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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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: 001-38560

WHITEHAWK THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**61-1547850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 Headquarters Plaza, East Building, 11th Floor Morristown, NJ	**07960**
(Address of principal executive offices)	**(Zip Code)**

(551) 321-2234
(Registrant's telephone number, including area code)
(Former name, former address and former fiscal year, if changed since last report)

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	WHWK	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of November 5, 2026, the registrant had 59,008,982 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

WHITEHAWK THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share data and par value)

(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 68,973	$ 37,568
Short-term investments	100,699	108,129
Prepaid expenses and other current assets	2,299	3,316
Total current assets	171,971	149,013
Property and equipment, net	3	3
Operating lease right-of-use assets	212	—
Other assets	1,500	1,814
Total assets	$ 173,686	$ 150,830
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,224	$ 917
Accrued liabilities	8,087	13,602
Operating lease liabilities, current portion	130	—
Total current liabilities	10,441	14,519
Operating lease liabilities, net of current portion	88	—
Total liabilities	10,529	14,519
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 59,008,982 and 47,145,719 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	5	4
Additional paid-in capital	576,661	489,437
Accumulated other comprehensive (loss) income	(216)	120
Accumulated deficit	(413,293)	(353,250)
Total stockholders' equity	163,157	136,311
Total liabilities and stockholders' equity	$ 173,686	$ 150,830

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

WHITEHAWK THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income

(In thousands, except share data and earnings per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue				
Product sales, net	$ —	$ —	$ —	$ 7,145
Total revenue	—	—	—	7,145
Operating expenses				
Selling, general and administrative	4,805	5,201	16,311	23,956
Research and development	18,138	14,345	48,263	71,942
Cost of goods sold	—	—	—	760
Total operating expenses	22,943	19,546	64,574	96,658
Loss from operations	(22,943)	(19,546)	(64,574)	(89,513)
Other income (expense)				
Gain on sale of business	—	(177)	—	87,266
Foreign exchange loss	(3)	—	(9)	(3)
Other income	—	127	—	285
Interest income	1,737	1,850	4,540	4,620
Total other income (expense), net	1,734	1,800	4,531	92,168
(Loss) income before income tax expense	(21,209)	(17,746)	(60,043)	2,655
Income tax expense (benefit)	—	—	—	—
Net (loss) income	$ (21,209)	$ (17,746)	$ (60,043)	$ 2,655
Other comprehensive (loss) income:				
Unrealized (loss) gain on investments, net of tax	(153)	130	(336)	123
Comprehensive (loss) income	(21,362)	(17,616)	(60,379)	2,778
Net (loss) income per share:				
Basic	$ (0.23)	$ (0.26)	$ (0.73)	$ 0.04
Diluted	$ (0.23)	$ (0.26)	$ (0.73)	$ 0.04
Weighted average shares outstanding:				
Basic	93,866,642	69,204,899	82,086,813	59,417,911
Diluted	93,866,642	69,204,899	82,086,813	60,057,872

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

WHITEHAWK THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity

(In thousands, including share amounts)

(Unaudited)

	For the Three and Nine Months Ended September 30, 2026					
	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balance at December 31, 2025	47,145	$ 4	$ 489,437	$ 120	$ (353,250)	$ 136,311
Share-based compensation expense	—	—	2,193	—	—	2,193
Issuance of common stock in conjunction with vesting of restricted stock units	51	—	—	—	—	—
Unrealized loss on investments, net of tax	—	—	—	(135)	—	(135)
Net loss	—	—	—	—	(22,194)	(22,194)
Balance at March 31, 2026	47,196	$ 4	$ 491,630	$ (15)	$ (375,444)	$ 116,175
Share-based compensation expense	—	—	1,520	—	—	1,520
Issuance of common stock upon exercise of warrants	3,210	—	—	—	—	—
Issuance of common stock upon exercise of stock options	24	—	56	—	—	56
Issuance of common stock under the employee stock purchase plan	16	—	28	—	—	28
Issuance of common stock in conjunction with vesting of restricted stock units	2,232	—	—	—	—	—
Private placement, net of transaction costs	4,331	1	81,833	—	—	81,834
Unrealized loss on investments, net of tax	—	—	—	(48)	—	(48)
Net loss	—	—	—	—	(16,640)	(16,640)
Balance at June 30, 2026	57,009	$ 5	$ 575,067	$ (63)	$ (392,084)	$ 182,925
Share-based compensation expense	—	—	1,746	—	—	1,746
Issuance of common stock upon exercise of warrants	2,000	—	—	—	—	—
Private placement, net of transaction costs	—	—	(152)	—	—	(152)
Unrealized loss on investments, net of tax	—	—	—	(153)	—	(153)
Net loss	—	—	—	—	(21,209)	(21,209)
Balance at September 30, 2026	59,009	$ 5	$ 576,661	$ (216)	$ (413,293)	$ 163,157

WHITEHAWK THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity

(In thousands, including share amounts)

(Unaudited)

	For the Three and Nine Months Ended September 30, 2025					
	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balance at December 31, 2024	24,681	$ 2	$ 385,114	$ 16	$ (332,654)	$ 52,478
Share-based compensation expense	—	—	1,680	—	—	1,680
Issuance of common stock upon exercise of warrants	426	—	—	—	—	—
Issuance of common stock upon exercise of stock options	22	—	21	—	—	21
Issuance of common stock in conjunction with vesting of restricted stock units	63	—	—	—	—	—
Private placement, net of transaction costs	21,592	2	94,546	—	—	94,548
Unrealized loss on investments, net of tax	—	—	—	(15)	—	(15)
Net income	—	—	—	—	73,016	73,016
Balance at March 31, 2025	46,784	$ 4	$ 481,361	$ 1	$ (259,638)	$ 221,728
Share-based compensation expense	—	—	3,087	—	—	3,087
Issuance of shares under the employee stock purchase plan	16	—	24	—	—	24
Issuance of common stock upon exercise of stock options	3	—	5	—	—	5
Issuance of common stock in conjunction with vesting of restricted stock units	325	—	—	—	—	—
Private placement, net of transaction costs	—	—	(171)	—	—	(171)
Unrealized gain on investments, net of tax	—	—	—	8	—	8
Net loss	—	—	—	—	(52,615)	(52,615)
Balance at June 30, 2025	47,128	$ 4	$ 484,306	$ 9	$ (312,253)	$ 172,066
Share-based compensation expense	—	—	2,718	—	—	2,718
Unrealized gain on investments, net of tax	—	—	—	130	—	130
Net loss	—	—	—	—	(17,746)	(17,746)
Balance at September 30, 2025	47,128	$ 4	$ 487,024	$ 139	$ (329,999)	$ 157,168

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

WHITEHAWK THERAPEUTICS, INC.

