurred qualifying expenses in excess of cash received of approximately \$1.2 million, which is included in unbilled grant receivable on the unaudited condensed consolidated balance sheets. During the six months ended June 30, 2023 and 2022, the Company received cash of \$1.4 million and \$4.6 million, respectively.

### **Short-term and Long-term Investments**

The Company generally invests its excess cash in investment grade short- to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term investments, and long-term investments on the unaudited condensed consolidated balance sheets, classified as available-for-sale, and reported at fair value with unrealized gains and losses included in accumulated other comprehensive loss. Amortization and accretion are included in other income, net. Realized gains and losses on the sale of these securities are recognized in other income, net.

The Company periodically evaluates whether declines in fair values of its investments below their book value are due to expected credit losses, as well as the Company's ability and intent to hold the investment until a forecasted recovery occurs. Expected credit losses are recorded as an allowance through other income, net.

## **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates include those used for fair value of assets and liabilities, accrued liabilities, valuation allowance for deferred tax assets, and stock-based compensation. Management evaluates related assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

## **Research and Development Expenses**

Research and development expenses consist primarily of direct and indirect costs incurred for research activities, including development of the pipeline from the Company's proprietary drug discovery platform ("ATH platform"), the Company's drug discovery efforts and the development of its product candidates. Direct costs include laboratory materials and supplies, contracted research and manufacturing, clinical trial costs, consulting fees, and other expenses incurred to sustain the Company's research and development program. Indirect costs include personnel-related expenses, consisting of employee salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities, and facilities and other expenses consisting of direct and allocated expenses for rent and depreciation and lab consumables.

Research and development costs are expensed as incurred. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. The Company estimates the period over which such services will be performed and the level of effort to be expended in each period. If actual timing of performance or the level of effort varies from the estimate, the Company adjusts the amounts recorded accordingly. The Company has not experienced any material differences between accrued or prepaid costs and actual costs since inception.

## **General and Administrative Expenses**

General and administrative expenses consist primarily of personnel-related costs, consisting of employee salaries, related benefits, and stock-based compensation expense for employees in the executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include third-party costs such as legal costs, insurance costs, accounting, auditing and tax related fees, consulting fees and facilities and other expenses not otherwise included as research and development expenses. General and administrative costs are expensed as incurred.

## **Leases**

The Company adopted Accounting Standards Codification ("ASC") *Topic 842 - Leases* effective January 1, 2020. The Company determines if an arrangement contains a lease at inception. The Company performed an evaluation of contracts in accordance with ASC 842 and has determined it has an operating lease agreement for the laboratory and office facilities that the Company occupies. Operating lease right-of-use ("ROU") assets and operating lease liabilities are recognized at the date the underlying asset becomes available for the Company's use. Operating lease liabilities are based on the present value of the future minimum lease payments over the lease term. ROU assets are measured at the amount of the lease liability, adjusted for any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. As the Company's leases generally do not provide an implicit interest rate, the present value of the future minimum lease payments is determined using the Company's incremental borrowing rate. This rate is an estimate of the collateralized borrowing rate the Company would incur on its future lease payments over a similar term and is based on the information available to the Company at the lease commencement date, discussed in more detail below.

The Company's leases contain options to extend the leases; lease terms are adjusted for these options only when it is reasonably certain the Company will exercise these options. The Company's lease agreements do not contain residual value guarantees or covenants.

The Company has made a policy election regarding its real estate leases not to separate non-lease components from lease components, to the extent they are fixed. Non-lease components that are not fixed are expensed as incurred as

variable lease expense. The Company's lease includes variable non-lease components, such as common-area maintenance costs. The Company has elected not to record on the balance sheet a lease that has a lease term of 12 months or less and does not contain a purchase option that the Company is reasonably certain to exercise. The Company accounts for leases with initial terms of 12 months or less as operating expenses on a straight-line basis over the lease term.

Lease expense is recognized within operating expenses on a straight-line basis over the terms of the lease. Incentives granted under the Company's facilities lease, including rent holidays, are recognized as adjustments to lease expense on a straight-line basis over the term of the lease.

### ***Stock-based Compensation***

The Company measures compensation expense for all stock-based payments to employees, officers and directors based on the estimated fair value of the award at the grant date. For stock options, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The grant date fair value of restricted stock units is based upon the fair market value of the Company's common stock based on its closing price as reported on the date of grant on the Nasdaq Global Select Market. Compensation expense is recognized over the requisite service period on a straight-line basis. Forfeitures are recognized as they occur.

The Company records compensation expense for stock option and restricted stock unit grants subject to performance-based milestone vesting over the remaining implicit service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

### ***Net Loss Per Share Attributable to Common Stockholders***

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company.

### ***Segments***

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

### ***Emerging Growth Company Status***

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (1) no longer an emerging growth company and (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act, unless early adoption is permitted. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

### ***Recently Adopted Accounting Pronouncements***

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments: Credit Losses (Topic 326)* as clarified in ASU 2019-04, ASU 2019-05, and ASU 2020-02. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than-temporary impairments on investment securities are recorded. The Company adopted ASU 2016-13 effective January 1, 2023 and it did not have a material impact on its financial condition, results of operations or cash flows.

### 3. Fair Value

The Company has certain assets and liabilities that are measured at fair value on a recurring basis according to a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are:

*Level 1*—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

*Level 2*—Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

*Level 3*—Inputs are generally unobservable and reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are determined using model-based techniques, including probability-based simulation methodologies.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data, which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

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

	June 30, 2023				Fair Value
	Level	Amortized Cost	Unrealized Gains	Unrealized Losses	
<b>Cash equivalents:</b>					
Commercial paper	2	93,243	—	(22)	93,221
<b>Total cash equivalents</b>		<b>\$ 93,243</b>	<b>\$ —</b>	<b>\$ (22)</b>	<b>\$ 93,221</b>
<b>Short-term investments:</b>					
Commercial paper	2	17,287	—	(19)	17,268
U.S. government debt and agency securities	2	54,485	3	(785)	53,703
Corporate bonds	2	1,500	—	(9)	1,491
<b>Total short-term investments</b>		<b>\$ 73,272</b>	<b>\$ 3</b>	<b>\$ (813)</b>	<b>\$ 72,462</b>
<b>Long-term investments:</b>					
U.S. government debt and agency securities	2	10,324	—	(107)	10,217
<b>Total long-term investments</b>		<b>\$ 10,324</b>	<b>\$ —</b>	<b>\$ (107)</b>	<b>\$ 10,217</b>
<b>December 31, 2022</b>					
	Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Cash equivalents:</b>					
Money market fund	1	\$ 7	\$ —	\$ —	\$ 7
Commercial paper	2	78,028	—	(26)	78,002
<b>Total cash equivalents</b>		<b>\$ 78,035</b>	<b>\$ —</b>	<b>\$ (26)</b>	<b>\$ 78,009</b>
<b>Short-term investments:</b>					
Commercial paper	2	36,933	—	(168)	36,765
U.S. government debt and agency securities	2	65,157	—	(784)	64,373
Corporate bonds	2	3,302	—	(62)	3,240
<b>Total short-term investments</b>		<b>\$ 105,392</b>	<b>\$ —</b>	<b>\$ (1,014)</b>	<b>\$ 104,378</b>
<b>Long-term investments:</b>					
U.S. government debt and agency securities	2	45,745	—	(916)	44,829
<b>Total long-term investments</b>		<b>\$ 45,745</b>	<b>\$ —</b>	<b>\$ (916)</b>	<b>\$ 44,829</b>

All the commercial paper, U.S. government debt, municipal bonds and agency securities, U.S. treasury bills, and corporate bonds designated as short-term investments have an effective maturity date that is equal to or less than one year from the respective balance sheet date. Those that are designated as long-term investments have an effective maturity date that is more than one year, but less than two years, from the respective balance sheet date.

As of June 30, 2023, the Company does not intend to sell any securities in unrealized loss positions, and it is not more-likely-than-not that the Company will be required to sell such securities prior to the recovery of the amortized cost basis. Based on the Company's assessment, the Company concluded all impairments as of June 30, 2023 to be due to factors other than credit loss, such as changes in interest rates. A credit loss allowance was not recognized and the unrealized losses for available-for-sale securities were recorded in other comprehensive loss.

#### 4. Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Lab equipment	\$ 661	\$ 433
Office furniture, fixtures, and computer equipment	712	692
Leasehold improvement	<u>4,322</u>	<u>4,296</u>
Property and equipment, at cost	5,695	5,421
Less: accumulated depreciation	<u>(1,848)</u>	<u>(1,368)</u>
Property and equipment, net	<u>\$ 3,847</u>	<u>\$ 4,053</u>

Depreciation expense was \$244,000 and \$480,000 for the three and six months ended June 30, 2023, respectively. Depreciation expense was \$221,000 and \$375,000 for the three and six months ended June 30, 2022, respectively.

#### 5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Research and development expenses	\$ 6,205	\$ 3,843
Employee compensation and benefits	2,661	3,415
Professional services and other	<u>1,837</u>	<u>1,346</u>
Total accrued liabilities	<u>\$ 10,703</u>	<u>\$ 8,604</u>

#### 6. Significant Agreements

##### ***Washington State University ("WSU") License Agreement***

The Company is party to an amended and restated exclusive license agreement with sublicensing terms with Washington State University ("WSU") that the Company entered into in 2015. Under this agreement, the Company has an exclusive license to make, use, sell, and offer for sale products covered by certain licensed patents, including dihexa, the chemical compound into which fosgonimeton metabolizes following administration.

To keep in good standing, the agreement requires the Company to meet certain development milestones and pay annual maintenance fees. All contractual requirements have been met as of June 30, 2023.

During the year ended December 31, 2020, the Phase 2 clinical trial milestone had been reached and a payment of \$50,000 to WSU was recorded.

The Company may also be obligated to pay the following if the related milestones are reached:

- \$300,000 – At initiation of the first Phase 3 clinical trial in the United States, European Union or Japan for the first licensed product; and
- \$600,000 – Upon receipt of marketing approval in the United States, European Union or Japan for the first licensed product.

Under the terms of the agreement, the Company will pay a royalty in the mid-single digits of net sales, with the first \$100,000 of net sales being exempt from royalty payment, and annual minimum royalty payments of \$25,000 beginning after the first commercial sale of a licensed product. As of June 30, 2023, no sales of any licensed products had occurred and the Company had not incurred a royalty obligation under this agreement.

Additionally, the agreement allows the Company to sublicense the rights conveyed by the agreement, subject to additional payments to WSU based upon the sublicense consideration received in such event. Such amounts are dependent on the terms of the underlying sublicense and range from the mid-single digits to mid-teens of any non-sales based payments received, and low twenties of net sales based sublicense royalties. As of June 30, 2023, the Company has not entered into or incurred any liability from a sublicense agreement.

## 7. Commitments and Contingencies

### Legal Proceedings

From time to time, the Company is subject to various legal proceedings or claims that arise in the ordinary course of business. The Company accrues a liability when the Company's management believes that it is both probable that a liability has been incurred and the amount of loss can be reasonably estimated. The following is a brief description of the more significant legal proceedings.

### Securities Class Actions

On June 25, 2021, plaintiffs Fan Wang and Hang Gao filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against the Company and the Company's former chief executive officer Dr. Leen Kawas, captioned *Wang v. Athira Pharma, Inc., et al.*, No. 2:21-cv-00861. Plaintiffs Wang and Gao assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5, alleging that the defendants made materially false and misleading statements and omitted material adverse facts regarding the Company's business. Specifically, the Wang plaintiffs allege that the Company failed to disclose to investors that certain research conducted by Dr. Kawas was allegedly tainted by scientific misconduct during her doctoral work at WSU, including the manipulation of data, and that as a result, the defendants' positive statements about the Company's business, operations, and prospects were materially misleading. The Wang plaintiffs seek unspecified compensatory and punitive damages, and reasonable costs and expenses, including attorneys' fees.

That same day, on June 25, 2021, plaintiff Harshdeep Jawandha filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against the Company, Dr. Kawas, the Company's then chief financial officer, certain members of the Company's board of directors at the time of the Company's initial public offering ("IPO"), as well as the IPO underwriters, captioned *Jawandha v. Athira Pharma, Inc., et al.*, No. 2:21-cv-00862. The Jawandha complaint asserts violations of Sections 11 and 15 of the Securities Act of 1933 ("Securities Act"), alleging that the Company's IPO registration statement was materially false and misleading because it omitted to state that certain of Dr. Kawas's published doctoral research papers at WSU contained allegedly improperly altered images, that the research was allegedly foundational to the Company's efforts to develop treatments for Alzheimer's disease, and that the defendants' positive statements about the Company's business, operations, and prospects were materially misleading. The Jawandha plaintiff seeks unspecified compensatory damages, and reasonable costs and expenses, including attorneys' fees.

Also on June 25, 2021, plaintiffs Timothy Slyne and Tai Slyne filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against the Company, Dr. Kawas, the Company's then chief financial officer, and the same members of the Company's board of directors and underwriters as in the Jawandha complaint, captioned *Slyne v. Athira Pharma, Inc. et al.*, No. 2:21-cv-00864. The Slyne complaint asserts violations of Sections 11 and



15 of the Securities Act, alleging that purported issues with Dr. Kawas's doctoral research at WSU should have been disclosed in the Company's IPO registration statement. The *Slyne* plaintiffs seek unspecified compensatory damages, reasonable costs and expenses, including attorneys' fees, and injunctive and other equitable relief.

On August 9, 2021, the court issued an order consolidating the three cases. On October 5, 2021, the district court issued an order appointing lead plaintiffs and approved their selection of lead and liaison counsel.

On January 7, 2022, lead plaintiffs filed a consolidated amended complaint, which asserts violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 and Sections 11, 12, and 15 of the Securities Act. The consolidated amended complaint is brought against the Company, Dr. Kawas, the Company's then chief financial officer, certain members of the Company's board of directors at the time of the Company's IPO and secondary public offering ("SPO"), and the IPO and SPO underwriters. As with the previous complaints, it is based on allegations that the IPO and SPO registration statements and/or other public statements were materially false and misleading because they omitted to state that certain of Dr. Kawas's published doctoral research papers at WSU contained allegedly improperly altered images. Lead plaintiffs seek unspecified compensatory damages, as well as equitable and injunctive relief on behalf of themselves and the purported class. On March 8, 2022, the defendants filed a motion to dismiss lead plaintiffs' consolidated amended complaint for failure to state a claim under the federal securities laws. On July 29, 2022, the court issued an order granting in part and denying in part the motion to dismiss. The order dismissed the Section 10(b) and Section 20(a) claims arising under the Exchange Act, dismissed the Section 11 claim arising under the Securities Act as to all defendants other than the Company and Dr. Kawas, dismissed the Section 12(a)(2) claim arising under the Securities Act as to the lead plaintiffs, and dismissed the Section 15 claim arising under the Securities Act against all defendants other than Dr. Kawas. The order permitted lead plaintiffs until August 19, 2022 to file a second consolidated amended complaint. Lead plaintiffs did not file a second consolidated amended complaint.

On August 12, 2022, defendant Dr. Kawas filed a motion for partial reconsideration of the court's July 29, 2022 order. On October 24, 2022, the parties filed a (1) joint status report and discovery plan and (2) stipulation and case scheduling order, wherein the parties proposed deadlines for material case events, including the completion of fact discovery, expert discovery, and dispositive motion practice. On November 2, 2022, the court entered an order setting certain case deadlines. On November 4, 2022, the Company and Dr. Kawas filed their individual answers to the consolidated amended complaint. In mid-November 2022, the parties began conducting fact discovery.

On March 10, 2023, following a mediation and the parties' agreement in principle to settle the securities class action, the court entered a stipulated order setting a deadline of April 28, 2023 for the parties to file a stipulation of settlement and for lead plaintiffs to file a motion for preliminary approval of the settlement, which the parties filed on that date. The settlement is subject to preliminary and final approval by the U.S. District Court for the Western District of Washington. On May 31, 2023, the court issued a minute order requiring the parties to file a joint status report on or before June 30, 2023 addressing several aspects of the proposed settlement, including revision of certain notices to putative class members regarding the settlement, which the parties filed on that date.

As a result of the foregoing, the Company recorded a legal settlement expense of \$10.0 million in operating expenses in the fourth quarter of 2022 and an accrued liability of \$10.0 million on the accompanying unaudited condensed consolidated balance sheets.

## Shareholder Derivative Actions

On April 14, 2022, a shareholder derivative action was filed by plaintiff Stephen Bushansky in the U.S. District Court for the Western District of Washington against certain current and former members of the Company's board of directors, captioned *Bushansky v. Kawas et al.*, No. 2:22-cv-497. Plaintiff purports to bring the action derivatively on behalf of the Company, which is a nominal defendant to the action. The derivative complaint alleges that the Company's board of directors breached its fiduciary duties by failing to prevent alleged misstatements in the Company's public filings, failing to discover altered images in certain research papers, and failing to take appropriate action. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and waste of corporate assets. The derivative complaint seeks unspecified damages, disgorgement of profits, benefits, and other compensation received by the individual defendants, restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

On May 6, 2022, a second shareholder derivative action was filed by plaintiff Thomas Houlihan in the U.S. District Court for the Western District of Washington against certain current and former directors and officers of the Company, captioned *Houlihan v. Kawas et al.*, No. 2:22-cv-620. Plaintiff purports to bring the action derivatively on behalf of the Company, which is a nominal defendant to the action. The derivative complaint alleges that certain of the Company's current and former directors and officers breached their fiduciary duties by failing to prevent alleged misstatements in the Company's public filings and failing to take appropriate action regarding altered images in certain research papers. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duties, contribution, and indemnification. The derivative complaint seeks unspecified damages, unspecified corporate governance reforms, restitution, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

On May 26, 2022, the court issued an order consolidating the cases and staying them until further order of the court. The Company believes it has adequate reserves related to this matter as of the balance sheet date.

## Government Investigations

In November 2022, the Company received a Civil Investigative Demand from the Civil Division of the Department of Justice ("the Demand"). The Demand seeks documents and information relating to our relationship with WSU, certain of our grant applications in 2016 and 2019 with the National Institutes of Health ("NIH"), and our receipt of a NIH grant in 2020. The Company is cooperating with the Department of Justice with respect to the Demand.

In February 2023, the Securities and Exchange Commission ("SEC"), sent the Company a subpoena seeking documents and information relating to, among other things, the Company's former chief executive officer's alterations of images in certain research papers. The Company is cooperating with the SEC with respect to the subpoena.

The Company cannot predict the outcome of these lawsuits or government investigations. Failure by the Company to obtain a favorable resolution of these actions could have a material adverse effect on our business, results of operations and financial condition.

## Operating Leases

The Company has operating leases for laboratory and office facilities in Bothell, Washington that expire in August 2027. The initial terms of the leases range from 6.3 to 7 years and the Company has options to extend the leases for an additional five years that it is not reasonably certain to exercise. As of June 30, 2023, the Company was not party to any finance leases.

The following table reconciles the Company's undiscounted operating lease cash flows to its operating lease liability (in thousands):

	June 30, 2023
Remaining 2023	236
2024	480
2025	494
2026	509
Thereafter	346
Total undiscounted lease payments	2,065
Present value adjustment for minimum lease commitments	(311)
Net lease liability	<u>\$ 1,754</u>

The weighted average remaining lease term and the weighted average discount rate used to determine the operating lease liability were as follows:

	June 30, 2023
Weighted average remaining lease term (years)	4.2
Weighted average discount rate	8.1%

Operating lease expense and variable lease expense consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease expense	\$ 88,000	\$ 88,000	\$ 176,000	\$ 177,000
Variable lease expense	\$ 42,000	\$ 41,000	\$ 102,000	\$ 85,000

## 8. Common Stock

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and if declared by the Company's board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No cash dividends have been declared by the board of directors from inception.

The Company has reserved the following shares of common stock for future issuance, on an as-converted basis, as follows:

	June 30, 2023	December 31, 2022
Shares issuable upon the exercise of outstanding common stock options and the vesting of outstanding common restricted stock units granted	7,676,606	4,269,861
Shares available for future grant under the 2020 Equity Incentive Plan	2,659,883	4,253,854
Shares available for future grant under the Employee Stock Purchase Plan	1,199,313	916,640
Total	<u>11,535,802</u>	<u>9,440,355</u>

The Company's 2020 Equity Incentive Plan ("2020 Plan") provides for annual increases in the number of shares that may be issued under the 2020 Plan on January 1, 2021 and each subsequent January 1, thereafter, by a number of shares

equal to the least of (1) 3,230,000 shares, (2) 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or 3) an amount determined by the Company's board of directors.

The Company's 2020 Employee Stock Purchase Plan ("ESPP") provides for annual increases in the number of shares that may be issued under the ESPP on January 1, 2021 and each subsequent January 1, thereafter, by a number of shares equal to the least of (1) 646,000 shares, (2) 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, and (3) an amount determined by the Company's board of directors.

Effective January 1, 2023, the Company's 2020 Plan and ESPP reserves increased by 1,893,869 shares and 378,774 shares, respectively.

## 9. Stock-based Compensation

Stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 1,287	\$ 971	\$ 2,284	\$ 1,756
General and administrative	1,832	2,124	3,617	4,070
Total stock-based compensation expense	\$ 3,119	\$ 3,095	\$ 5,901	\$ 5,826

### Valuation Assumptions

The fair value of stock options was determined using the Black-Scholes option-pricing model and the assumptions below. Each of these inputs is subjective and generally required significant judgment.

- *Fair Value of Common Stock*—The fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant, or other relevant determination date, as reported on The Nasdaq Global Select Market.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.
- *Expected Volatility*—Because the Company was previously privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life sciences companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term) as the Company has limited history of relevant stock option exercise activity.
- *Expected Dividend Yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends going forward. Therefore, it used an expected dividend yield of zero.

The fair value of each stock option was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2023	2022
Risk-free interest rate	3.52%	2.00%
Expected volatility	99.09%	92.78%
Expected term (in years)	5.83	6.01
Expected dividend yield	—	—

The grant date fair value of restricted stock units is based upon the fair market value of the Company's common stock based on its closing price as reported on the date of grant on the Nasdaq Global Select Market.

The fair value of options granted during the six months ended June 30, 2023 and 2022 was \$9.5 million and \$15.7 million, respectively. The fair value of restricted stock units granted during the six months ended June 30, 2023 and 2022 was \$0.4 million and \$0.1 million, respectively.

### **Stock Option and Restricted Stock Unit Activity**

Changes in shares available for grant under the 2020 Plan during the six months ended June 30, 2023 were as follows:

	<b>Shares Available for Grant</b>
Shares available for grant at December 31, 2022	4,253,854
2020 Plan reserve increase on January 1, 2023	1,893,869
Options and restricted stock units granted	(3,733,183)
Options and restricted stock units forfeited, cancelled, or expired	245,343
Shares available for grant at June 30, 2023	<u>2,659,883</u>

A summary of stock option activity under the 2020 Plan for the six months ended June 30, 2023 was as follows:

	<b>Shares</b>	<b>Weighted- Average Exercise price per Share</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Balance at December 31, 2022	4,033,522	\$ 11.75	8.40	\$ 827
Granted	3,597,183	3.35		
Exercised	(81,095)	1.35		
Forfeited/expired	(223,176)	6.52		
Balance at June 30, 2023	<u>7,326,434</u>	\$ 7.90	8.74	\$ 705
Expected to vest	<u>5,213,485</u>	\$ 6.61	9.13	\$ 181
Options exercisable	<u>2,112,949</u>	\$ 11.11	7.78	\$ 524

The total fair value of options granted that vested during the six months ended June 30, 2023 and 2022 was \$6.1 million and \$4.3 million, respectively.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock underlying all options that were in-the-money at June 30, 2023. The aggregate intrinsic value of options exercised was \$0.2 million and \$3.0 million during the six months ended June 30, 2023 and 2022, respectively, determined as of the date of option exercise. As of June 30, 2023, there was \$22.3 million of total unrecognized compensation cost related to unvested stock options. The Company expects to recognize this cost over a remaining weighted-average period of 2.4 years. The Company utilizes newly issued shares to satisfy option exercises.

Stock options outstanding and exercisable under the 2020 Plan consisted of the following at June 30, 2023:

<u>Exercise Price (\$)</u>	<u>Shares Outstanding</u>	<u>Shares Exercisable</u>
0.16 to 4.22	4,001,495	587,653
8.93 to 19.94	2,955,654	1,328,944
20.55 to 29.41	369,285	196,352
Total	<u>7,326,434</u>	<u>2,112,949</u>

A summary of restricted stock unit ("RSU"), activity for the six months ended June 30, 2023 is as follows:

	<u>Share Equivalent</u>	<u>Weighted- Average Grant Date Fair Value</u>
Non-vested at December 31, 2022	236,339	\$ 15.16
Granted	136,000	3.30
Cancelled	(22,167)	7.46
Vested	—	—
Non-vested at June 30, 2023	<u>350,172</u>	<u>\$ 11.04</u>

#### 10. Net Loss Per Share Attributable to Common Stockholders

The following outstanding shares of potentially dilutive securities were excluded from the computation of the diluted net loss per share attributable to common stockholders for the periods presented because their effect would have been anti-dilutive:

	<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Stock options to purchase common stock	7,326,434	3,839,003
Non-vested Restricted Stock Units	350,172	239,839
Employee stock purchase plan	3,473	4,836
Total	<u>7,680,079</u>	<u>4,083,678</u>

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

*You should read the following Management's Discussion and Analysis of Financial Condition and Results of Operations in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this report and with our audited financial statements and related notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 23, 2023.*

### Special Note Regarding Forward-Looking Statements

This report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. This section should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash, cash equivalents and investments to fund our future operating expenses and capital expenditure requirements;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our product candidates;
- the ability of our nonclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates;
- the success, cost and timing of our development activities, nonclinical studies and clinical trials;
- the rate and degree of market acceptance of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the potential learnings from our ACT-AD trial and LIFT-AD independent unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans;
- the potential of LIFT-AD to show clinical benefits of fosgonimeton following the September 2022 and May 2023 protocol amendments;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our product candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- our ability to attract and retain key managerial, scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the pricing and reimbursement of our product candidates, if approved;

- our reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates for nonclinical studies and clinical trials;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety and efficacy of our product candidates;
- regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our product candidates in the United States and other jurisdictions, and any related restrictions, limitations or warnings in the label of any approved product candidate;
- future agreements with third parties in connection with the commercialization of our product candidates;
- our plans, capacity and capability relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue regulatory approval;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the outcome of legal proceedings which have been or may in the future be instituted against us and certain of our directors and officers, including the legal proceedings discussed in Part II, Item 1 — "Legal Proceedings," and elsewhere in this report;
- the actions by activist stockholders, which have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the potential benefits of any strategic collaboration agreements we may enter into; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in "Part II, Item 1A—Risk Factors," and elsewhere in this report. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

This report includes our trademarks and registered trademarks, including Athira, Athira Pharma, the Athira logo, and other trademarks or service marks of Athira. Each other trademark, trade name or service mark appearing in this report belongs to its holder.

In this report, "we," "our," "us," "Athira," and "the Company" refer to Athira Pharma, Inc. and our wholly-owned subsidiary.

## Overview

We are a late clinical-stage biopharmaceutical company focused on developing small molecules engineered to restore neuronal health and slow neurodegeneration. Our approach is designed to target the hepatocyte growth factor, or HGF,



and its receptor, MET neurotrophic system, or HGF/MET system, that is critical to normal brain function and may play a key role in maintaining the health and functioning of neuronal networks. We believe that by acting on the HGF/MET system and its multiple downstream signaling pathways, we may be able to enhance the body's natural ability to protect and repair neuronal networks by reducing inflammation, promoting regeneration and reducing disease-specific protein pathologies, thereby positively impacting the course of disease. We aim to achieve these goals by advancing our pipeline of novel small molecule compounds which are designed to and have exhibited properties in enhancing the HGF/MET system in either the central nervous system, or CNS, by crossing the blood brain barrier, or BBB, or the peripheral nervous system, or PNS.

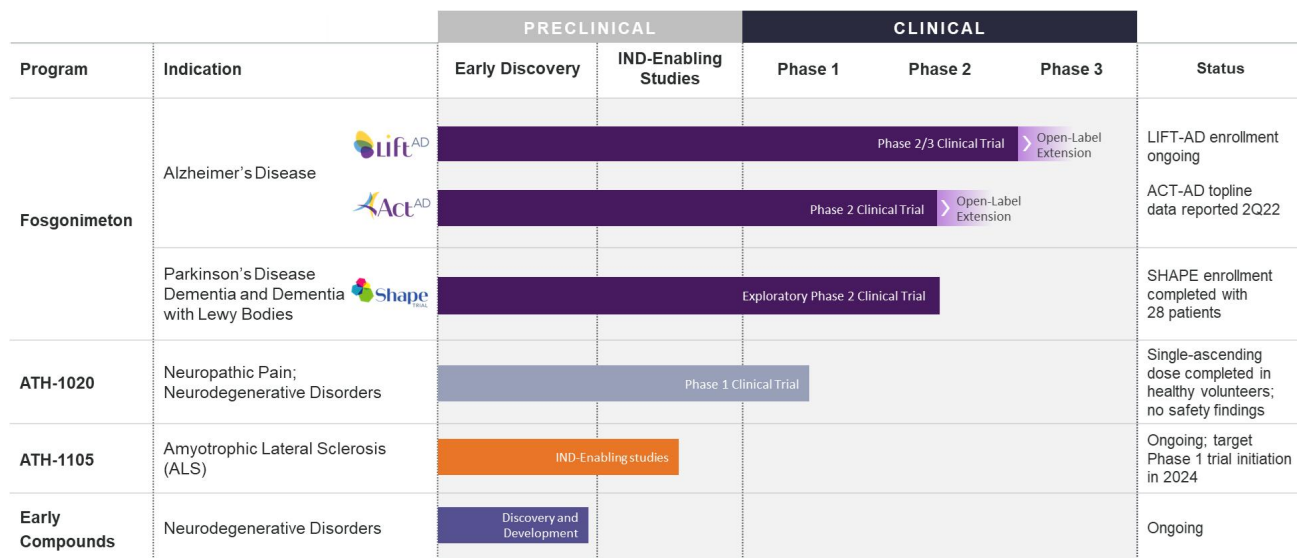
Our lead candidate, fosgonimeton, is a subcutaneously administered, small molecule positive modulator of the HGF/MET system for CNS disorders. The effects of fosgonimeton in its primary target indication, AD, are currently being evaluated in multiple clinical trials:

- ACT-AD\*, was a randomized, double-blind, placebo-controlled, parallel-group 26-week exploratory Phase 2 clinical trial in mild-to-moderate AD, with event-related potential, or ERP, P300 latency as the primary endpoint. Initiated in November 2020, the trial was designed to better characterize the overall effects of fosgonimeton on working memory processing speed and cognitive measures and inform the Phase 2/3 LIFT-AD trial. Topline results for this exploratory Phase 2 ACT-AD trial were announced in June 2022, and the primary and all secondary endpoints were not met by protocol analysis. However, a post hoc analysis of results from ACT-AD in a pre-specified subgroup suggested positive effects on measures of cognition, function and neurodegeneration in participants taking fosgonimeton alone without background acetylcholinesterase inhibitors, or AChEIs. Additionally, data from post hoc analysis of plasma biomarkers from participants on fosgonimeton without background AChEIs showed descriptive improvements (non-statistically significant) in markers of neuroinflammation and AD-specific protein pathologies when compared to placebo. Fosgonimeton was generally well tolerated in the ACT-AD study, with a favorable safety profile, and there were no treatment related serious adverse events or deaths observed.
- LIFT-AD, a randomized, double-blind, placebo-controlled, parallel-group 26-week Phase 2/3 clinical trial with fosgonimeton for the treatment of mild-to-moderate AD. In September 2020, we began site initiation and patient screening for LIFT-AD. The primary endpoint for the Phase 2/3 LIFT-AD trial will be measured by the Global Statistical Test, or GST, which is a composite score that combines the scores from cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale, or ADAS-Cog11), and function (Alzheimer's Disease Cooperative Study-Activities of Daily Living, or ADCS-ADL23). Guided by the results from the completed exploratory ACT-AD Phase 2 trial, in September 2022, we proactively amended LIFT-AD to focus on participants not on background AChEIs. In October 2022, we announced that following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD trial. The committee also determined that, with the additional enrollment of fewer than 150 participants for a total enrollment of less than 300 participants without background AChEIs, the amended trial will be well powered for the primary endpoint given the preliminary effect size observed. In May 2023, we further amended LIFT-AD to focus on 40 mg dosing, which we have selected for further development and potential dose for regulatory approval of fosgonimeton in this indication. This selection was based on a review of the totality of the preclinical and clinical data, biomarker results, observations from the open label extension study and in consultation with independent regulatory and biostatistical consultants based on patients treated with 40 mg fosgonimeton without concomitant AChEIs. The LIFT-AD study will now focus enrollment and the primary analysis on 40 mg dosing and will discontinue enrollment of the 70 mg arm going forward. We expect to report topline LIFT-AD results in the second half of 2024. In July 2023, we completed an end of Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, to gain alignment on our plans for the continued clinical development of fosgonimeton as a treatment for mild-to-moderate AD. During this meeting we provided an update and discussed with the FDA the ongoing LIFT-AD trial, including use of the 40 mg dose, concomitant AChEIs use, biomarker analyses including NFL, and the statistical analysis plan. The FDA noted the importance of showing effects on both cognition (ADAS-Cog11) and function (ADCS-ADL23) in the trial population. The FDA is open to ongoing dialogue with us regarding the LIFT-AD trial once completed as well as other aspects of our program to develop fosgonimeton as a potential treatment for mild-to-moderate AD.
- In July 2021, we announced that we are enrolling participants into a 26-week open-label extension trial\* for our LIFT-AD and ACT-AD clinical trials, allowing us to collect up to a total of one year of safety data with fosgonimeton. In May 2022, we announced that we extended the 26-week open-label extension trial for our LIFT-AD and ACT-AD clinical trials for an additional 12 months, enabling eligible participants who have completed either trial and elect to participate in the ongoing open label extension to receive up to 18 months of open-label treatment with fosgonimeton. In May 2023, we amended the open-label extension trial to further extend the trial by an additional 12 months. Following this additional extension, eligible participants who have completed the

LIFT-AD or ACT-AD trials and elect to participate in the ongoing open-label extension may now receive up to 30 months of open-label treatment, which allows us to collect up to 36 months total of long-term exposure data.

*\*The ACT-AD trial and the related open-label extension for ACT-AD participants was and are supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.*

The following figure illustrates the current development stage of our ATH compounds and early discovery and development programs. Our pipeline consists of both BBB permeable and peripherally restricted drug candidates for CNS, PNS and other indications. In addition, we are exploring the use of our ATH compounds in additional indications in the CNS and PNS as we aim to improve neuronal health in multiple neurodegenerative diseases. Our drug discovery efforts are focused on designing and testing new early compounds to enhance the HGF/MET system for a variety of clinical applications.



We constantly strive to grow and optimize our portfolio through in-house discovery and plan on additional external business development activities enabled by our innovative internal research and development capabilities.

We were incorporated in March 2011 and since our inception, we have devoted substantially all of our resources to our research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. We do not have any products approved for commercial sale, and we have not generated any revenues related to our products since inception. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of one or more of our product candidates which we expect will take a number of years.

We are focused on the development of small molecule therapeutics which enables us to use well-established and widely available manufacturing processes and infrastructure, formulation compositions and drug administration technologies or devices. We do not currently operate our own facilities for manufacturing, storing, or distributing our product candidates. We utilize third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials during the development of our product candidates. We believe the synthesis of fosgonimeton is reliable and reproducible and the synthetic methods can be further optimized to enable large-scale production that continues to avoid use of toxic materials or specialized equipment or handling during the manufacturing process. We plan to continue to optimize the manufacturing process to support future large-scale and commercial supply. Our goal is to identify and develop small molecule product candidates that are cost-effective to manufacture and easily transferable to third party CMOs. We expect to use similar contract resources for commercialization of our products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities.

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

To date, we have funded our operations primarily through proceeds from the sale of equity securities, including proceeds from the sale and issuance of common stock in our IPO and in a subsequent follow-on public offering, the sale and issuance of convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From inception to June 30, 2023, we have raised aggregate net cash proceeds of approximately \$407.4 million primarily from the issuance of our common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes. We have incurred significant operating losses to date. Our net losses were \$57.4 million and \$45.3 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$249.0 million and cash, cash equivalents and investments of \$196.3 million.

We expect to continue to incur increasing operating losses for the foreseeable future as we:

- continue to advance fosgonimeton and our other product candidates through preclinical studies and clinical trials, and further extend the open label extension of the ACT-AD and LIFT-AD trials;
- expand our pipeline of product candidates;
- continue to grow our discovery organization and invest in the ATH platform;
- ramp up manufacturing activities;
- attract, hire and retain additional personnel;
- obtain, maintain, expand and protect our intellectual property portfolio;
- operate as a public company;
- expand our laboratory and office facilities;
- implement and maintain operational, financial and management information systems;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval; and
- incur legal expenses associated with ongoing litigation, as further described in “Part II, Item 1—Legal Proceedings,” and elsewhere in this report.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to support our continuing operations and further the development of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaboration, licensing or similar arrangements, for the foreseeable future. Adequate funding may not be available when needed or on terms acceptable to us, or at all. If we are unable to raise additional capital as needed, we may have to significantly delay, scale back or discontinue development of our product candidates. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. Based upon our current operating plan, we estimate that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report.

## ***Our Collaboration and Grant Agreements***

We are party to certain collaboration and grant agreements, as described in the section titled “Part I, Item 1 – Business—Our Collaboration and Grant Agreements” in our Annual Report on Form 10-K filed with the SEC on March 23, 2023.

## **Components of Operating Results**

### ***Operating Expenses***

#### *Research and Development*

Research and development expenses consist primarily of direct and indirect costs incurred for our research activities, including development of the ATH platform, our drug discovery efforts and the development of our product candidates. Direct costs include laboratory materials and supplies, contracted research and manufacturing, clinical trial costs, consulting fees, and other expenses incurred to sustain our research and development program. Indirect costs include personnel-related expenses, consisting of employee salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities, and facilities and other expenses consisting of direct and allocated expenses for rent and depreciation, and lab consumables.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

As of the date of this report, we cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. We expect that our research and development expenses will increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we conduct larger clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, as we expand our product pipeline, as we maintain, expand, protect and enforce our intellectual property portfolio, and as we incur expenses associated with hiring additional personnel to support our research and development efforts. In particular, we have seen, and expect to continue to see, our research and development expenses increase as we conduct our clinical trials for fosgonimeton, including open-label extensions for those trials. Additionally, we may experience an overall increase in research and development expenses as a result of inflation.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Our research and development expenses may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our product candidates;
- the progress and results of our research and development activities;
- per subject trial costs;
- the number of trials required for regulatory approval, in particular with respect to fosgonimeton for the treatment of mild-to-moderate AD (including any potential confirmatory or Phase 3 registrational trials);
- the further extension of the open label extension of the ACT-AD and LIFT-AD trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;

- the length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights;
- the impact of health epidemics, including COVID-19, on timelines and clinical operations, which may lead to increased costs; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

#### *General and Administrative*

General and administrative expenses consist primarily of personnel-related costs, consisting of employee salaries, related benefits, and stock-based compensation expense for our employees in the executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include third-party costs such as legal costs, insurance costs, accounting, auditing and tax related fees, business development fees, consulting fees and facilities and other expenses not otherwise included as research and development expenses. We expense general and administrative costs as incurred.

We expect that our general and administrative expenses will increase for the foreseeable future as we increase our headcount to support our continued research activities and development of our programs. We also anticipate that we will continue to incur expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services. We expect continued legal expenses related to our ongoing legal proceedings and proposed settlement to resolve such claims. We also expect to continue to increase the size of our administrative function to support the growth of our business. Additionally, we may experience an overall increase in general and administrative expenses as a result of inflation.

#### **Grant Income**

Grant income consists of income related to the NIH grant and is recognized as qualifying expenses under the grant agreement are incurred. As of June 30, 2023, we had recognized aggregate grant income of \$15.2 million in connection with an NIH grant, equal to the total grant amount approved. We will not recognize additional grant income in connection with the NIH grant in the future.

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

Other income, net consists primarily of interest earned on our cash, cash equivalents and investments and the amortization of premiums and accretion of discounts on our available-for-sale securities. Absent further fundraising, we expect interest earned on our cash, cash equivalents and investments to decrease over the long term as we continue to expend our cash balances to fund our ongoing operations.

## Results of Operations

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

The following table summarizes our results of operations for the periods presented:

	Three Months Ended June 30,			
	2023	2022	Dollar Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 21,615	\$ 14,803	\$ 6,812	46%
General and administrative	10,025	8,766	1,259	14
Total operating expenses	31,640	23,569	8,071	34
Loss from operations	(31,640)	(23,569)	(8,071)	34
Grant income	—	(1,259)	1,259	(100)
Other income, net	2,043	493	1,550	314
Net loss	\$ (29,597)	\$ (24,335)	\$ (5,262)	22

### Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Three Months Ended June 30,			
	2023	2022	Dollar Change	% Change
	(in thousands)			
Direct costs:				
Fosgonimeton (ATH-1017)	\$ 14,619	\$ 9,406	\$ 5,213	55%
ATH-1020	193	647	(454)	(70)
Preclinical programs and other direct costs	1,607	1,264	343	27
Total direct costs	16,419	11,317	5,102	45
Indirect costs:				
Personnel-related costs, including stock-based compensation	4,691	3,114	1,577	51
Facilities and other costs	505	372	133	36
Total research and development expenses	\$ 21,615	\$ 14,803	\$ 6,812	46

Research and development expenses increased by \$6.8 million, from \$14.8 million for the three months ended June 30, 2022 to \$21.6 million for the three months ended June 30, 2023. The increase was driven primarily by an increase in expenses for fosgonimeton of \$5.2 million related to continued patient enrollment and clinical site visit activity for our Phase 2/3 clinical trial and the corresponding open-label extension for our Phase 2 and Phase 2/3 clinical trials, as well as higher costs relating to manufacturing process development and increases in manufacturing batch size capabilities, an increase in personnel-related costs of \$1.6 million due to an increase in headcount and stock-based compensation expense in connection with current period equity grants to new hires and existing employees, and an increase in preclinical research and development expenses of \$0.3 million, partially offset by a decrease in ATH-1020 program expenses of \$0.5 million.

### General and Administrative Expenses

General and administrative expenses increased by \$1.3 million, from \$8.8 million for the three months ended June 30, 2022 to \$10.0 million for the three months ended June 30, 2023. The increase was primarily due to an increase in consulting and professional services expenses of \$0.7 million, an increase in business development expenses of \$0.6 million, and an increase in personnel-related costs of \$0.2 million due to an increase in headcount, partially offset by a decrease in other general corporate expenses of \$0.2 million and a decrease in legal costs of \$0.1 million.

## Grant Income

During the three months ended June 30, 2022, we reversed \$1.3 million of grant income previously recorded in the three months ended March 31, 2022 as we were required to obtain additional approval from the NIH to carryover unused budgets to the second and final years of the grant. These approvals were subsequently received during the third quarter of 2022. As of March 31, 2023, we had recognized aggregate grant income of \$15.2 million in connection with the NIH grant, equal to the total grant amount approved. No grant income was recognized during the three months ended June 30, 2023.

## Other Income, Net

Other income, net, increased by \$1.6 million, from \$0.5 million for the three months ended June 30, 2022 to \$2.0 million for the three months ended June 30, 2023 due to higher income from accretion of discounts on debt securities purchased below par value and held to maturity, in addition to higher interest income earned on our available-for-sale securities resulting from rising interest rates on debt securities.

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

The following table summarizes our results of operations for the periods presented:

	Six Months Ended June 30,			
	2023	2022	Dollar Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 42,908	\$ 29,263	\$ 13,645	47%
General and administrative	18,502	17,693	809	5
Total operating expenses	61,410	46,956	14,454	31
Loss from operations	(61,410)	(46,956)	(14,454)	31
Grant income	157	975	(818)	(84)
Other income, net	3,836	666	3,170	476
Net loss	\$ (57,417)	\$ (45,315)	\$ (12,102)	27

## Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Six Months Ended June 30,			
	2023	2022	Dollar Change	% Change
	(in thousands)			
Direct costs:				
Fosgonimeton (ATH-1017)	\$ 28,890	\$ 19,592	\$ 9,298	47%
ATH-1020	383	1,019	(636)	(62)
Preclinical programs and other direct costs	3,249	2,124	1,125	53
Total direct costs	32,522	22,735	9,787	43
Indirect costs:				
Personnel-related costs, including stock-based compensation	9,337	5,800	3,537	61
Facilities and other costs	1,049	728	321	44
Total research and development expenses	\$ 42,908	\$ 29,263	\$ 13,645	47

Research and development expenses increased by \$13.6 million, from \$29.3 million for the six months ended June 30, 2022 to \$42.9 million for the six months ended June 30, 2023. The increase was driven primarily by an increase in expenses for fosgonimeton of \$9.3 million related to continued patient enrollment and clinical site visit activity for our Phase 2/3 clinical trial and the corresponding open-label extension for our Phase 2 and Phase 2/3 clinical trials, as well as higher costs relating to manufacturing process development and increases in manufacturing batch size capabilities, an increase in personnel-related costs of \$3.5 million due to an increase in headcount and stock-based compensation expense in connection with current period equity grants to new hires and existing employees, an increase in preclinical research and development

expenses of \$1.1 million, and an increase in facilities and other indirect costs of \$0.3 million, partially offset by a decrease in ATH-1020 program expenses of \$0.6 million.