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

	Nine months ended September 30, 2026	2025
Cash flows from operating activities:		
Net (loss) income	$ (60,043)	$ 2,655
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Share-based compensation expense	5,459	7,485
Gain on sale of business	—	(87,266)
Discount amortization on short-term investments	(1,048)	(696)
Non-cash lease expense	17	74
Depreciation expense	2	78
Changes in operating assets and liabilities:		
Accounts receivable	—	(1,000)
Inventory	—	170
Prepaid expenses and other current assets	2,988	(59)
Other non-current assets	439	(601)
Operating lease liabilities	(12)	(89)
Accounts payable and accrued liabilities	(4,212)	(748)
Other liabilities	—	(202)
Net cash used in operating activities	(56,410)	(80,199)
Cash flows from investing activities:		
Proceeds from sale of business, net cash, cash equivalents, and restricted cash	—	101,286
Purchases of property and equipment	(3)	(552)
Purchase of short-term investments	(105,415)	(125,770)
Maturity of short-term investments	111,587	20,081
Net cash provided by (used in) investing activities	6,169	(4,955)
Cash flows from financing activities:		
Proceeds from sale of common stock and prefunded warrants in PIPE financing	87,500	100,002
Proceeds from issuance of common stock under employee stock purchase plan	29	24
Issuance of common stock upon exercise of stock options	56	26
Payment of PIPE financing related transaction costs	(5,819)	(5,625)
Deferred offering costs paid for financing	(120)	(76)
Net cash provided by financing activities	81,646	94,351
Net increase in cash and cash equivalents	31,405	9,197
Cash, cash equivalents and restricted cash, beginning of period	37,568	28,734
Cash and cash equivalents, end of period	$ 68,973	$ 37,931
Supplemental disclosure of cash flow information:		
Deferred offering costs included in accounts payable and accrued liabilities	$ 5	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 227	$ —

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

WHITEHAWK THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of Organization and Operations

Whitehawk Therapeutics, Inc. (together with its subsidiaries, the "Company") is a clinical-stage oncology therapeutics company applying advanced technologies to established tumor biology that are intended to efficiently develop improved cancer treatments. The Company has deep experience in chemistry, formulation, and drug delivery, as well as research, clinical, and commercial pharmaceutical development, and taking product candidates from the clinic to approval, launch, and commercialization.

Current ADC Business

On December 19, 2024, the Company entered into an intellectual property license agreement (the "License Agreement") with WuXi Biologics (Shanghai FX) Co., Ltd. ("WuXi Biologics") for the development and global commercialization of a portfolio of three next generation antibody drug conjugates ("ADCs") targeting clinically validated, broadly overexpressed tumor antigens in high potential cancer indications with significant unmet need. Refer to Note 7 for further information on the WuXi Biologics License Agreement and its terms.

Legacy FYARRO Business

For the periods presented and through the FYARRO Divestiture (as defined below), the Company's lead drug product was FYARRO® (sirolimus protein-bound particles for injectable suspension (albumin-bound); nab-sirolimus). The Company exclusively licensed FYARRO, previously called ABI-009, nab-sirolimus, from Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company ("BMS"). The Company refers to the development, production and commercial sale of FYARRO herein as the "FYARRO Business". On February 22, 2022, the Company launched FYARRO in the United States for treatment of advanced malignant perivascular epithelioid cell tumor ("PEComa").

On December 19, 2024, the Company entered into a Stock Purchase Agreement (the "Divestiture Agreement") with KAKEN INVESTMENTS INC., a Delaware corporation ("KAKEN"), KAKEN PHARMACEUTICAL CO., LTD, and Aadi Subsidiary, Inc., a Delaware corporation and the Company's former wholly owned subsidiary and the operating company for the FYARRO Business ("Aadi Subsidiary"). Under the Divestiture Agreement, KAKEN acquired 100% of the outstanding shares of capital stock of Aadi Subsidiary from the Company for a cash payment of $102.4 million (following applicable purchase price adjustments under the Divestiture Agreement) (the "FYARRO Divestiture"). The FYARRO Divestiture closed on March 25, 2025 and, as a result, the Company no longer operates the FYARRO Business.

Company Name Change

In connection with the FYARRO Divestiture, the Company changed the Company's name from "Aadi Bioscience, Inc." to "Whitehawk Therapeutics, Inc." and the Company's common stock thereafter has been traded under the symbol "WHWK".

Merger with Aerpio Pharmaceuticals, Inc.

On August 26, 2021 (the "Closing Date"), Aadi Bioscience, Inc., a Delaware corporation (f/k/a Aerpio Pharmaceuticals, Inc.), completed its business combination with Aadi Subsidiary, Inc. (f/k/a Aadi Bioscience, Inc., or "Private Aadi"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated May 16, 2021, by and among the Company, Aspen Merger Subsidiary, Inc. ("Merger Sub") and Private Aadi (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Private Aadi, with Private Aadi surviving as a wholly owned subsidiary of the Company (the "Reverse Merger") until the FYARRO Divestiture.

Liquidity

Since inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations. Prior to the FYARRO Divestiture, the Company also realized revenues from the commercial sale of FYARRO.

The Company has experienced net losses since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $413.3 million as of September 30, 2026, and net loss of $60.0 million and net income of $2.7 million for the nine months ended September 30, 2026 and 2025, respectively. The net income recorded for the nine months ended September 30, 2025 is primarily attributable to the gain on sale related to the FYARRO Divestiture. Prior to the FYARRO Divestiture, the Company's operating losses were funded primarily from outside sources of invested capital through the issuance of convertible promissory notes, grant funding, the sale of securities, and proceeds from license agreements.

The Company had cash, cash equivalents and short-term investments of $169.7 million at September 30, 2026. Management believes the Company's cash, cash equivalents and short-term investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the issuance of these financial statements. If the Company is unable to achieve and maintain profitability, it will need additional financing to support its continuing operations and pursue its strategic objectives. Additional financing may be achieved through a combination of equity offerings and debt financing. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all.

On March 17, 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company may offer and sell, from time to time at the Company's sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through Cowen as its sales agent for an at-the-market-offering. Any sales under the Sales Agreement may result in dilution to existing shareholders. As of September 30, 2026, no shares of common stock had been sold under this Sales Agreement.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements, and the related disclosures, have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and U.S. Securities and Exchange Commission ("SEC") regulations and, in the opinion of management include all adjustments necessary for a fair presentation of the results of operations, financial position, changes in stockholders' equity and cash flows for each period presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The Company's condensed consolidated financial statements are stated in U.S. dollars.