### **General and Administrative Expenses**

General and administrative expenses increased by \$0.8 million, from \$17.7 million for the six months ended June 30, 2022 to \$18.5 million for the six months ended June 30, 2023. The increase was primarily due to a increase in business development expenses of \$0.7 million, an increase in consulting and professional services expenses of \$0.7 million, an increase in personnel-related expenses of \$0.5 million due to an increase in headcount, partially offset by a decrease in legal costs of \$0.8 million and a decrease in general corporate expenses of \$0.3 million.

### **Grant Income**

Grant income decreased by \$0.8 million, from \$1.0 million for the six months ended June 30, 2022 to \$0.2 million for the six months ended June 30, 2023. Grant income recognized during the six months ended June 30, 2023 of \$0.2 million represented the remaining balance of the total \$15.2 million approved grant amount available at the beginning of the year. All of which grant income was recognized during the three months ended March 31, 2023.

### **Other Income, Net**

Other income, net, increased by \$3.2 million, from \$0.7 million for the six months ended June 30, 2022 to \$3.8 million for the six months ended June 30, 2023 due to higher income from accretion of discounts on debt securities purchased below par value and held to maturity, in addition to higher interest income earned on our available-for-sale securities resulting from rising interest rates on debt securities.

### **Liquidity and Capital Resources**

#### **Sources of Liquidity**

Since our inception, we have funded our operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From our inception through June 30, 2023, we have raised aggregate net cash proceeds of \$407.4 million primarily from the issuance of our common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes.

As of June 30, 2023, we had \$196.3 million in cash, cash equivalents and investments and have not generated positive cash flows from operations. Since our inception, we have devoted substantially all of our resources to our research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

#### **Material Cash and Future Funding Requirements**

Our material cash requirements include our operating leases for laboratory and office facilities. As of June 30, 2023, we had lease payment obligations of \$2.1 million, with \$0.5 million payable within 12 months. For additional information regarding our lease commitments, see Note 7 to our unaudited condensed consolidated financial statements included elsewhere in this report. We are contingently committed to \$0.9 million of potential future milestone payments, in addition to sales-based payments and royalties, under our license agreement with WSU. Payments generally are due and payable only upon achievement of certain developmental, regulatory, and sales milestones for which the specific timing cannot be predicted. Refer to Note 6 to our unaudited condensed consolidated financial statements for additional information regarding the WSU license agreement. Additionally, we have purchase obligations and open purchase orders that support normal operations and are primarily due in the next 12 months. These purchase obligations and open purchase orders are generally cancellable in full or in part through the contractual provisions. We also anticipate that our research and development expenses and our general and administrative expenses will increase over at least the near-term as we advance our clinical development and our product candidates through clinical trials, increase our headcount to support our operations, and incur legal and other professional expenses related to our ongoing legal proceedings. We cannot predict with certainty the amount and timing of these increased expenses.



Based upon our current operating plan, we estimate that our \$196.3 million of cash, cash equivalents and investments at June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report. We will need to raise substantial additional capital to fund the development of our product candidates. Until such time as we can generate significant revenue from product sales, we expect to finance our operations through the sale of equity securities, debt financings, or other capital, which could include income from collaboration, licensing or similar arrangements with third parties, or receiving research contributions, or grants. For example, in January 2023, we entered into a sales agreement with Cantor Fitzgerald and BTIG to sell shares of our common stock having aggregate sales proceeds of up to \$75.0 million, from time to time, through an at-the-market, or ATM, equity offering program under which Cantor Fitzgerald and BTIG are acting as sales agents. As of the date of this report, we have not sold any securities pursuant to this ATM offering. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us or may reduce the value of our common stock. Adequate funding may not be available when needed or on terms acceptable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flows from operating activities.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the number of trials required for regulatory approval, in particular with respect to fosgonimeton for the treatment of mild-to-moderate AD;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, licensing or other similar arrangements, and the financial terms of any such arrangements, including the timing and amount of any future milestone, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs related to ongoing legal proceedings;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- the costs associated with expanding our laboratory and office facilities; and

- the extent to which we acquire or in-license other companies' product candidates and technologies or engage in other strategic transactions.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plan may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plan.

### **Cash Flows**

The following table summarizes our cash flows for the periods indicated:

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(in thousands)</b>	
<b>Net cash (used in) provided by:</b>		
Operating activities	\$ (50,476)	\$ (35,162)
Investing activities	68,008	19,385
Financing activities	341	507
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>\$ 17,873</b>	<b>\$ (15,270)</b>

### **Operating Activities**

During the six months ended June 30, 2023, net cash used in operating activities was \$50.5 million. This consisted primarily of a net loss of \$57.4 million, partially offset by non-cash charges of \$5.7 million and a decrease in our net operating assets of \$1.2 million. The non-cash charges primarily consisted of stock-based compensation expense, amortization of premiums and accretion of discounts on available-for-sale securities, and depreciation expense. The decrease in our net operating assets was primarily due to a decrease in unbilled grant receivable and an increase in accrued expenses, partially offset by a decrease in accounts payable and an increase in prepaid expenses and other current assets.

During the six months ended June 30, 2022, net cash used in operating activities was \$35.2 million. This consisted primarily of a net loss of \$45.3 million, partially offset by non-cash charges of \$6.4 million and a decrease in our net operating assets of \$3.7 million. The non-cash charges primarily consisted of stock-based compensation expense, depreciation expense, and amortization of premiums and accretion of discounts on available-for-sale securities. The decrease in our net operating assets was primarily due to a decrease in unbilled grant receivable, a decrease in prepaid expenses and other current assets, and an increase in accounts payable and accrued expenses.

### **Investing Activities**

During the six months ended June 30, 2023, net cash provided by investing was \$68.0 million. This consisted of maturities of available-for-sale securities of \$93.2 million, partially offset by purchases of available-for-sale securities of \$24.9 million and property and equipment of \$0.3 million.

During the six months ended June 30, 2022, net cash provided by investing was \$19.4 million. This consisted of maturities of available-for-sale securities of \$72.0 million, partially offset by purchases of available-for-sale securities of \$51.7 million and property and equipment of \$0.9 million.

### **Financing Activities**

During the six months ended June 30, 2023, net cash provided by financing activities was \$0.3 million, consisting of proceeds received from exercises of stock options and the issuance of common stock under our employee stock purchase plan.

During the six months ended June 30, 2022, net cash provided by financing activities was \$0.5 million, consisting of proceeds received from exercises of stock options and the issuance of common stock under our employee stock purchase plan.

## Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience 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. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies and significant judgments and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

During the six months ended June 30, 2023, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgments and Use of Estimates” in our Annual Report on Form 10-K filed with the SEC on March 23, 2023 and Note 2 to our unaudited condensed consolidated financial statements included in “Part I, Item 1—Financial Statements (Unaudited)” of this report. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- research and development costs;
- stock-based compensation;
- income taxes;
- grant income.

## Recent Accounting Pronouncements

See Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this report for additional information.

## Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company and (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least \$1.235 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year in which the fifth anniversary of our initial public offering occurred.

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

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305 of Regulation S-K.

### **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, or 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 Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required 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 disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

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 at the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

#### ***Changes in Internal Control Over Financial Reporting***

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings.**

From time to time, we are subject to various legal proceedings or claims that arise in the ordinary course of business. The following is a brief description of the more significant legal proceedings in which we are involved.

**Securities Class Actions**

On June 25, 2021, plaintiffs Fan Wang and Hang Gao filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against us and our former chief executive officer, Dr. Leen Kawas, captioned *Wang v. Athira Pharma, Inc., et al.*, No. 2:21-cv-00861. Plaintiffs Wang and Gao assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, or Exchange Act, and SEC Rule 10b-5, alleging that the defendants made materially false and misleading statements and omitted material adverse facts regarding our business. Specifically, the *Wang* plaintiffs allege that we failed to disclose to investors that certain research conducted by Dr. Kawas was allegedly tainted by scientific misconduct during her doctoral work at WSU including the manipulation of data, and that as a result, the defendants' positive statements about our business, operations, and prospects were materially misleading. The *Wang* plaintiffs seek unspecified compensatory and punitive damages, and reasonable costs and expenses, including attorneys' fees.

That same day, on June 25, 2021, plaintiff Harshdeep Jawandha filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against us, Dr. Kawas, our then chief financial officer, certain members of our board of directors at the time of our IPO, as well as the IPO underwriters, captioned *Jawandha v. Athira Pharma, Inc., et al.*, No. 2:21-cv-00862. The *Jawandha* complaint asserts violations of Sections 11 and 15 of the Securities Act of 1933, or Securities Act, alleging that that our IPO registration statement was materially false and misleading because it omitted to state that certain of Dr. Kawas's published doctoral research papers at WSU contained allegedly improperly altered images, that the research was allegedly foundational to Athira's efforts to develop treatments for Alzheimer's, that, as a result, and that the defendants' positive statements about our business, operations, and prospects were materially misleading. The *Jawandha* plaintiff seeks unspecified compensatory damages, and reasonable costs and expenses, including attorneys' fees.

Also on June 25, 2021, plaintiffs Timothy Slyne and Tai Slyne filed a putative securities class action lawsuit in the U.S. District Court for the Western District of Washington against us, Dr. Kawas, our then chief financial officer, and the same members of our board of directors and underwriters as in the *Jawandha* complaint, captioned *Slyne v. Athira Pharma, Inc. et al.*, No. 2:21-cv-00864. The *Slyne* complaint asserts violations of Sections 11 and 15 of the Securities Act, alleging that purported issues with Dr. Kawas's doctoral research at WSU should have been disclosed in our IPO registration statement. The *Slyne* plaintiffs seek unspecified compensatory damages, reasonable costs and expenses, including attorneys' fees, and injunctive and other equitable relief.

On August 9, 2021, the court issued an order consolidating the three cases. On October 5, 2021, the district court issued an order appointing lead plaintiffs and approved their selection of lead and liaison counsel.

On January 7, 2022, lead plaintiffs filed a consolidated amended complaint, which asserts violations of Sections 10(b) and 20(a) of the Securities Exchange Act and SEC Rule 10b-5 and Sections 11, 12, and 15 of the Securities Act. The consolidated amended complaint is brought against us, Dr. Kawas, our then chief financial officer, certain members of our board of directors at the time of our IPO and secondary public offering, or SPO, and the IPO and SPO underwriters. As with the previous complaints, it is based on allegations that the IPO and SPO registration statements and/or other public statements were materially false and misleading because they omitted to state that certain of Dr. Kawas's published doctoral research papers at WSU contained allegedly improperly altered images. Lead plaintiffs seek unspecified compensatory damages, as well as equitable and injunctive relief on behalf of themselves and the purported class. On March 8, 2022, the defendants filed a motion to dismiss lead plaintiffs' consolidated amended complaint for failure to state a claim under the federal securities laws. On July 29, 2022, the court issued an order granting in part and denying in part the motion to dismiss. The order dismissed the Section 10(b) and Section 20(a) claims arising under the Exchange Act, dismissed the Section 11 claim arising under the Securities Act as to all defendants other than the Company and Dr. Kawas, dismissed the Section 12(a)(2) claim arising under the Securities Act as to the lead plaintiffs, and dismissed the Section 15 claim arising under the Securities Act against all defendants other than Dr. Kawas. The order permitted lead plaintiffs until August 19, 2022 to file a second consolidated amended complaint. Lead plaintiffs did not file a second consolidated amended complaint.

On August 12, 2022, defendant Dr. Kawas filed a motion for partial reconsideration of the court's July 29, 2022 order. On October 4, 2022, the court denied the motion. On October 24, 2022, the parties filed a (1) joint status report and discovery plan and (2) stipulation and case scheduling order, wherein the parties proposed deadlines for material case events, including the completion of fact discovery, expert discovery, and dispositive motion practice. On November 2, 2022, the court entered an order setting certain case deadlines. On November 4, 2022, we and Dr. Kawas filed our individual answers to the consolidated amended complaint. In mid-November 2022, the parties began conducting fact discovery.

On March 10, 2023, following a mediation and the parties' agreement in principle to settle the securities class action for \$10 million, the court entered a stipulated order setting a deadline of April 28, 2023 for the parties to file a stipulation of settlement and for lead plaintiffs to file a motion for preliminary approval of the settlement, which the parties filed on that date. The settlement is subject to preliminary and final approval by the U.S. District Court for the Western District of Washington. On May 31, 2023, the court issued a minute order requiring the parties to file a joint status report on or before June 30, 2023 addressing several aspects of the proposed settlement, including revision of certain notices to putative class members regarding the settlement, which the parties filed on that date.

As a result of the foregoing, we recorded a legal settlement expense of \$10.0 million in operating expenses in the fourth quarter of 2022 and an accrued liability of \$10.0 million on the accompanying unaudited condensed consolidated balance sheets.

### **Shareholder Derivative Actions**

On April 14, 2022, a shareholder derivative action was filed by plaintiff Stephen Bushansky in the U.S. District Court for the Western District of Washington against certain current and former members of our board of directors, captioned *Bushansky v. Kawas et al.*, No. 2:22-cv-497. Plaintiff purports to bring the action derivatively on our behalf, and we are a nominal defendant to the action. The derivative complaint alleges that our board of directors breached its fiduciary duties by failing to prevent alleged misstatements in our public filings, failing to discover altered images in certain research papers, and failing to take appropriate action. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and waste of corporate assets. The derivative complaint seeks unspecified damages, disgorgement of profits, benefits, and other compensation received by the individual defendants, restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

On May 6, 2022, a second shareholder derivative action was filed by plaintiff Thomas Houlihan in the U.S. District Court for the Western District of Washington against certain of our current and former directors and officers, captioned *Houlihan v. Kawas et al.*, No. 2:22-cv-620. Plaintiff purports to bring the action derivatively on our behalf, and we are a nominal defendant to the action. The derivative complaint alleges that certain of our current and former directors and officers breached their fiduciary duties by failing to prevent alleged misstatements in our public filings and failing to take appropriate action regarding altered images in certain research papers. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duties, contribution, and indemnification. The derivative complaint seeks unspecified damages, unspecified corporate governance reforms, restitution, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

On May 26, 2022, the court issued an order consolidating the cases and staying them until further order of the court. We believe we have adequate reserves related to this matter as of the balance sheet date.

### **Government Investigations**

In November 2022, we received a Civil Investigative Demand from the Civil Division of the Department of Justice, or the Demand. The Demand seeks documents and information relating to our relationship with WSU, certain of our grant applications in 2016 and 2019 with the National Institutes of Health, or NIH, and our receipt of a NIH grant in 2020. We are cooperating with the Department of Justice with respect to the Demand.

In February 2023, the Securities and Exchange Commission, or SEC, sent us a subpoena seeking documents and information relating to, among other things, our former chief executive officer's alterations of images in certain research papers. We are cooperating with the SEC with respect to the subpoena.

We cannot predict the outcome of these lawsuits or government investigations. Failure by us to obtain a favorable resolution of these actions could have a material adverse effect on our business, results of operations and financial condition.

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

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and our unaudited condensed consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

### **Risks Relating to Our Business and the Development of Our Product Candidates**

#### ***We are a late clinical-stage biopharmaceutical company with a limited operating history.***

We are a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Our limited operating history may make it difficult to evaluate the success of our business. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product candidate, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product candidate commercialization. Our history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We may fail to or be unable to design and execute clinical trials to support marketing approval of fosgonimeton or any of our other product candidates. We cannot be certain that our current or planned clinical trials or any other future clinical trials will be completed on time or be successful. We cannot guarantee that the FDA or foreign regulatory authorities will agree with our study design, protocol or protocol amendments, or statistical plan, or that they will interpret clinical trial results as we do, and more clinical trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates (including potential confirmatory or Phase 3 registrational trials). Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

#### ***Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.***

Our business depends entirely on the successful discovery, development and commercialization of our product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate product revenue will depend heavily on the successful clinical development and eventual commercialization of fosgonimeton and one or more of our other future product candidates. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of nonclinical and clinical development of our product candidates and any future product candidates, as well as the associated costs, including any unforeseen costs;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and internationally, of our product candidates and any future product candidates;

- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether inhouse or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we are, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies and potential confirmatory or Phase 3 registrational trials, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a new drug application, or NDA, to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.



***Our development of fosgonimeton may never lead to a marketable product.***

We are developing fosgonimeton as a small molecule aimed at restoring neuronal health. We have not received regulatory approval for fosgonimeton and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. The primary and all secondary endpoints of the ACT-AD trial were not met by protocol analysis. While we are continuing with the LIFT-AD study, we may not succeed in demonstrating safety and efficacy of fosgonimeton in our LIFT-AD trial or in other clinical trials.

Advancing fosgonimeton as a small molecule aimed at restoring neuronal health creates significant challenges for us, including:

- obtaining marketing approval;
- if fosgonimeton is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating fosgonimeton into existing treatment regimens, including in combination with other treatments for AD or as a monotherapy; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our prospects are highly dependent on the successful development of fosgonimeton. If we do not demonstrate the safety and efficacy of fosgonimeton in our LIFT-AD trial, we may explore strategic alternatives to maximize stockholder value, which could involve, without limitation, exploring the potential for a possible merger, business combination, investment, a purchase, license or other acquisition of assets or return of capital to stockholders.

***Our approach to targeting brain growth factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from our Phase 1a/1b and Phase 2 clinical trials to date, and we cannot be certain that future trials will yield data in support of the safety, efficacy and tolerability of our product candidates.***

We have discovered and are developing a platform of small molecule product candidates from which we have selected our lead product candidate, fosgonimeton, which is under development to treat AD, Parkinson's Disease Dementia, or PDD, and Dementia with Lewy Bodies, or DLB. Our product candidates target an endogenous brain growth factor which is expected to protect and repair neuronal networks, which we believe could ultimately result in improvements in clinical outcomes and disease-relevant biomarkers. The therapeutic promise of brain growth factors in neurodegenerative diseases had been hampered in earlier therapies by the lack of efficient and non-invasive delivery to the brain. Our small molecule product candidates are designed to penetrate the blood brain barrier and enhance the activity of a brain growth factor, but we cannot be certain of the safety and efficacy of our product candidates in applicable patients or that our clinical trials will provide sufficient evidence that our design approach results in the intended therapeutic effect.

Based on the results of our nonclinical and clinical studies to date, we believe fosgonimeton has the potential to rapidly improve cognition, function and restore the lives of patients suffering from AD. However, these ideas and this approach are novel, and we currently have limited data based on our Phase 1a/b and Phase 2 clinical trials to date.

The primary and all secondary endpoints of our Phase 2 ACT-AD clinical trial were not met by protocol analysis. A subsequent post hoc analysis of the data in a pre-specified subgroup from patients on fosgonimeton without background therapy, or AChEIs, showed a meaningful, but not statistically significant, improvement in both ERP P300 latency and cognitive performance compared to placebo at 26 weeks. Although post hoc analyses cannot be used to establish efficacy, these analyses can be helpful in informing the design of current and future clinical studies. Following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study of fosgonimeton in patients with mild-to-moderate AD. The committee also determined that, with the additional enrollment of fewer than 150 patients for a total enrollment of less than 300 patients without background therapy (AChEIs), the study will be well powered for the primary endpoint given the preliminary effect size observed. There is no assurance that the amendments to our ongoing LIFT-AD trial based on our findings from the ACT-AD trial and our interim analyses will ultimately result in a successful trial. For example, our biomarker data may not translate into a statistically significant clinical benefit, FDA may not agree with our statistical plan or analyses, or the trial may not be sufficiently powered for our endpoint measures.

Data from our Phase 1a/1b and Phase 2 clinical trials to date were obtained from a relatively small number of subjects and we cannot be certain that future trials involving a larger number of subjects and clinical sites will yield data in support

of the safety, efficacy and tolerability of our product candidates. We may ultimately discover that fosgonimeton, or any of our other small molecules, do not possess certain properties required for therapeutic effectiveness. We have limited evidence regarding the efficacy, safety and tolerability of fosgonimeton and other small molecules in our product platform. We may spend substantial funds attempting to develop these product candidates and never succeed in doing so.

***We have concentrated our research and development efforts on the treatment of central and peripheral nervous system degenerative disorders, a field that has seen very limited success in product development.***

We have focused our research and development efforts on addressing central nervous system, or CNS, and peripheral nervous system, or PNS, degenerative disorders. Collectively, efforts by pharmaceutical companies in the field of CNS and peripheral degenerative disorders have seen very limited successes in product development. The development of CNS therapies presents unique challenges, including an imperfect understanding of the biology, the presence of the blood brain barrier, or BBB, that can restrict the flow of drugs to the brain, a frequent lack of translatability of preclinical study results in subsequent clinical trials and dose selection, and the product candidate having an effect that may be too small to be detected using the outcome measures selected in clinical trials or if the outcomes measured do not reach statistical significance. There are few effective therapeutic options available for patients with AD and other CNS or peripheral disorders. Our future success is highly dependent on the successful development of our technology and our product candidates for treating CNS and peripheral disorders. Developing and, if approved, commercializing our product candidates for treatment of CNS and peripheral disorders subjects us to a number of challenges, including ensuring that we have selected the optimal doses, executing an appropriate clinical trial to test for efficacy and obtaining regulatory approval from the FDA and other regulatory authorities.

***An independent special committee of our board of directors engaged in a review of papers co-authored by our former chief executive officer in connection with her doctoral research at Washington State University. The special committee's findings included that (1) our former chief executive officer altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at Washington State University, and published from 2011 to 2014, (2) that we cited challenged research papers in certain communications and applications, and (3) that WSU's dihexa patent, exclusively licensed to us, incorporated certain of these altered images. Washington State University has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at Washington State University. We cannot predict when WSU's investigation will be completed or what conclusions WSU will reach.***

An independent special committee of our board of directors engaged in a review of papers co-authored by our former chief executive officer, Dr. Leen Kawas, in connection with her doctoral research at WSU, including, among other things, an investigation of allegations that Dr. Kawas altered images used in research published by Dr. Kawas in connection with her doctoral studies.

The independent special committee's primary finding was that our former chief executive officer altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at WSU, and published from 2011 to 2014. While the conduct that was the subject of the allegations is not related to any of our current product candidates or ongoing clinical research, this finding could have a material adverse effect on our reputation, our in-licensed patents and pending patent applications, licenses and grants, and could lead to further investigation from government agencies, including the FDA, any of which could have a material adverse impact on our business and prospects.

As disclosed elsewhere in this report, including in this "Risk Factors" section under the heading "*—We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management's attention,*" and in "Part II, Item 1—Legal Proceedings," lawsuits have been filed against us and certain of our directors and officers, alleging violations of federal securities laws related to alleged false and misleading statements in connection with the alleged misconduct of Dr. Kawas and others associated with us. As a result of these allegations and the ongoing litigation against us and certain of our directors and officers and related matters, we have been the subject of negative publicity. This negative publicity may harm our credibility, reputation and relationships with current and future investors, government regulators, patent offices, courts, current and prospective employees, key opinion leaders, prospective collaborators, advocacy groups, current and future patients enrolled in our clinical trials, physicians and prospective patients and vendors. For example, this negative publicity may adversely affect our ability to recruit and hire talented employees, maintain existing business relationships with CROs, clinical trial sites and other parties, enter into new business relationships, enroll patients in our clinical trials, and maintain a viable business in the future. Also, it is possible that the negative publicity and its effect on our work environment could cause our employees to terminate their employment or, if they remain employed by us, result in reduced morale that could have a material adverse effect on our business. In addition, negative publicity has and may continue to adversely affect our stock price and, therefore, employees

and prospective employees may be less inclined to seek or continue employment with us. As a result, our business, financial condition, results of operations and cash flows could be materially adversely affected.

***Washington State University has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at Washington State University.***

In addition to the investigation of the independent special committee of our board of directors noted above, WSU has also announced that it has undertaken a review of claims of potential research misconduct involving research conducted by Dr. Kawas during her doctoral studies at WSU. We understand this review is ongoing, and at this time we cannot predict what, if any, effect the investigation will ultimately have on our business and reputation. We are also unable to predict with any certainty when WSU's investigation will be completed. It is possible that the ongoing investigation by WSU will come to different conclusions, or uncover additional or different information, than the investigation of the independent special committee of our board of directors, the conclusions of which are discussed under "*—An independent special committee of our board of directors engaged in a review of papers co-authored by our former chief executive officer in connection with her doctoral research at Washington State University. The special committee's findings included that (1) our former chief executive officer altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at Washington State University, and published from 2011 to 2014, (2) that we cited challenged research papers in certain communications and applications, and (3) that WSU's dihexa patent, exclusively licensed to us, incorporated certain of these altered images. Washington State University has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at Washington State University. We cannot predict when WSU's investigation will be completed or what conclusions WSU will reach*". The conclusions from WSU's investigation could have a material adverse impact on our business, reputation, scientific credibility, and prospects, as well as our in-licensed patents and pending patent applications, current grants and pending grant applications, and our relationship with WSU, from whom we in-license patents and patent applications underlying certain of our product candidates.

***We are and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations and other legal, regulatory and administrative proceedings and face potential liability and expenses related thereto, which could have a material adverse effect on our business, operating results and financial condition.***

We are and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations and other legal, regulatory and administrative proceedings. In November 2022, we received a Civil Investigative Demand from the Civil Division of the Department of Justice, or the Demand. The Demand seeks documents and information relating to our relationship with WSU, certain of our grant applications in 2016 and 2019 with the National Institutes of Health, or NIH, and our receipt of a NIH grant in 2020. We are cooperating with the Department of Justice with respect to the Demand. In February 2023, the Securities and Exchange Commission, or SEC, sent us a subpoena seeking documents and information relating to, among other things, our former chief executive officer's alteration of images in certain research papers. We are cooperating with the SEC with respect to the subpoena.

The outcome of these or any other investigations, claims, or proceedings cannot be predicted with any degree of certainty. In the ordinary course of business we have been and may in the future be the subject of various legal claims. Any such claims, investigations or proceedings against us, whether meritorious or not, could be time-consuming, result in costly litigation, be harmful to our reputation, require significant management attention and divert significant resources, and the resolution of any such claims, investigations or proceedings could result in substantial damages, settlement costs, fines or penalties that could adversely affect our business, financial condition or operating results or result in harm to our reputation and brand, sanctions, consent decrees, injunctions or other remedies requiring a change in our business practices.

Further, under certain circumstances we may have contractual or other legal obligations to indemnify and to incur legal expenses on behalf of investors, directors, officers employees, customers, vendors or other third-parties. For example, our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees, agents and other persons, to the fullest extent permitted by the Delaware General Corporation Law. We have also entered into indemnification agreements with directors and officers that require us, among other things, to indemnify them against claims that may arise due to their service in those capacities. These indemnification agreements also require us to advance expenses reasonably and actually incurred by them in investigating or defending any such claims, and it may be difficult or impossible to recover any advanced expenses if it turns out the person was not entitled to indemnification. If we are required or agree to defend or indemnify, or advance expenses to, any of our investors, directors, officers, employees, customers,

vendors or other third-parties, we could incur material costs and expenses that could adversely affect our business, results of operations or financial condition.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale preclinical studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.***

Our lead product candidate, fosgonimeton, is in clinical development for the potential treatment of AD, PDD and DLB. Our additional early product candidates, including ATH-1105 for ALS, are in preclinical development. It is impossible to predict when or if any of our product candidates will prove to be effective and safe in humans or will receive regulatory approval.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each target indication. Nonclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the nonclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in nonclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through nonclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. For example, our Phase 1a/b clinical trial, which enrolled 88 patients, including only 11 patients with mild-to-moderate AD, of whom seven patients were treated with fosgonimeton and the other four patients were randomized to the control, suggested improvements in brain network activity including potentially positive effects on brain function. However, our Phase 2 ACT-AD clinical trial, which included a larger patient population, approximately 60% of which were receiving standard-of-care AChEIs, did not meet its primary endpoint of a change in ERP P300 latency for the full study population nor did it meet the secondary endpoints. Although a post hoc analysis of results from ACT-AD in a pre-specified subgroup suggested positive effects on measures of cognition, function and neurodegeneration in patients taking fosgonimeton alone without background acetylcholinesterase inhibitors (AChEIs), we cannot be sure that data from future trials will support our earlier findings or demonstrate the safety and effectiveness of fosgonimeton for treatment of AD to the satisfaction of the FDA in order to support regulatory approval. Likewise, early, smaller-scale studies, biomarker analyses, and clinical trials with a single or relatively few clinical trial sites may not be predictive of eventual safety and effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials (including potential confirmatory or Phase 3 registrational trials), which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials, and adversely impact our business. Our ability to achieve regulatory approval for fosgonimeton is further complicated by the nature of AD, which historically has been a challenging indication for drug development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence nonclinical studies and clinical trials are never approved as products.

In some instances, there can be significant variability in safety or efficacy results between different nonclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. For example, we believe the topline results of our Phase 2 ACT-AD clinical trial may have differed from the treatment data from our Phase 1a/b clinical trial at least in part due to differences in the patient population and treatment duration, and potential effects from background AChEI treatment. If future trials show that the effect of fosgonimeton when given in combination with add-on standard-of-care AChEIs is diminished, we may be required to seek a narrower indication or restrict our target population to those where fosgonimeton shows a greater effect, which could have a material adverse effect on our business and prospects.

On July 6, 2021, we announced the initiation of an open-label extension for the LIFT-AD and ACT-AD trials and in May 2022 we announced the extension of the open label extension for an additional 12 months. In May 2023, we amended

the open-label extension trial to further extend the trial by an additional 12 months. Upon completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, patients may continue on the open-label extension and receive treatment with fosgonimeton for up to an additional 30 months. Investigators and patients remain blinded to treatment group assignment in the original trials. Such open-label extension studies are, and some of the clinical trials we conduct in the future may be, open-label in study design conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, of the institutions in which such clinical trials are being conducted, by a data safety monitoring board for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our ATH clinical development strategy or statistical plan;
- changes in governmental regulations or administrative actions;
- delays in our ability to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- failure to demonstrate a benefit from using a product candidate;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in nonclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries, as we intend to 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 protocol 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 study. 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 authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If the results of our current and future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- 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 including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product 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;
- be sued; or
- experience damage to our reputation.