The financial statements noted above reflect the financial position and results of operations of the Company. The comparative period includes the results of operations of the Company and Aadi Subsidiary, prior to its sale on March 25, 2025. The transaction did not meet the criteria for discontinued operations under ASC 205-20, and therefore no reclassification has been made to prior period statements.

The condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025 excludes the assets and liabilities of Aadi Subsidiary, which were divested as of the sale date. See Note 14 for additional information.

Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, the accompanying unaudited condensed consolidated interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto for

the year ended December 31, 2025, which are included in the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2026.

Risks and Uncertainties

Following the FYARRO Divestiture, the Company is a clinical-stage biopharmaceutical company with a limited operating history and three clinical product candidates and additional preclinical programs. The Company's ability to generate revenue and achieve profitability depends significantly on the ability to achieve several objectives relating to the discovery, development and commercialization of the Company's portfolio of three next generation antibody drug conjugates (the "ADC Therapies") and any other product candidates that may be developed in the future.

Comprehensive (Loss) Income

Comprehensive (loss) income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments. Comprehensive (loss) income has been reflected in the condensed consolidated statements of operations and comprehensive (loss) income for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. In the opinion of management, all adjustments that are considered necessary for fair presentation have been included. The most significant estimates in the Company's condensed consolidated financial statements relate to share-based compensation expense and accrued research and development costs. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Restructuring Charges

Restructuring charges consist primarily of employee severance, contract termination costs and other costs. Liabilities for costs associated with a restructuring activity are recognized when the liability is incurred and are measured at fair value. For one-time employee termination benefits, the Company recognizes the liability in full on the communication date when future services are not required or amortizes the liability ratably over the service period, if required. The fair value of termination benefits reflects the Company's estimate of expected utilization of certain Company-funded post-employment benefits. One-time termination benefits include severance and continuation of health insurance coverage for certain employees.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents, and available-for-sale marketable debt securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception.

Customer Concentration

The Company did not have customer revenue for the three and nine months ended September 30, 2026 and the three months ended September 30, 2025. For the nine months ended September 30, 2025, two customers represented 37% and 60% of the Company's revenue.

The Company did not have accounts receivable as of September 30, 2026 and December 31, 2025.

Cash and Cash Equivalents

The Company considers all highly liquid marketable securities purchased with original maturities of three months or less at the date of purchase to be cash equivalents.

Fair Value of Financial Instruments

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

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

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

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions which reflect those that a market participant would use

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

In determining the fair value of its financial instruments, the Company considers the source of observable market data inputs, liquidity of the instrument, the credit risk of the counterparty to the contract, and its risk of nonperformance. In the case fair value is not observable, for the items subject to fair value measurements, the Company applies valuation techniques deemed the most appropriate under the GAAP guidance based on the nature of the assets and liabilities being measured.

The carrying amounts of cash equivalents, accounts payable, and accrued liabilities are reasonable estimates of their fair value because of the short maturity of these items.

Short-Term Investments

The Company invests in various types of securities, including United States government treasury bills, commercial paper, and corporate debt securities. The Company classifies its investments as available-for-sale and records them at fair value based upon market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive income as a separate component of stockholders' equity. Dividend and interest income are recognized when earned. The Company recognizes purchase premiums and discounts as interest income using the interest method over the terms of the securities. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold. The Company classifies short-term investments with remaining maturities greater than one year as current assets because such short-term investments are available to fund the Company’s current operations.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the decline in fair value below amortized cost is a result of credit losses or other factors, whether the Company expects to recover the amortized cost of the security, the Company's intent to sell and if it is more likely than not that the Company will be required to sell the securities before the recovery of amortized cost. The Company records changes in allowance for expected credit loss in other income (expense), net. There has been no allowance for expected credit losses recorded during any of the periods presented. See Note 4 for further information.

Property and Equipment, Net

Property and equipment, consisting of computers and software, furniture and fixtures, and construction in process are stated at cost, less accumulated depreciation. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Such costs are periodically reviewed for recoverability when impairment indicators are present.

Details of property and equipment are presented as follows (in thousands):

	September 30, 2026	December 31, 2025
Computers and Software	$ 341	$ 341
Furniture and fixtures	36	36
Construction in process	2	—
Total	$ 379	$ 377
Accumulated depreciation	(376)	(374)
Property and equipment, net	$ 3	$ 3

Depreciation expense on property and equipment amounted to $0.8 thousand and $5.6 thousand for the three months ended September 30, 2026 and 2025, respectively. Depreciation expense on property and equipment amounted to $2.4 thousand and $0.1 million for the nine months ended September 30, 2026 and 2025, respectively.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months.

The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: (i) the lease has a purchase option that is reasonably certain of being exercised, (ii) the present value of the future cash flows is substantially all of the fair market value of the underlying asset, (iii) the lease term is for a significant portion of the remaining economic life of the underlying asset, (iv) the title to the underlying asset transfers at the end of the lease term, or (v) if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized at the commencement date of the lease based on the present value of lease payments over the expected lease term.

Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. For finance leases, depreciation expense is recognized for the leased asset acquired and interest expense is recognized related to the portion of the financing in the condensed consolidated statements of operations and comprehensive (loss) income. For operating leases, lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expense in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in

proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable that a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of September 30, 2026 and December 31, 2025.

Revenue Recognition and Related Allowances

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, Revenue from Contracts with Customers ("Topic 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Net Sales

FYARRO was approved by the FDA in November 2021. On February 22, 2022, the Company launched sales of FYARRO to specialty distributors ("SDs") and a specialty pharmacy ("SP"). The Company recognizes product sales when the SDs and SP obtain control of the product. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowance for rebates includes mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. The Company's estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to the Company the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued at the time of product sale to SDs and SP based on estimated patient participation and average co-pay benefit to be paid per claim. The Company's estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

Product Returns: Consistent with industry practice, the Company offers the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SDs and SP and has the ability to control the amount of product that is sold to the SDs and SP the Company's estimate of future potential product returns is based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Revenue and allowances described above were recorded through the FYARRO Divestiture date of March 25, 2025. The total amount deducted from gross product sales for the allowances described above for the three months ended September 30, 2026 and 2025 was $0. The total amount deducted from gross product sales for the allowances described above for the nine months ended September 30, 2026 and 2025 was $0 and $2.1 million, respectively.

The following table sets forth the changes in the accrued revenue allowances (in thousands):

	Nine Months Ended September 30, 2025
Balance at beginning of period	$ 1,411
Provision for current period sales	2,085
Payments	(1,686)
Allowances transferred in sale of Aadi Subsidiary, Inc.	(1,810)
Balance at end of period	$ —

Cost of Goods Sold

Cost of goods sold consists primarily of royalties paid to BMS, costs incurred on sales of FYARRO and costs to manufacture and prepare the product for sales subsequent to the FDA approval in November 2021. Cost of goods sold was recorded through the FYARRO Divestiture date of March 25, 2025.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, share-based compensation expense, contract services, and other external development expenses. The Company records research and development activities conducted by third-party service providers, which include work related to preclinical studies, clinical trials, and contract manufacturing activities, to research and development expense as incurred. The Company is required to estimate the amount of services provided but not yet invoiced and include these expenses in accrued expenses on the condensed consolidated balance sheets and within research and development expenses in the condensed consolidated statements of operations and comprehensive (loss) income. These expenses are a significant component of the Company's research and development expenses and require significant estimates and judgments. The Company accrues for these expenses based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. As actual expenses become known, the Company adjusts its accrued expenses.

In-Process Research and Development (IPR&D)

Acquired in-process research and development expenses are recorded when incurred and reflect costs of externally-developed in-process research and development ("IPR&D") projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use, including upfront and pre-commercialization milestone payments related to various collaborations and the costs of rights to IPR&D projects. Refer to Note 7 for further information on the License Agreement and its terms.

For the three months ended September 30, 2026 and 2025, the Company recorded $3.2 million and $0, respectively, in IPR&D for development milestone-related expense. The Company recorded $8.5 million and $40.4 million in IPR&D for development milestone-related expense for the nine months ended September 30, 2026 and 2025, respectively.

Warrants

The Company determines the accounting classification of warrants it issues as either liability or equity classified by first assessing whether the warrants meet the liability classification in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480"), then in accordance with ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ("ASC 815"). If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40. In order for a warrant to be classified in stockholders' equity, the warrant must be (a) indexed to the Company's equity and (b) meet the conditions for equity classification in ASC 815-40, Derivatives and Hedging - Contracts in an Entity's Own Equity. If a warrant does not meet the conditions for equity classification, it is carried on the balance sheet as a warrant liability measured at fair value, with subsequent changes in the fair value of the warrant recorded in the statement of operations as change in fair value of warrants in other income (expense). If a warrant meets both conditions for equity classification, the warrant is initially recorded in additional paid-in capital on the balance sheets, and the amount initially recorded is not subsequently remeasured at fair value. The Company has classified its pre-funded warrants as equity.

Share-Based Compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options and restricted stock units in the condensed consolidated statements of operations and comprehensive (loss) income based on their fair values. All of the Company's share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. Compensation expense for awards to employees is calculated on a straight-line basis by recognizing the fair value over the associated service period of the award, which is generally the vesting term. Options granted during the year have a maximum contractual term of ten years.

Employee Stock Purchase Plan

Share-based compensation expense for employee stock purchases under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") is recorded at the estimated fair value of the purchase as of the plan enrollment date and is recognized as an expense on a straight-line basis over the applicable six-month 2021 ESPP offering period.

Other Income (Expense)

During the three and nine months ended September 30, 2026, other income includes interest income earned on cash, cash equivalents and short-term investments, and foreign exchange loss. During the three months ended September 30, 2025, other income includes interest income earned on cash, cash equivalents, short-term investments, foreign exchange loss, and income received for billable services not part of the Company's ordinary activities provided by its employees to KAKEN under a Transition Services Agreement ("TSA"). The TSA was entered into in connection with the sale of the business on March 25, 2025 and expired September 30, 2025. During the nine months ended September 30, 2025 other income includes interest income earned on cash, cash equivalents, short-term investments, gain on sale of a business,

foreign exchange loss, and income received for billable services not part of the Company's ordinary activities provided by its employees to KAKEN under the TSA.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense (benefit).

Net (Loss) Income per Share

Basic net (loss) income per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Basic and diluted weighted average shares of common stock outstanding for the three and nine months ended September 30, 2026 includes the weighted average effect of 17,991,021 and 16,866,574 pre-funded warrants, respectively, which were issued in May 2026 and March 2025, respectively. Basic and diluted weighted average shares of common stock outstanding for the three and nine months ended September 30, 2025 includes the weighted average effect of 20,076,500 and 2,000,037 pre-funded warrants, which were issued in March 2025 and September 2022, respectively. The pre-funded warrants were issued for the purchase of shares of common stock, for which the remaining unfunded exercise price is $0.0001 per share. See Note 8 for more information on the pre-funded warrants.

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive.

The Company incurred net losses for the three and nine months ended September 30, 2026 and therefore did not include potentially dilutive common stock equivalents in the computation of diluted net loss per share. For the three months ended September 30, 2025, the Company incurred net losses and therefore did not include potentially dilutive common stock equivalents in the computation of diluted net loss per share. For the nine months ended September 30, 2025 options to purchase common stock totaling 3,805,985 shares, were excluded from the calculation of diluted net income per share as their effect would have been anti-dilutive.

The computations for basic and diluted EPS were as follows (in thousands, except shares and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net (loss) income for basic and diluted EPS	$ (21,209)	$ (17,746)	$ (60,043)	$ 2,655
Weighted-average shares for basic EPS	93,866,642	69,204,899	82,086,813	59,417,911
Effect of dilutive stock options	—	—	—	35,423
Effect of dilutive restricted stock units	—	—	—	604,538
Weighted-average shares for diluted EPS	93,866,642	69,204,899	82,086,813	60,057,872
Net income (loss) per share:				
Basic EPS	$ (0.23)	$ (0.26)	$ (0.73)	$ 0.04
Diluted EPS	$ (0.23)	$ (0.26)	$ (0.73)	$ 0.04

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. ASU 2024-03 requires additional disclosure of the nature of expenses included in the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2024-03 on the financial statements and related disclosures.