***Any “topline”, interim, initial, or 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 publicly disclose preliminary or topline data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our nonclinical studies and clinical trials. For example, in October 2022 we announced that an independent data monitoring committee had conducted an unblinded interim efficacy and futility analysis with respect to our Phase 2/3 LIFT-AD clinical trial. 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Additionally, we rely on data received from clinical trials, whether preliminary or final, to inform decisions on future clinical trials, including trial design, trial size, and whether or not to initiate additional clinical trials (including any potential confirmatory or Phase 3 registrational trials). For example, in November 2020, we initiated ACT-AD, an exploratory Phase 2 clinical trial, to better understand the overall effects of fosgonimeton on working memory processing speed and cognitive measures. Topline results of ACT-AD were announced in June 2022. We used these data to help inform strategic decisions around LIFT-AD and expect to use these data to help inform strategic decisions in the future around current clinical trials and any additional trials that we may initiate. Topline results are based on a preliminary analysis of then-available data, and

a more comprehensive and full review of the data may result in different conclusions, which could have a negative impact on our decisions regarding any additional trials for fosgonimeton. There is no assurance that the amendments to our ongoing LIFT-AD trial based on our findings from the ACT-AD trial and our interim analysis of the LIFT-AD trial will ultimately result in a successful trial. For example, our biomarker data may not translate into a statistically significant clinical benefit, FDA may not agree with our statistical plan or analyses, or the trial may not be sufficiently powered for our endpoint measures.

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

***If we experience delays or difficulties in the enrollment or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these clinical trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment may also be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Additionally, publicly reported results of our completed clinical trials may impact enrollment of our trials in progress. If we are unable to locate a sufficient number of such patients, our clinical trial and development plans could be delayed.

If we are delayed or unsuccessful in enrolling the desired number of subjects in our trials, whether as a result of the outcomes of prior trials conducted by us, competing clinical trials, overly stringent eligibility requirements, or other factors, our clinical trial results could be delayed, the costs of our clinical trials could materially increase, and the overall development timeline for fosgonimeton could be negatively impacted. For example, enrollment in our ongoing clinical trials had slowed due to the effects of the COVID-19 pandemic, including governmental restrictions imposed in Australia, where certain of our clinical trial sites are located. In our ACT-AD clinical trial, this slowed recruitment resulted in a change in the timing of topline results from our Phase 2 ACT-AD clinical trial, which were announced in June 2022. We cannot ensure that similar enrollment issues will not occur again in the future. Even if we are successful in enrolling the targeted number of subjects in our trials, the FDA and other regulators may request additional clinical trials with larger numbers of subjects (including potential confirmatory or Phase 3 registrational trials) as a condition to any regulatory approval.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Further, to the extent any of our clinical trial sites fail to comply with the approved study protocol, good clinical practices, or FDA regulations, we may be required to exclude such sites, participants such sites may have enrolled, as well as the data collected by such sites. If any of these events were to occur, or if we are required to exclude any data for any reason, we may be required to recruit more sites or more participants than we initially thought. Enrollment delays or other delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.***

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face competitive pressures from both large and small pharmaceutical companies, emerging biotechnology companies, as well as academic, government and private research institutions. Many of our competitors have access to greater financial resources, market presence, expertise in development, preclinical and clinical

testing, manufacturing, commercialization, regulatory approval process, or marketing and sales than we do. Our competitors may compete with us in patient recruitment, clinical research organization, and operational resources. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. For example, the FDA recently granted traditional approval for lecanemab, a drug developed by Biogen Inc. and Eisai Co., Ltd., and Eli Lilly and Company is also developing product candidates for Alzheimer's disease. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. For example, CMS announced a two-part National Coverage Determination under which Medicare will cover monoclonal antibodies that target amyloid (or plaque) for the treatment of Alzheimer's disease that receive traditional approval from the FDA under coverage with evidence development. Additionally, for drugs that FDA has not determined to have shown a clinical benefit or that received an accelerated approval, Medicare will provide coverage in FDA or National Institutes of Health approved clinical trials. In June 2023, CMS announced that Medicare will cover new Alzheimer's drugs with traditional FDA approval when a physician and clinical team participate in CMS' registry to collect evidence about how these drugs work in the real world. Current and future CMS coverage restrictions on classes of drugs that encompass our product candidates could have a material adverse impact on our ability to commercialize our product candidates, if approved, generate revenue and attain profitability. It is unclear how future CMS coverage decisions and policies will impact our business. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see the section titled "Part I, Item 1 – Business—Competition" in our Annual Report on Form 10-K filed with the SEC on March 23, 2023.

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

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. 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, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

***We may develop product candidates in combination with other therapies, which exposes us to additional risks.***

We may develop product candidates in combination with one or more other approved or unapproved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies 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.

We also may choose to evaluate product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety,



efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

***Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.***

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in clinical and nonclinical development. A product candidate can unexpectedly fail at any stage of nonclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from nonclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other future product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other future product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other future product candidates.

***We have conducted certain research and development operations through our Australian wholly owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.***

In July 2020, we formed a wholly owned Australian subsidiary to conduct various preclinical and clinical activities for our product and development candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our product and development candidates in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we lose our ability to operate our subsidiary in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operations may be adversely affected.

***The loss of any of our key personnel could significantly harm our business, results of operations and competitive position.***

In order to compete, we must attract, retain, and motivate executives and other key employees. Hiring and retaining qualified executives, scientists, technical and legal and accounting staff are critical to our business, and competition for experienced employees in our industry can be high. The loss of one or more of these key employees, or our inability to hire additional key personnel when needed, could have a material adverse effect on our business and prospects.

## Risks Relating to Health Epidemics

***The potential effects of health epidemics, including the novel coronavirus disease, or COVID-19, pandemic, could adversely impact our business, including our nonclinical studies and clinical trials.***

Our business could in the future be adversely impacted by the effects of possible health epidemics and other outbreaks, including COVID-19, which could cause disruptions that could severely impact our business, nonclinical studies and clinical trials. Such disruptions may include:

- delays or difficulties in enrolling and retaining patients in our clinical trials, particularly elderly subjects, who may be at a higher risk of severe illness or death, which can be further complicated by the presence of comorbidities that are often present in AD subjects;
- difficulties interpreting data from our clinical trials due to the possible effects of such diseases on cognition of the subjects enrolled in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of some or all of our employees working remotely;
- interruption or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

In the event of a disease outbreak or resurgence of COVID-19, we could be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from such diseases. On May 11, 2023, the federal government ended the COVID-19 public health emergency, which ended a number of temporary changes made to federally funded programs while some continue to be in effect. Since March 2020, the FDA has issued various COVID-19 related guidance documents for sponsors and manufacturers, many of which have expired or were withdrawn with the expiration of the COVID-19 public health emergency declaration, although some COVID-19 related guidance documents continue in effect. The full impact of this termination of the national emergency and the wind-down of the public health emergency on FDA and other regulatory policies and operations is unclear.

The trading prices for shares of biopharmaceutical companies have in the past been and could in the future be highly volatile as a result of health epidemics, including the COVID-19 pandemic, and the trading prices for shares of our common stock could also experience high volatility. In the event of an emergence of new disease outbreaks or a resurgence of COVID-19, we could face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from a health epidemic, including a resurgence of COVID-19, could materially and adversely affect our business and the value of our common stock.

The ultimate impact of a possible health epidemic or other outbreak, including a resurgence of COVID-19, on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. In addition, our business could be significantly adversely affected by other business disruptions to us or our third-party providers that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, commercial manufacturing organizations, or CMOs, and other contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

### **Risks Relating to Our Financial Position and Capital Needs**

***We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.***

We have not generated any revenue from product sales and our product candidates will require substantial additional investment before they may provide us with any revenue. We had net losses of \$57.4 million and \$45.3 million for the six months ended June 30, 2023 and 2022, respectively, and an accumulated deficit of \$249.0 million as of June 30, 2023.

We have devoted most of our financial resources to research and development, including our clinical and nonclinical development activities. To date, we have financed our operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we:

- continue our research and nonclinical and clinical development of our product candidates;
- expand the scope of our clinical studies for our current and prospective product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates, including any potentially pivotal trials with respect to fosgonimeton for the treatment of mild-to-moderate AD in addition to LIFT-AD, and further extend the open label extension of the ACT-AD and LIFT-AD trials;
- change or add additional manufacturers or suppliers and manufacture drug supply and drug product for clinical trials and commercialization;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- attract, hire and retain additional personnel;
- operate as a public company;
- continue to expand our facilities and lab space;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies or engage in other strategic transactions;
- make milestone or other payments under our in-license or other agreements;
- maintain, protect and expand our intellectual property portfolio;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts;
- incur expenses in connection with legal proceedings, and addressing potential stockholder activism; and
- experience any delays or encounter issues with any of the above.

Our expenses could increase beyond expectations for a variety of reasons, including if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity.

***We will require substantial additional funding to finance our operations, complete the development and commercialization of fosgonimeton, and develop and commercialize other and future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce, or eliminate our product development programs or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, fosgonimeton. Developing fosgonimeton and conducting clinical trials for the treatment of AD, PDD, DLB, and any other indications that we may pursue in the future will require substantial amounts of capital. In addition, if we obtain marketing approval for fosgonimeton or any future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing, and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As of June 30, 2023, we had cash, cash equivalents and investments of \$196.3 million. Based upon our current operating plan, we estimate that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

The amount and timing of our future funding requirements depends on many factors, some of which are outside of our control, including but not limited to:

- the progress, costs, clinical trial design, results of and timing of our LIFT-AD trial and other clinical trials of fosgonimeton, including for potential additional indications that we are pursuing beyond AD, such as PDD, DLB, and a potential further extension of the open label extension of the ACT-AD and LIFT-AD trials;
- the willingness of the FDA and EMA to accept our LIFT-AD trial, as well as data from our completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of fosgonimeton for AD and the potential need for additional clinical trials (including potential confirmatory or Phase 3 registrational trials);
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of our product candidates;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- the cost, timing and outcomes of any litigation involving our company, including securities class actions and government investigations which we may be or may in the future become involved in;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific, clinical and other personnel;
- the effect of competing drugs and product candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

In January 2023, we entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald, and BTIG, LLC, or BTIG, to sell shares of our common stock having aggregate sales proceeds of up to \$75.0 million, from time to time, through an at-the-market, or ATM, equity offering program under which Cantor Fitzgerald and BTIG are acting as sales agents. We have not sold any securities pursuant to this ATM offering. However, additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail or abandon one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

***Adverse events or perceptions affecting the financial services industry could adversely affect our operating results, liquidity, financial condition and prospects.***

Limited liquidity, defaults, non-performance or other adverse developments affecting financial institutions or parties with which we do business, or perceptions regarding these or similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed and placed in receivership and subsequently, additional financial institutions have been placed into receivership. We did not hold cash deposits or other accounts with SVB and did not, and as of the date of this report do not, otherwise have a direct business relationship with SVB or similarly situated financial institutions. However, companies that did have a business relationship with SVB faced:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of obligations, including U.S. federal and state wage laws and contracts that required them to maintain letters or credit or other credit support arrangements; and
- termination of cash management arrangements or delays in accessing or actual loss of funds subject to cash management arrangements.

As a result of U.S. government intervention, account holders subsequently regained access to their accounts, including the uninsured portion of deposit accounts; however, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB and similarly situated financial institutions were unable to access to such sources of liquidity. There is no guarantee that the U.S. government will intervene to provide access to uninsured funds in the future in the event of the failure of other financial institutions, or that they would do so in a timely fashion. In such an event, parties with which we have commercial agreements may be unable to satisfy their obligations to, or enter into new commercial arrangements with, us.

Concerns regarding the U.S. or international financial systems could impact the availability and cost of financing, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Any of these risks could materially impact our operating results, liquidity, financial condition and prospects.

***The value of our investments is subject to significant capital markets risk related to changes in interest rates and credit spreads as well as other investment risks, which may adversely affect our operating results, liquidity, financial condition and prospects.***

Our results of operations are affected by the performance of our investment portfolio. Our excess cash is invested by an external investment management service provider, under the direction of our management in accordance with our investment policy. The investment policy defines constraints and guidelines that restrict the asset classes that we may invest in by type, duration, quality and value. Our investments are subject to market-wide risks, and fluctuations, as well as to risks

inherent in particular securities. The failure of any of the investment risk strategies that we employ could have a material adverse effect on our operating results, liquidity, financial condition and prospects.

The value of our investments is exposed to capital market risks, and our results of operations, liquidity, financial condition or cash flows could be adversely affected by realized losses, impairments and changes in unrealized positions as a result of: significant market volatility, changes in interest rates, changes in credit spreads and defaults, a lack of pricing transparency, a reduction in market liquidity, declines in equity prices, changes in national, state/provincial or local laws and the strengthening or weakening of foreign currencies against the U.S. dollar. Levels of write-down or impairment are impacted by our assessment of the intent to sell securities that have declined in value as well as actual losses as a result of defaults or deterioration in estimates of cash flows. If we reposition or realign portions of the investment portfolio and sell securities in an unrealized loss position, we will incur realized losses. Any such charge may have a material adverse effect on our results of operations and business.

***Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.***

As of December 31, 2022, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$9.5 million and federal tax credit carryforwards of approximately \$5.6 million, which expire over a period of 9 to 15 years. Federal NOLs of \$104.4 million were generated after 2017, and therefore do not expire. At December 31, 2022, we also had state NOLs of \$2.7 million, which expire over a period of 19 to 20 years. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our NOLs and tax credit carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and tax credit carryforwards to expire unutilized. In addition, future changes in our stock ownership as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law or limited pursuant to provisions of the Tax Cuts and Jobs Act amendments to the Code, as modified by the Coronavirus Aid, Relief, and Economic Security Act. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

***Changes in tax laws could have a material adverse effect on our business, cash flows, results of operations or financial condition.***

We are subject to the tax laws, regulations, and policies of several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions or our tax liabilities. For example, many countries and local jurisdictions and organizations such as the Organization for Economic Cooperation and Development have proposed or implemented new tax laws or changes to existing tax laws, including additional taxes on payroll or employees. Any new or changes to tax laws could adversely affect our effective tax rate, operating results, tax credits or incentives or tax payments, which could have a material adverse effect on our business, cash flows, results of operations or financial condition.

**Risks Relating to Regulatory Approval and Other Legal Compliance Matters**

***The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain marketing approval.

Obtaining approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount

of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Further, securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval or resulting in delays in our regulatory approval, including, for example, legislation or agency policies that aim to reform the accelerated approval process and FDA's increased scrutiny of post-approval confirmatory studies, which can result in withdrawal of accelerated approval if such studies fail to confirm a clinical benefit.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a risk evaluation and mitigation strategy, or REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

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

***Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that***

**may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.**

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates 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. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the clinical trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing separate treatments which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials, including, for example, by interfering with the effects of our product candidates. A pre-specified group analysis of patients in our ACT-AD clinical trial identified a potential diminished effect of the combination of standard-of-care (AChEIs) and fosgonimeton. While more clinical studies are needed to determine the safety and efficacy of fosgonimeton, to the extent standard-of-care AChEIs impact the effects of fosgonimeton and if a significant portion of the patient population has already been treated with AChEIs, the potential target patient population or the indication we seek for fosgonimeton may be significantly smaller than we had anticipated, which could materially harm our business and prospects.

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

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure



or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP regulations, good laboratory practice, or GLP, regulations and good clinical practice, or GCP regulations, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to

which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

***Disruptions at the FDA, the Securities and Exchange Commission 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 or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, 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 the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA 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, in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 public health emergency, since March 2020 when foreign and domestic inspections facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current inspection pace, and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required, travel restrictions, or staffing shortages, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw accelerated approval.***

We may seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint

is a marker, such as a laboratory measurement or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback 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 receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Further, to the extent the FDA materially changes its policies or regulatory requirements with respect to the accelerated approval program or its internal review process for such program, our clinical development plans and regulatory approval under such program could be materially impacted or delayed. In view of the recent controversy regarding the FDA's approval of Biogen's Aduhelm, a biologic, through the accelerated approval pathway, the FDA has requested the Office of the Inspector General to investigate the FDA's review of Aduhelm leading up to its approval. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. It is unclear how these proposals, future policy changes, and changes in FDA regulation will impact new drug applications in the treatment of Alzheimer's disease and our clinical development programs.