On December 8, 2025, the FASB issued Accounting Standards Update ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements, which primarily amends FASB Accounting Standards Codification 270, Interim Reporting, clarifying the applicability of the interim reporting guidance, the types of interim reporting, and the form and content of interim financial statements. The amendments in ASU 2025-11 apply to all entities that provide interim financial statements and notes in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Early adoption is permitted. ASU 2025-11 can be applied prospectively or retrospectively and is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is evaluating the impact of ASU 2025-11 on the financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, "Codification Improvements." This ASU addresses suggestions received from stakeholders regarding the Accounting Standards Codification and makes other incremental improvements to U.S. GAAP. The update represents changes to the Codification that clarify, correct errors in or make other improvements to a variety of topics that are intended to make it easier to understand and apply. ASU 2025-12 is effective for fiscal years beginning after December 15, 2026 and interim periods within those fiscal years. Entities are required to apply the amendments to ASC 260 retrospectively. All other amendments may be applied prospectively or retrospectively. The Company is evaluating the effect that ASU 2025-12 will have on its consolidated financial statements and related disclosures.

3. Fair Value Measurement

The following table sets forth the recurring fair value of the Company's financial assets and liabilities, allocated into the Level 1, Level 2 and Level 3 hierarchy that were measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	$ 68,723	$ —	$ —	$ 68,723
U.S. government treasury bills	49,021	—	—	49,021
Commercial paper	—	13,667	—	13,667
Corporate bonds	—	38,011	—	38,011
Total financial assets	$ 117,744	$ 51,678	$ —	$ 169,422

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	$ 37,318	$ —	$ —	$ 37,318
U.S. government treasury bills	43,881	—	—	43,881
Commercial paper	—	16,262	—	16,262
Corporate bonds	—	47,986	—	47,986
Total financial assets	$ 81,199	$ 64,248	$ —	$ 145,447

(1) Included in cash and cash equivalents in the accompanying condensed consolidated balance sheets.

4. Short-Term Investments and Cash Equivalents

The following table summarizes the Company's short-term investments (in thousands):

		As of September 30, 2026			
	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds		$ 68,723	$ —	$ —	$ 68,723
U.S. government treasury bills	Less than 1	47,593	—	(76)	47,517
Commercial paper	Less than 1	13,696	—	(29)	13,667
Corporate bonds	Less than 1	32,659	3	(78)	32,584
U.S. government treasury bills	More than 1 less than 2	1,512		(8)	1,504
Corporate bonds	More than 1 less than 2	5,455	—	(28)	5,427
Total		$ 169,638	$ 3	$ (219)	$ 169,422

		As of December 31, 2025			
	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds		$ 37,318	$ —	$ —	$ 37,318
U.S. government treasury bills	Less than 1	43,857	24	—	43,881
Commercial paper	Less than 1	16,239	23	—	16,262
Corporate bonds	Less than 1	44,907	66		44,973
Corporate bonds	More than 1 less than 2	3,006	7	—	3,013
Total		$ 145,327	$ 120	$ —	$ 145,447

As of September 30, 2026, available-for-sale debt securities in unrealized loss positions had an aggregate fair value of $96.1 million and gross unrealized losses of $0.2 million. The available-for-sale debt securities have been in unrealized loss positions for less than 12 months. There were no available-for-sale debt securities in unrealized loss positions as of

December 31, 2025. The unrealized losses were attributable to changes in market interest rates and not to deterioration in the creditworthiness of the issuers. The Company does not intend to sell these securities, and it is not more likely than not that the Company will be required to sell them before recovery of their amortized cost basis, which may be at maturity. No allowance for credit losses was recorded as of September 30, 2026 or December 31, 2025. No realized losses were recorded as of September 30, 2026 and December 31, 2025.

5. Accrued Liabilities

Details of accrued liabilities are presented as follows (in thousands):

	September 30, 2026	December 31, 2025
Accrued professional fees	$ 548	$ 968
Accrued salaries and payroll	1,295	602
Accrued restructuring charges	—	192
Accrued bonus	2,576	3,160
Accrued contract manufacturing	43	3,935
Accrued clinical	1,618	12
Accrued research and development	1,897	4,627
Accrued other	110	106
Total accrued liabilities	$ 8,087	$ 13,602

6. Operating Leases

In April 2019, the Company entered into a twenty-eight month facility lease agreement for office space in Pacific Palisades, California (the "Pacific Palisades Lease"). The Pacific Palisades Lease commenced on May 1, 2019, included four months of rent abatement and a rent escalation clause and was set to expire on August 31, 2021. In August 2021, the Company exercised its option to extend the term of the Pacific Palisades Lease for an additional three-year period and entered into an amendment to the lease agreement (the "Pacific Palisades Lease Amendment"). Pursuant to the Pacific Palisades Lease Amendment, the Company and the landlord agreed to extend the term for an additional period of three (3) years and six (6) months, until February 28, 2025, with an option to renew for an additional three (3) years in accordance with the terms of the Pacific Palisades Lease. Included in the Pacific Palisades Lease Amendment were nine months of rent abatement and a rent escalation clause. The Pacific Palisades Lease expired on February 28, 2025.

In April 2022, the Company entered into a lease agreement for office space in Morristown, New Jersey (the "Morristown Lease"). The Morristown Lease has a term of seventy-three months, unless terminated sooner, and includes rent abatement for the first three months and the forty-seventh and forty-eighth calendar months after lease commencement. Included in the Morristown Lease are fixed rent escalations of approximately 2% on each anniversary year of the lease term. In connection with the FYARRO Divestiture, KAKEN assumed the Morristown Lease.

In August 2026, the Company's sublease agreement with KAKEN for shared office space became effective upon receipt of landlord and sublandlord consent. The agreement has a term of twenty-one months and expires in May 2028. The Company accounts for the arrangement as an operating lease under ASC 842, with the related right-of-use asset and lease liability recognized in the condensed consolidated balance sheets.

The following table summarizes information related to the Company's leases (in thousands):

	September 30, 2026	December 31, 2025
Assets:		
Operating lease right-of-use assets	$ 212	$ —
Liabilities:		
Operating lease liabilities, current	$ 130	$ —
Operating lease liabilities, non-current	88	—
Total operating lease liabilities	$ 218	$ —

Rent expense for the three and nine months ended September 30, 2026 and 2025 is presented on the following table (in thousands):

	Three Months Ended September 30, 2026	2025	Nine Months Ended September 30, 2026	2025
Operating lease rent expense	$ 41	$ 34	$ 87	$ 142

Cash paid for leases and included in operating cash flows for the nine months ended September 30, 2026 and 2025 is presented on the following table (in thousands):

	Nine Months Ended September 30, 2026	2025
Cash paid included in operating cash flows	$ —	$ 99

The future minimum lease payments required under the operating leases as of September 30, 2026, are summarized below (in thousands):

Future Minimum Lease Payments:	
2026	$ 34
2027	140
2028	54
Total minimum lease payments	$ 228
Less: amount representing interest	(10)
Present value of operating lease liabilities	$ 218
Less: operating lease liabilities, current	(130)
Operating lease liabilities, non-current	$ 88
Remaining lease term (in years)	1.6
Incremental borrowing rate	6.75%

7. License Agreements

Former Bristol-Myers Squibb Company License Agreement

On April 9, 2014, the Company entered into a license agreement (as amended the "BMS License Agreement") with BMS for exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to FYARRO.