***We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to our manufacturing arrangements;
- additions or modifications to product labeling;
- the recall or discontinuation of our products; or
- additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The

Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, or HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The ACA also established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In December 2020, the U.S. Centers for Medicare & Medicaid Services, or CMS, issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

As discussed above, since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures of the Biden administration will impact the ACA. Complying with any new legislation and regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

The Bipartisan Budget Act of 2018 also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has published a final rule to give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. The American Taxpayer Relief Act of 2012, or ATRA, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other legislative changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2031 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under the Consolidated Appropriations Act, 2023, the 2% Medicare sequester is extended for the first six months of FY 2032 and the sequester percentage is revised to up to 2% for FY 2030 and 2031.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and

redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Further, the Biden administration released an additional executive order on October 14, 2022, directing the U.S. Department of Health and Human Services, or HHS, to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of IRA are unconstitutional. The impact of these judicial challenges as well as other legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

In April 2022, CMS released a finalized national policy for coverage of aducanumab, or Aduhelm, and any future monoclonal antibodies directed against amyloid approved by the FDA with an indication for use in treating Alzheimer's disease. According to the two-part National Coverage Determination, or NCD, Medicare will cover monoclonal antibodies that target amyloid (or plaque) for the treatment of Alzheimer's disease that receive traditional approval from the FDA when furnished in accordance with the coverage criteria specified under coverage with evidence development. CMS will also provide enhanced access and coverage for Medicare patients participating in CMS-approved studies, such as data collection through routine clinical practice or registries. Additionally, for drugs that FDA has not determined to have shown a clinical benefit or that received an accelerated approval, Medicare will provide coverage in FDA or National Institutes of Health approved clinical trials. In June 2023, CMS announced that Medicare will cover new Alzheimer's drugs with traditional FDA approval when a physician and clinical team participate in CMS' registry to collect evidence about how these drugs work in the real world. Current and future CMS coverage restrictions on classes of drugs that encompass our product candidates could have a material adverse impact on our ability to commercialize our product candidates, if approved, generate revenue and attain profitability. It is unclear how future CMS coverage decisions and policies will impact our business.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. 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.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and

- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities, and our participation in the federal health care programs and acceptance of federal grant funding, such as funding from the National Institutes of Health, may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Similarly, our participation in the federal health care programs and acceptance of federal grant funding from the NIH may subject us to federal false claims laws, civil penalties and assessments, criminal prosecution, and other administrative, civil, and criminal remedies.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, or FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.
- federal civil and criminal false claims laws, including the FCA, which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have

violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. Under the FCA, a "claim" also includes any request (including grant request) or demand for money or property made to the United States or to a contractor, recipient, if the Federal government provides or will reimburse any portion of the funds claimed. "Funds" include money that the NIH awards as part of research grants. Even if a federal grant is not awarded, the grant applicant may be subject to FCA liability if the information contained in or submitted as part of a grant application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including our advisory board arrangements with physicians, some of whom receive stock or stock options as compensation for services provided, and any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative

penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

In addition to the risks relating to the outcome of the independent special committee's investigation noted above, we are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our 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 have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials



and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

### **Risks Relating to Our Reliance on Third Parties**

***We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our nonclinical studies and clinical trials under agreements with us.

We expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our nonclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these nonclinical studies and clinical trials and the management of data developed through nonclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. These third parties 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, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our nonclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***We contract with third parties for the manufacture of our product candidates for nonclinical studies and our clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates***

***or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for nonclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier and sometimes involve long lead times from order to receipt of the materials. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

***Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

***If our third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

***We may use strategic collaborations, licensing arrangements or partnerships to accelerate the development and maximize the commercial potential of our programs, and we may not realize the benefits of such collaborations, arrangements or partnerships.***

We own worldwide rights to fosgonimeton as well as our pipeline of small molecule candidates. Where appropriate, we may use strategic collaborations, licensing arrangements or partnerships to accelerate the development and maximize the commercial potential of our programs. Any of these relationships 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.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval. In addition, the effects to our business and reputation discussed in "*—An independent special committee of our board of directors engaged in a review of papers co-authored by our former chief executive officer in connection with her doctoral research at Washington State University. The special committee's findings included that (1) our former chief executive officer altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at Washington State University, and published from 2011 to 2014, (2) that we cited challenged research papers in certain communications and applications, and (3) that WSU's dihexa patent, exclusively licensed to us, incorporated certain of these altered images. Washington State University has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at Washington State University. We cannot predict when WSU's investigation will be completed or what conclusions WSU will reach,*" may discourage potential counterparties from entering into relationships with us.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Even if we are successful in entering into collaborations involving our product candidates, these relationships are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional strategic collaborations, licensing arrangements or partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic collaboration, licensing arrangement or partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic collaborations, licensing arrangements or partnerships related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

***If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.***

From time to time, we evaluate various acquisition opportunities and strategic transactions and partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;

- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

### **Risks Relating to Our Ability to Commercialize our Product**

***Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance or reimbursement of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the extent of physician acceptance of FDA-approved therapies for AD or other target indications;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from such product candidates and our financial results could be negatively impacted.

***We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.***

We have never commercialized a product candidate. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. 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 not generate revenues from them or be able to reach or sustain profitability.

***If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.***

We intend to initially focus our product candidate development on treatments for various CNS and peripheral disorder indications. The addressable patient populations that may benefit from treatment with our product candidates, if approved, are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these CNS and peripheral disorders. Any regulatory approval of our product candidates would be limited to the therapeutic indications examined in our clinical trials and as determined by the FDA, which would not permit us to market our products for any other therapeutic indications not expressly approved by the FDA. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. For example, pre-specified subgroup analysis based on topline data from our ACT-AD clinical trial identified a potential diminished effect of the combination of standard-of-care (AChEIs) and fosgonimeton. If such hypothesis is supported by additional research, patients receiving AChEIs could be excluded from the addressable patient population for fosgonimeton. Even if we receive regulatory approval for any of our product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

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

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

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

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

***The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

***A variety of risks associated with marketing our product candidates internationally may materially adversely affect our business.***

We plan to eventually 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 in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States;



- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of health epidemics, including COVID-19, on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- 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 legal requirements applicable to privacy, data protection, information security and other matters;
- 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;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- 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
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

#### **Risks Relating to Our Intellectual Property**

##### ***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications 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 the patent applications of any current or future licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, found unenforceable or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties or the patent owner before various patent offices or in courts. Thus, the degree of future protection for our and any current or future licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties or limitations

in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our pending patent applications or those of any current or future licensors, will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our owned or in-licensed patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- 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, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents and patent applications may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- changes to patent laws in the United States or in other countries may limit the ability to obtain, defend or enforce patents, or may apply retroactively to affect the terms or scope of patents;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope or term of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any current or future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any current or future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed. Certain of these parties may also be subject to public information disclosure statutes and could determine to disclose patentable aspects of our research and development output pursuant to a request thereunder, notwithstanding the existence of a non-disclosure and confidentiality agreement. Any of these actions could jeopardize our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates or their use 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.

***If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.***

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity,

enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of any current or future licensors may not result in patents being issued which protect our product candidates or their use or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed, invalidated or rendered unenforceable as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of any current or future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents or the patents of any current or future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and *inter partes* review, or IPR, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Moreover, our patents or the patents of any current or future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our claim of priority of invention, scope, validity or patentability with respect to our patents and patent applications and those of any current or future licensors.

For example, in view of the lawsuits disclosed elsewhere in this report including in this “Risk Factors” section under the heading “—We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management’s attention,” and in “Part II, Item 1—Legal Proceedings,” third parties may challenge the validity or enforceability of our in-licensed patents and patent applications. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar technology and products such as other modifications to dihexa not covered by our issued patents. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our in-licensed patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. Further, these proceedings could have a material adverse effect on our business, results of operations and financial condition.

Even though we own patents and patent applications covering fosgonimeton and its use, our patents and any future patents we obtain may not effectively prevent others from developing or commercializing products similar to our product candidates. While the fosgonimeton patent family is distinct from, and not part of the same patent family as, the dihexa patent licensed from WSU, and therefore is not implicated in the allegations that Dr. Kawas altered images in connection with her doctoral studies, third parties may use these allegations to cast doubt on the validity and enforceability of our owned patents or patent applications. Such events may result in substantial cost and require significant time from our scientists and management, and could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates, even if the eventual outcome is favorable to us.

We or WSU may in the future file one or more requests for supplemental examination of certain patents for the USPTO to reconsider the enforceability and validity of the patents (including any patents relating to dihexa) in view of the allegations that Dr. Kawas altered images in connection with her doctoral studies. The outcome of any supplemental examination procedure is unpredictable. If a substantial new question of patentability is found, the USPTO Director will order *ex parte* reexamination of the patent. An adverse determination in such a proceeding could reduce the scope of, or invalidate or render unenforceable, the affected patent rights. While supplemental examination proceedings that result in our favor would bolster the presumption of validity and enforceability of the examined patents, third parties may still challenge the patents and patent applications in litigation or other legal proceedings.

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or any current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or any current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.***

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation and other legal actions, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, reexaminations, IPR proceedings and PGR proceedings and oppositions before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to compositions, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents or patent applications that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate, its use, or our technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates or their use may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale

or import our product candidates that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any defense to claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion for management and other personnel. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, our treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property, or if we are unable to maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***We may be involved in lawsuits to protect or enforce our patents or any current or future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or any current or future licensors' patents could be found invalid or unenforceable if challenged in court.***

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable, or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates or their method of use, the defendant could counterclaim that our patent or the patent of any current or future licensors is invalid or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including allegations of a lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent application misrepresented or fraudulently withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents or any current or future licensors' patents in such a way that they no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to a validity claim, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

The outcome following legal assertions of invalidity or unenforceability is unpredictable, and prior art could render our patents or any current or future licensors' patents invalid. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or the patents and patent applications of any current or future licensors has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of any current or future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Additionally, a finding that issued claims lack sufficient written description or are not enabled could render our patent or any current or future licensors' patent invalid.

If a third party were to prevail on a legal assertion of invalidity or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of any current or future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. There could also 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 material adverse effect on the price of our common stock.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

***Intellectual property litigation or legal proceedings may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.***

During the course of any intellectual property litigation or legal proceeding, there could be public announcements of the initiation of the litigation or legal proceeding as well as results of hearings, rulings on motions, and other interim proceedings. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

***Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.***

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of any current or future licensors or of third parties. An unfavorable outcome 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. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other personnel. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of any current or future licensors and the enforcement or defense of our issued patents or those of any current or future licensors.***

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that filed a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours or our current or future licensors even if we or our current or future licensors had made the invention before it was made by such third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or any current or future licensors are the first to either (1) file any patent application related to our product candidates, their use, or our technology or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also included a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of printed publications to the USPTO during patent prosecution and additional procedures to attack the validity or enforceability of a patent by USPTO-administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or those of our current or future licensors that would not have been invalidated if first challenged by the third party in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and

costs surrounding the prosecution of our patent applications or those of any current or future licensors and the enforcement or defense of our issued patents or those of any current or future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to 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 decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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 patent and the patents we might obtain or license in the future. As an example, European patent applications now provide the option, upon grant of a patent, of becoming a Unitary Patent, which is subject to the jurisdiction of the Unitary Patent Court, or UPC. The option of a Unitary Patent is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

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

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates or their use are obtained, once the patent life has expired, we may be open to competition from competitive products, including generic versions of our products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If we do not obtain patent term extension for our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of any current or future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during clinical trials and 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent



term extension may also be available in certain foreign countries upon regulatory approval of our product candidates, although the requirements and terms of such extensions vary country-by-country. However, we may not be granted an extension because of, for example, 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 restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products or launch generic versions of our products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case.

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

We own and in-license patents and pending patent applications in the United States and in jurisdictions outside of the United States. However, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may 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 will 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 inventions 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 product candidates, and our patents, the patents of any current or future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or any current or future licensors' patents or marketing of competing products in violation of our proprietary rights. 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 or the patents of any current or future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of any current or future licensors 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Geopolitical actions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications and those of any current or future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest, and it may be difficult and costly to register, maintain or protect our rights to these trademarks and trade names in jurisdictions in and outside of the United States. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with our employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party improperly disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

***We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of third parties.***

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and

used or disclosed their trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.***

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

***Our rights to develop and commercialize our product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.***

We have entered into license agreements with third parties and we may enter into additional license agreements in the future with others to advance our research and development or allow commercialization of product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and other rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Further, these and other licenses may also include certain restrictions or obligations that limit our ability to engage with third parties, including potential restrictions on sublicensing or outsourcing certain activities.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering our product candidates that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If any of our current or future licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

Our licensors and any future licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If it is later determined that third parties own the rights to our in-licensed patents, or if other third parties have ownership rights to our in-licensed patents, such third parties may be able to license such patents to our competitors, and our competitors could market products similar or identical to our product candidates. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same rights licensed to us. In that event, we may be required to expend significant time and resources to redesign our product

candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current manufacturing methods, product candidates, methods of use, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights or other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

Disputes may arise between us and our current or future licensors regarding intellectual property and other rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our product candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or other rights from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or other rights, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property or other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates covered by these license agreements. If these in-licenses 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 identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

***The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.***

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patent applications and patents relating to our product candidates and their use, there may be times when the filing and prosecution activities for patent applications and patents relating to our product candidates are controlled by licensors or collaboration partners. If a licensor or collaboration partner fails to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patent applications and patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling products similar or identical to our product candidates. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or

inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

***Intellectual property discovered or developed through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a manufacturing 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, which could adversely affect our ability to successfully develop and commercialize our products.***

We entered an exclusive license agreement with WSU for certain licensed patents that include intellectual property that was generated through the use of U.S. government funding, and we received a grant from the National Institute on Aging of the National Institute on Health to support our ACT-AD clinical trial. Pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act, the U.S. government may have certain rights in any invention developed or reduced to practice with government funding. In addition, in the future we may discover, develop, acquire, or license new intellectual property that has been generated through the use of U.S. government funding or grants in which the U.S. government may have certain rights pursuant to the Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). Such “march-in” rights would apply to new subject matter arising from the use of such government funding or grants and would not extend to pre-existing subject matter or subject matter arising from funds unrelated to the government funding or grants. If the U.S. government exercises its march-in rights in our intellectual property rights that are generated through the use of U.S. government funding or grants, we could be required to license or sublicense intellectual property discovered or developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. Reporting of a subject invention and compliance with the Bayh-Dole requirements were delayed for the patent family directed to methods of treating Alzheimer’s disease with fosgonimeton. As such, this patent family may be subject to U.S. government action which may include loss of rights in the subject invention, suspending or terminating the grant or future awards, or withholding further awards. Should any of these events occur, it could significantly harm our business, results of operations and prospects. In addition, the Bayh-Dole Act requires that, in certain circumstances, any products embodying intellectual property generated with the use of U.S. government funds or produced through the use of any such intellectual property be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property, which could adversely affect our ability to successfully develop and commercialize our products and have a material adverse effect on our business, financial condition, results of operations, and prospects.