The BMS License Agreement will remain in effect from the effective date of April 9, 2014 until expiration of all milestone and royalty payment obligations under the agreement, unless terminated by either of the parties pursuant to the terms of the BMS License Agreement, including providing advance notice as specified in the agreement. Under the terms of the BMS License Agreement, BMS agreed to supply the Company with licensed products of FYARRO necessary for clinical or non-clinical development.

Under the terms of the BMS License Agreement, BMS is entitled to receive royalties on net sales from licensed products under the agreement and any sublicense fees. During the three months ended September 30, 2026 and 2025, royalties on net product sales were $0. During the nine months ended September 30, 2026 and 2025, royalties on net product sales were $0 and $0.5 million, respectively. No payments related to sublicense fees were paid during the three and nine months ended September 30, 2026 and 2025.

As part of its purchase of the FYARRO Business, KAKEN acquired the Company's rights and responsibilities under the BMS License Agreement.

WuXi Biologics License Agreement

On December 19, 2024, the Company entered into an Intellectual Property License Agreement (the “License Agreement”) with WuXi Biologics (Shanghai FX) Co., Ltd. (“WuXi Biologics”) for exclusive rights to certain patents and know-how pertaining to WuXi Biologics’ preclinical antibody drug conjugate programs leveraging Hangzhou DAC Biotechnology Co., Ltd.’s (“Hangzhou DAC”) linker-payload technology targeting each of the ADC Therapies. Under the License Agreement, the Company paid WuXi Biologics a non-refundable, partial upfront payment of $6.0 million on December 20, 2024. An additional non-refundable, upfront payment of $38.0 million was due within one-hundred twenty (120) days after the effective date of the License Agreement for the rights and licenses granted to the Company by WuXi Biologics and was paid on April 16, 2025.

In accordance with the License Agreement, WuXi Biologics is eligible to receive from the Company (a) up to an aggregate of $265.0 million upon the achievement of certain development milestones, and (b) up to an aggregate of $540.0 million upon the achievement of certain commercial milestones, across all ADC Therapies. WuXi Biologics is also entitled to running royalties ranging from low-single-digit to upper-single-digit percentages of annual net sales of licensed products in the territory on a product-by-product and region-by-region basis from the first commercial sale of the applicable licensed product in a particular region until the date which is the later of (i) expiration of the last to expire valid claim of a license patent in such region covering the sale of such licensed product in such region or (ii) ten years after the first commercial sale of such licensed product in such region.

Each party may terminate the License Agreement in its entirety, or on a program-by-program basis, as applicable, if the other party remains in material breach of the License Agreement following a cure period to remedy the material breach or if the other party is declared insolvent or in similar financial distress. In addition, WuXi Biologics may terminate the License Agreement on a program-by-program basis if the Company does not meet certain development due diligence milestones. The Company may terminate the License Agreement in its entirety, or on a program-by-program basis, as applicable, with or without cause.

8. Stockholders’ Equity

Preferred Stock

As of September 30, 2026 and December 31, 2025, under the Company’s certificate of incorporation, as amended and restated, the Company has 10,000,000 shares of preferred stock, par value $0.0001 per share, in authorized capital with no shares outstanding.

Common Stock and Pre-Funded Warrants

As of September 30, 2026 and December 31, 2025, the Company had 300,000,000 shares of authorized common stock, par value of $0.0001 per share, under the Company's certificate of incorporation, as amended and restated. As of September 30, 2026 and December 31, 2025, the shares of common stock outstanding were 59,008,982 and 47,145,719, respectively.

In March 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC (“Cowen”), with respect to an “at the market offering” program pursuant to which the Company may offer and sell, from time to time at its sole discretion, shares of common stock having aggregate gross proceeds of up to $75.0 million through Cowen as its sales agent. The Company will pay Cowen 3.0% of the aggregate gross proceeds from each sale of shares of common stock under the Sales Agreement. As of September 30, 2026, no shares of common stock had been sold pursuant to the Sales Agreement.

On September 22, 2022, the Company entered into a securities purchase agreement (the “Purchase Agreement”) for a private investment in public equity financing (the “2022 PIPE Financing”) with certain investors (the “2022 PIPE Investors”) for the sale by the Company of (i) 3,373,526 shares of the Company’s common stock for a price of $12.50 per share and (ii) pre-funded warrants (the "2022 Pre-Funded Warrants") to purchase an aggregate of 2,426,493 shares of the Company's common stock at a purchase price of $12.4999 per 2022 Pre-Funded Warrant. The 2022 PIPE Financing closed on September 26, 2022. Aggregate net proceeds, after deducting certain expenses incurred of $0.3 million related

to the issuance of the securities, were $72.2 million. As of September 30, 2026, all of the 2022 Pre-Funded Warrants have been exercised.

On December 19, 2024, the Company entered into the Subscription Agreement for a private investment in public equity financing (the "2024 PIPE Financing") with certain investors (the "2024 PIPE Investors"), pursuant to which the Company agreed to sell to the 2024 PIPE Investors (i) 21,592,000 shares of the Company's common stock, par value $0.0001 per share, at a purchase price of $2.40 per share, and (ii) pre-funded warrants to purchase an aggregate of 20,076,500 shares of the Company's common stock (the "2024 Pre-Funded Warrants"), at a purchase price of $2.3999 per 2024 Pre-Funded Warrant, for aggregate net proceeds of $94.4 million, after deducting certain expenses incurred of $5.6 million related to the issuance of shares. The 2024 PIPE Financing was conditioned upon the Company's shareholders approving the 2024 PIPE Financing and closed on March 4, 2025 after such approval was obtained. As of September 30, 2026, 16,866,574 of the 2024 Pre-Funded Warrants were outstanding.

On May 13, 2026, the Company entered into a securities purchase agreement for a private investment in public equity financing (the "2026 PIPE Financing") with certain investors (the "2026 PIPE Investors"), pursuant to which the Company agreed to sell to the 2026 PIPE Investors (i) 4,330,866 shares of the Company's common stock, par value $0.0001 per share, at a purchase price of $3.92 per share, and (ii) pre-funded warrants to purchase an aggregate of 17,991,021 shares of the Company's common stock (the "2026 Pre-Funded Warrants" and together with the 2022 Pre-Funded Warrants and 2024 Pre-Funded Warrants, the "Pre-Funded Warrants"), at a purchase price of $3.9199 per 2026 Pre-Funded Warrant, for aggregate net proceeds of $81.7 million, after deducting certain expenses incurred of $5.8 million related to the issuance of shares. As of September 30, 2026, all 17,991,021 of the 2026 Pre-Funded Warrants were outstanding.

For each of the 2022 PIPE Financing, 2024 PIPE Financing and 2026 PIPE Financing, the Pre-Funded Warrants are exercisable at an exercise price of $0.0001 per share of the Company's common stock and will be exercisable until exercised in full. The holders of such Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% or 9.99%, at the election of the holder, of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. The holders of such Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

The Pre-Funded Warrants are indexed to the Company's common stock and meet the conditions for equity classification in accordance with ASC 815-40. As such, the Pre-Funded Warrants are classified as additional paid-in capital within the stockholders' equity on the Company's condensed consolidated balance sheets.

Dividends

The holders of common stock are entitled to receive cash dividends, if and when declared by the board of directors of the Company (the "board of directors"). Since the Company's inception, no cash dividends have been declared or paid to the holders of common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's assets.

Voting

The holders of common stock are entitled to one vote at all meetings of stockholders for each share of common stock held by such stockholders as of the record date.

9. Share-Based Compensation

2014 Plan (as amended and restated in February 2017, the "Private Aadi Plan")

In connection with the Reverse Merger, the Company assumed the Private Aadi Plan, which was amended and restated in February 2017, and the issued and outstanding stock options under the Private Aadi Plan (the Private Aadi common

stock underlying the awards was adjusted for shares of the Company's common stock pursuant to the Merger Agreement). The Private Aadi Plan allowed for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock unit awards and other stock awards. In connection with the closing of the Reverse Merger and the adoption of the 2021 Plan (as defined below), no further awards will be issued under the Private Aadi Plan.

The options that are granted from the Private Aadi Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The Private Aadi Plan stock options generally vest over a four-year term.

2011 Plan and 2017 Plan

In connection with the closing of the Reverse Merger, the Company assumed the Aerpio 2011 Equity Incentive Plan (the "2011 Plan") and the Aerpio 2017 Stock Option and Incentive Plan (the "2017 Plan," and together with the 2011 Plan, the "Prior Plans"). No new awards will be granted under the Prior Plans effective as of the closing of the Reverse Merger and the adoption of the 2021 Plan (as defined below).

2021 Plan

At the closing of the Reverse Merger, the Company adopted the Aadi Bioscience, Inc. 2021 Equity Incentive Plan, which is now named the Whitehawk Therapeutics, Inc. 2021 Equity Incentive Plan (the "2021 Plan"), which permits the award of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance grants to employees, members of the board of directors, and outside consultants.

Subject to the adjustment provisions contained in the 2021 Plan and the evergreen provision described below, a total of 2,070,784 shares of common stock were initially reserved for issuance pursuant to the 2021 Plan. In addition, the shares reserved for issuance under the 2021 Plan include any shares of common stock (i) subject to awards of stock options or other awards granted under the Prior Plans that expire or otherwise terminate without having been exercised in full and shares of common stock granted under the Prior Plans that are forfeited or repurchased by the Company, and (ii) any shares of common stock subject to stock options or similar awards granted under the Private Aadi Plan that were assumed in the Reverse Merger (provided that the maximum number of shares that may be added to the 2021 Plan pursuant to this provision is 764,154 shares).

From the adoption of the 2021 Plan until February 28, 2025, the number of shares available for issuance under the 2021 Plan included an annual increase, or the evergreen feature, on the first day of each of the Company's fiscal years, beginning with the Company's fiscal year 2022, equal to the least of:

- 2,070,784 shares of common stock;
- a number of shares equal to 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the board of directors or its designated committee may determine.

On February 28, 2025, the Company's stockholders approved the amendment and restatement of the 2021 Plan to (i) increase the number of shares available for future grant under the 2021 Plan from 2,000,284 shares to 8,300,284 shares and (ii) modify the 2021 Plan's default annual automatic share reserve increase occurring on January 1 of each year to be equal to the least of 8,300,284 shares, 5% of outstanding shares on the last day of the immediately preceding fiscal year, or such number of shares as the board of directors or its designated committee may determine. Upon stockholder approval, such amendment and restatement of the 2021 Plan became effective.

As a result of the evergreen increase, a total of 2,357,286 shares of common stock were added to the 2021 Plan on January 1, 2026 and 987,228 shares of common stock were added to the 2021 Plan on January 1, 2025.

Shares issuable under the 2021 Plan are authorized, but unissued, or reacquired shares of common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by the combined company due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated).

2023 Inducement Equity Incentive Plan

On September 27, 2023, the Company adopted the 2023 Inducement Equity Incentive Plan (the "Inducement Plan"), pursuant to which the Company may from time to time make equity grants to new employees as a material inducement to their employment. The Company reserved 600,000 shares of common stock for issuance under the Inducement Plan. The only persons eligible to receive awards under the Inducement Plan are individuals who are new employees and satisfy the standards for inducement grants under applicable Nasdaq listing rules.

As of September 30, 2026, 105,469, 15,036, 12,570,634, and 490,000 shares were outstanding under the Private Aadi Plan, 2017 Plan, 2021 Plan, and 2023 Inducement Plan, respectively.

The following table summarizes the stock option activity during the nine months ended September 30, 2026:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	8,120,654	$ 6.31	8.19	$ 2,642
Granted	4,093,120	3.73		
Exercised	(24,286)	2.29		
Cancelled/Forfeited	(41,539)	9.76		
Outstanding as of September 30, 2026	12,147,949	$ 5.44	8.20	$ 10,271
Options exercisable as of September 30, 2026	5,065,930	$ 8.71	6.89	$ 4,559
Vested and expected to vest as of September 30, 2026	12,147,949	$ 5.44	8.20	$ 10,271

As of September 30, 2026, there was $14.4 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 1.61 years.

The total intrinsic value of the options exercised during the three months ended September 30, 2026, and 2025, was $0. The total intrinsic value of the options exercised during the nine months ended September 30, 2026 and 2025 was $48.7 thousand and $43.6 thousand, respectively.

As of September 30, 2026, and December 31, 2025, 73,332 and 2,520,585 shares were reserved for future awards under the 2021 Plan, respectively. As of September 30, 2026 and December 31, 2025, 110,000 shares were reserved for future awards under the 2023 Inducement Plan.