#### **Risks Relating to Cybersecurity**

***We are dependent on networks, infrastructure and data, which exposes us to data security risks, including security failures or breaches of our systems or those used by our CROs or other contractors or consultants. We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Likewise, data privacy or security incidents or breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public or may otherwise be misused. Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our personal, sensitive, confidential or proprietary information and information technology systems, and those of the third

parties upon which we rely. For example, in April 2023, CRO Evotec SE faced a cybersecurity attack that temporarily disrupted its systems and operations. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Increases in remote work impacting how our employees work and access our systems could lead to additional opportunities for bad actors to launch cyberattacks or for employees to cause inadvertent security risks or incidents and may amplify the impacts of any security breach or incident. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies.

We may rely on third-party service providers and technologies to operate critical business systems to process sensitive information and other company data in a variety of contexts. We may also rely on third-party service providers to provide certain products or services, or otherwise to operate our business. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. Security incidents or other interruptions suffered by our third-party service providers could cause us to experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised.

Our business partners face similar risks, and any security breach of, or security incident impacting, their systems or that they otherwise suffer could adversely affect our security posture. A security breach or incident or privacy violation that leads to loss of or unauthorized use, disclosure or modification of, or access to trade secrets, company resources, personal, sensitive, confidential or proprietary information, including protected health information or other patient information, or that prevents access to patient information, as well as the perception that any of the foregoing has occurred, could harm our reputation, compel us to comply with federal or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, cause us to provide other notification or take other steps in response to such breach or violation, require us to verify the correctness of database contents and otherwise subject us to litigation, claims, investigations, penalties or other liability under laws and regulations, any of which could disrupt our business or result in increased costs or loss of revenue or company resources. Moreover, the prevalent use of mobile devices that access confidential information, increase the risk of security breaches and incidents.

Despite efforts to create security barriers to the above-described threats, it is impossible for us to entirely mitigate these risks. To date, we have not experienced any material impact to our business, financial position or results of operations resulting from cyberattacks or other information security incidents such as phishing, social engineering, ransomware or malware attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of such attacks, our business, financial position or results of operations could be adversely impacted in the future. We may be unable to anticipate or prevent techniques used to obtain unauthorized access or to compromise our systems because they change frequently and are generally not detected until after an incident has occurred. If a compromise or other security breach or incident were to occur and cause the loss or corruption of data or interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss, unavailability, or corruption of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any disruption or security breach or incident resulting in loss or unavailability of, or damage to, our data or systems, or inappropriate use, disclosure or modification of personal, sensitive, confidential or proprietary information, could result in us incurring liability and in delays to further development and commercialization of our product candidates could be delayed. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that

our efforts will prevent service interruptions, or prevent or identify vulnerabilities or security breaches or incidents, that could adversely affect our business and operations or result in the loss, unavailability, or corruption of, or inappropriate access to or use of, critical or sensitive information or company resources. Any such interruptions, breaches or incidents, or the perception any have occurred, could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other privacy and security breaches or incidents.

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

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

As we conduct our clinical trials and continue to enroll patients in our current and future clinical trials, we may be subject to additional restrictions relating to privacy, data protection and data security. The collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the European Economic Area, or EEA, is subject to the EU General Data Protection Regulation, or GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are subject to uncertainty, including as the result of legal proceedings in the EU. For example, a July 2020 decision by the Court of Justice for the EU invalidated the EU-U.S. Privacy Shield and imposed additional obligations in connection with the use of standard contractual clauses approved by the EU Commission. These and other developments with respect to cross-border data transfers may increase the complexity of transferring personal data across borders and may require us to review and amend our mechanisms relating to cross-border data transfer.

Further, the exit of the United Kingdom, or UK, from the EU has created uncertainty regarding data protection regulation in the UK. The UK has implemented legislation similar to the GDPR, referred to as the UK GDPR, which provides for fines of up to the greater of up to the greater of £17.5 million or 4% of global turnover. The GDPR and UK GDPR increased our responsibility and liability in relation to personal data that we process where subject to these regimes, and we may be required to put in place or modify policies and measures to ensure compliance with the GDPR, including as implemented by individual countries, and the UK GDPR, each of which may require us to modify our policies and procedures and engage in additional contractual negotiations, and which may cause us to incur liabilities, expenses, costs, and operational losses. Compliance with the GDPR and UK GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite our efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our activities in the EEA and the UK.

In addition, in the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). California has enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The California Privacy Rights Act of 2020 (CPRA), which became operative January 1, 2023, expands the CCPA's requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA and CPRA may increase compliance costs

and potential liability with respect to other personal data we maintain about California residents. Additionally, numerous other states have proposed or enacted laws addressing privacy and security, many of which impose obligations similar to those of the CCPA. The CCPA, CPRA, and other evolving legislation relating to privacy, data protection, and information security may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA/CPRA, require us to impose specific contractual restrictions on our service providers, and we may also be subject to use and disclosure limitations in our contracts with providers who share information with us for clinical trials. Additionally, we may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our business model, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and information security could result in governmental investigations, proceedings and enforcement actions (which could result in civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with laws relating to privacy, data protection, or information security, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

#### **Risks Relating to Ownership of Our Common Stock**

***We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management's attention.***

As described elsewhere in this report in "Part II, Item 1—Legal Proceedings," we and certain of our executive officers and directors have been named as defendants in class action lawsuits that generally allege that we and certain of our officers and directors violated Sections 10(b) or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false or misleading statements and omitted material adverse facts regarding the Company's business. These complaints seek unspecified compensatory and punitive damages, and reasonable costs and expenses, including attorneys' fees. As of the date of this report, we are unable to predict the outcome of these matters. Although we have insurance, it provides for a substantial retention of liability and is subject to limitations and may not cover a significant portion, or any, of the expenses or liabilities we may incur or be subject to in connection with class action lawsuit or other litigation to which we are party. Moreover, any conclusion of these matters in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the litigation has caused and will continue to cause our management and board of directors to divert time and attention to the litigation and could adversely impact our reputation and further divert management and our board of directors' attention and resources from other priorities, including the execution of our business plan and strategies that are important to our ability to grow our business and advance our product candidates, any of which could have a material adverse effect on our business. In addition, additional lawsuits may be filed,



the conclusion of which in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business.

***Actions by activist stockholders have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business.***

Our business could be negatively affected as a result of stockholder activism, which could be disruptive and cause uncertainty about the strategic direction of our business. For example, in February 2022, an activist stockholder announced his intention to nominate himself and one other candidate for election to our board of directors at our 2022 annual meeting of stockholders. While this proxy contest was unsuccessful, stockholder activism could recur and have an adverse effect on our business, results of operations, and financial condition. For example, as of the date of this report, our market capitalization was less than the aggregate value of our cash, cash equivalents and investments. Other similarly situated biotechnology companies have received proposals from shareholder activists to liquidate and return capital to investors.

We strive to maintain constructive communications with our stockholders and welcome their views and opinions with the goal of enhancing value for all stockholders. However, a proxy contest or other activist behaviors could have an adverse effect on us because:

- responding to actions by activist stockholders can disrupt our operations, is costly and time-consuming, and diverts the attention of our board of directors and senior management team from the pursuit of business strategies, each of which could adversely affect our results of operations and financial condition;
- perceived uncertainties as to our future direction as a result of changes to the composition of our board of directors may lead to the perception of a change in the direction of our business, as well as instability or lack of continuity, all of which may be exploited by our competitors, may result in the loss of potential business opportunities, may cause concern for those enrolling in our clinical trials, and make it more difficult to attract and retain qualified personnel and business partners;
- actions by activist stockholders may interfere with any efforts that we undertake in the future to raise capital;
- actions by activist stockholders could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business; and
- if individuals are elected to our board of directors with a specific agenda as a result of a proxy contest, it may adversely affect our ability to effectively implement our business strategy and to create additional value for our stockholders.

Even if a proxy contest or other activist efforts are not successful, the increased costs that we would bear and the distraction of our board of directors and senior management could negatively impact our business, although we cannot predict with certainty the extent of such negative impacts.

***We do not know whether an active market for our common stock will be sustained, and, as a result, it may be difficult for you to sell your shares of our common stock.***

If an active market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

***The market price of our common stock may be volatile, which could result in substantial losses for investors.***

The market price of our common stock may be volatile. As a result, you may not be able to sell your common stock at or above the price that you paid for such shares. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of nonclinical studies and clinical trials;
- the potential impact of health epidemics, including COVID-19, on our business;
- the success of existing or new competitive products or technologies;

- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- results of nonclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- investor reactions to other companies' drug development results, including product failures or negative responses from regulatory authorities;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- negative press coverage;
- the status of ongoing litigation and government investigations and potential commencement of additional litigation or investigations;
- the results of the investigation by the independent special committee of the board of directors and the separate ongoing investigation by WSU;
- the level of expenses related to any of our research programs, product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts, including, but not limited to, under our ATM offering;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- volatility with the banking system;
- direct or indirect impacts on our business, our suppliers and other third parties and our clinical sites as a result of geopolitical events, including the Russia-Ukraine war;
- general economic, industry, and market conditions; and
- the other factors described in this "Part II, Item 1A—Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

***A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares,

could reduce the market price of our common stock. In addition, shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available-for-sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

Moreover, as of June 30, 2023, the holders of approximately 5.1 million shares of our common stock are eligible to exercise certain rights, subject to various conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also register shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

***Our directors, executive officers and significant stockholders own a substantial percentage of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.***

Our directors, executive officers, significant holders of our outstanding common stock and their respective affiliates beneficially own a substantial amount of our outstanding common stock as of June 30, 2023. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, 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. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. 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.

***Failure to build and maintain our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.***

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the regulations of The Nasdaq Global Select Market, the rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We may experience difficulty in meeting these reporting requirements in the future.

The process of building and maintaining our accounting and financial functions and infrastructure has required and will continue to require significant additional professional fees, internal costs and management efforts. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all

errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

***Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and limit our stock price.***

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, the amended and restated certificate of incorporation and amended and restated bylaws:

- permit the board of directors to issue up to 100,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes;
- provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;
- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors; and
- provide that stockholders are permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

***Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our***

***stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could have a material adverse effect on our business, financial condition, and results of operations.

### **General Risk Factors**

***Our advisors and consultants are classified as independent contractors, and we can face consequences if it is determined that they are misclassified as such.***

There is often uncertainty in the application of worker classification laws, and consequently there is risk to us that our independent contractors could be deemed to be misclassified under applicable law. The tests governing whether a service provider is an independent contractor or an employee are typically highly fact sensitive and can vary by governing law. Laws and regulations that govern the status and misclassification of independent contractors are also subject to divergent interpretations by various authorities, which can create uncertainty and unpredictability. A misclassification determination or allegation creates potential exposure for us, including but not limited to monetary exposure arising from or relating to failure to withhold and remit taxes, unpaid wages, and wage and hour laws and requirements (such as those pertaining to minimum wage and overtime); claims for employee benefits, social security, workers' compensation and unemployment; claims of discrimination, harassment, and retaliation under civil rights laws; claims under laws pertaining to unionizing, collective bargaining, and other concerted activity; and other claims, charges, or other proceedings under laws and regulations applicable to employers and employees, including risks relating to allegations of joint employer liability. Such claims could result in monetary damages (including but not limited to wage-based damages or restitution, compensatory damages, liquidated damages, and punitive damages), interest, fines, penalties, costs, fees (including but not limited to attorneys' fees), criminal and other liability, assessment, or settlement. Such an allegation, claim, adverse determination, including but not limited to with respect to advisors and consultants that provide services to us could also harm our brand and reputation, which could adversely impact our business.

***If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.***

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, 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 to decline.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market, 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. We have hired, and we expect that we will continue to need to hire, additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We continue to evaluate and monitor these rules and regulations 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.

***If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.***

As a public company, we are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

***Attention to ESG (environmental, social and governance) matters may cause us to incur additional costs or expose us to additional risks.***

A variety of stakeholder groups, including investors, governmental and nongovernmental organizations are focused on corporate environmental, social and governance, or ESG, practices. Our ESG practices may not meet the standards of our investors or other stakeholders, and they as well as advocacy groups may campaign for us to change our business, operations or practices to better address ESG-related concerns. A failure, or perceived failure, of us to respond to any such campaigns could harm our business and reputation and have a negative impact on the market price of our common stock. Moreover, if ESG best practices, reporting standards and disclosure requirements continue to develop, we may incur increasing costs related to ESG monitoring and reporting.

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

None.

***Use of Proceeds from Initial Public Offering***

On September 22, 2020, we closed our IPO, in which we sold and issued 12,000,000 shares of our common stock at a price to the public of \$17.00 per share. On October 16, 2020, we sold and issued an additional 1,397,712 shares of common stock at \$17.00 per share, less underwriting discounts and commissions, to the underwriters of our IPO following the partial exercise of their option to purchase additional shares of common stock.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-248428), which was declared effective by the SEC on September 17, 2020.

There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 18, 2020.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits.**

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Company</a>	10-Q	001-39503	3.1	November 12, 2020
3.2	<a href="#">Amended and Restated Bylaws of the Company</a>	8-K	001-39503	3.1	November 18, 2022
10.1*	<a href="#">Employment Offer Letter between the Company and Andrew Gengos, dated as of May 18, 2023.</a>	8-K	001-39503	10.1	May 22, 2023
10.2*	<a href="#">Change in Control and Severance Agreement between the Company and Andrew Gengos, dated as of May 18, 2023.</a>	8-K	001-39503	10.2	May 22, 2023
10.3*	<a href="#">Transition Services Agreement between the Company and Glenna Mileson, dated as of May 18, 2023.</a>	8-K	001-39503	10.3	May 22, 2023
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2	<a href="#">Certification of Principal Accounting and Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
32.2**	<a href="#">Certification of Principal Accounting and Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
101.INS	Inline XBRL Instance Document				
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 in Inline XBRL and included in Exhibit 101)				

\* Indicates a management contract or compensatory plan.

\*\* The certifications filed as Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.



**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.

**Athira Pharma, Inc.**

Date: August 10, 2023

By: /s/ Mark Litton  
Mark Litton  
President and Chief Executive Officer (*Principal Executive Officer*)

Date: August 10, 2023

By: /s/ Andrew Gengos  
Andrew Gengos  
Chief Financial Officer and Chief Business Officer (*Principal Financial and Accounting Officer*)



**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Litton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athira Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2023

/s/ Mark Litton

Mark Litton

*President and Chief Executive Officer*

*(Principal Executive Officer)*

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**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andrew Gengos, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athira Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2023

/s/ Andrew Gengos

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Andrew Gengos

*Chief Financial Officer and Chief Business Officer*

*(Principal Financial and Accounting Officer)*

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

In connection with the Quarterly Report on Form 10-Q of Athira Pharma, Inc. (the "Company") for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Litton, President and Chief Executive Officer (*Principal Executive Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: August 10, 2023

/s/ Mark Litton

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Mark Litton

*President and Chief Executive Officer*

*(Principal Executive Officer)*

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

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

In connection with the Quarterly Report on Form 10-Q of Athira Pharma, Inc. (the "Company") for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Gengos, Chief Financial Officer and Chief Business Officer (*Principal Financial and Accounting Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: August 10, 2023

/s/ Andrew Gengos

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Andrew Gengos

*Chief Financial Officer and Chief Business Officer*

*(Principal Financial and Accounting Officer)*

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

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