Restricted Stock Units

Restricted stock consists of restricted stock unit awards ("RSUs") which have been granted to employees. The value of an RSU award is based on the Company's stock price on the date of grant. Employee grants vest over one to four years. Forfeitures of RSUs are recognized as they occur. The shares underlying the RSU awards are not issued until the RSUs vest. Upon vesting, each RSU converts into one share of the Company's common stock.

Activity with respect to the Company's restricted stock units during the nine months ended September 30, 2026 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Nonvested shares at December 31, 2025	2,452,690	$ 1.73
Granted	876,192	4.09
Vested/Issued	(2,282,458)	1.70
Forfeited	(13,234)	1.74
Nonvested shares at September 30, 2026	1,033,190	$ 3.78

As of September 30, 2026, there was $3.6 million of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 0.96 years.

Compensation Expense Summary

The Company recognized the following compensation cost related to employee and non-employee share-based compensation activity for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Selling, general and administrative	$ 1,055	$ 1,777	$ 3,383	$ 4,917
Research and development	691	941	2,076	2,568
Total	$ 1,746	$ 2,718	$ 5,459	$ 7,485

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for share-based option awards. Option pricing and models require the input of various assumptions, including the option's expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock. Forfeitures are recognized and accounted for as they occur.

The calculation was based on the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Weighted average grant date fair value (per share)	$3.96-$4.63	$ 1.86	$2.88-$4.63	$ 1.85
Risk-free interest rate	4.47%-4.87%	3.94%	3.72%-4.87%	3.94% - 4.19%
Expected volatility	79.43%-79.60%	84.69%	79.13%-82.12%	84.03% - 89.48%
Expected term (in years)	5.77-6.08	6.08	5.50-6.08	5.49 - 6.08
Expected dividend yield	—	—	—	—

The Company determines the assumptions used in the option pricing model in the following manner:

Risk-Free Interest Rate – For the determination of the risk-free interest rates, the Company utilizes the U.S. Treasury yield curve for instruments in effect at the time of measurement with a term commensurate with the expected term assumption.

Expected Volatility – The Company based its estimate of expected volatility on a weighted average using the Company's limited historical stock price volatility data, supplemented with the estimated and expected volatilities of a guideline group of publicly traded companies. For these analyses, the Company selected companies with comparable characteristics including enterprise value, risk profiles, and with historical share price information sufficient to meet the expected life of the share-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its share-based awards. 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 Dividend – The expected dividend yield is assumed to be zero because the Company has never paid dividends and does not have current plans to pay any dividends on its common stock.

Expected Term – The Company estimates the expected term of its stock options granted to employees and non-employee directors using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. The Company utilizes this method since it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

10. Employee Stock Purchase Plan

On August 17, 2021, a special meeting of the Company's stockholders was held to approve the Reverse Merger and related matters, at which the Company's stockholders considered and approved the Company's 2021 ESPP which permits participants to contribute up to 15% of their eligible compensation during defined rolling six-month offering periods to purchase the Company's common stock. The purchase price of the shares will be 85% of the lower of the fair market value of the Company's common stock on the first day of trading of the offering period or on the applicable purchase date. Upon approval of the 2021 ESPP by the stockholders, Aerpio's Amended and Restated 2017 Employee Stock Purchase Plan terminated. An aggregate of 519,563 shares of common stock was initially reserved for issuance under the 2021 ESPP. The number of shares of common stock available for issuance under the 2021 ESPP is automatically increased on the first day of each fiscal year beginning with the 2022 fiscal year in an amount equal to the least of:

- 310,617 shares of common stock;
- one percent (1%) of the outstanding shares of all classes of common stock on the last day of the immediately preceding fiscal year; or
- an amount to be determined by the board of directors or its designated committee no later than the last day of the immediately preceding fiscal year.

Under this mechanism, a total of 310,617 and 246,807 shares of common stock were added to the 2021 ESPP on January 1, 2026 and 2025, respectively. Shares of common stock issuable under the 2021 ESPP will be authorized, but unissued, or reacquired shares of common stock. If the Company's capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the 2021 ESPP will be appropriately adjusted. The Company opened enrollment into the 2021 ESPP in May 2022.

The Company uses the Black-Scholes model to determine the estimated fair value for purchases under the 2021 ESPP. Black-Scholes models require the input of various assumptions, including the expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock. The expected volatility used in calculating the estimated fair value for purchases under the 2021 ESPP is based on the historical volatility of the Company's common stock.

The calculation was based on the following assumptions:

	Three and Nine Months Ended September 30, 2026	Three and Nine Months Ended September 30, 2025
Strike price (per share)	$1.82-$4.00	$1.69 - $2.11
Risk-free interest rate	3.77%-3.80%	4.29% - 4.44%
Expected volatility	73.73%-80.01%	55.26% - 88.23%
Expected term (in years)	0.5	0.5
Expected dividend yield	—	—

As of September 30, 2026, and December 31, 2025, 1,318,718 and 1,023,856 shares of common stock were available for issuance under the 2021 ESPP, respectively. The Company had an outstanding liability of $125.0 thousand and $24.0 thousand as of September 30, 2026, and December 31, 2025, respectively, which will be recognized over six months. For the nine months ended September 30, 2026 and 2025, 15,755 and 16,337 shares were issued under the 2021 ESPP, respectively.

11. Income Taxes

The Company recorded no income tax expense for the nine months ended September 30, 2026 and 2025. The Company continues to maintain a full valuation allowance.

12. Commitments and Contingencies

Litigation

From time to time, the Company could be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Regardless of the outcome, legal proceedings can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. The Company has no ongoing legal proceedings or claims where a liability has been recorded as of September 30, 2026 and December 31, 2025.

Purchase Commitments

The Company has ongoing contracts with vendors for clinical trials, research and development, and contract manufacturing. These contracts are generally cancellable, with notice, at the Company’s option. The Company recorded accrued expenses of $3.6 million and $8.6 million for expenditures incurred by clinical, research and development, and contract manufacturing vendors as of September 30, 2026, and December 31, 2025, respectively.

13. Restructuring

On August 21, 2024, the Company announced a restructuring plan to reduce the Company’s workforce by approximately 32% in response to the Company's announcement on August 20, 2024 that it planned to halt the registration-intended PRECISION1 trial of nab-sirolimus in patients with solid tumors harboring *TSC1* or *TSC2* inactivating alterations. The Company recorded a total restructuring charge of $2.6 million, which consisted of one-time termination benefits such as severance costs and related benefits. As of September 30, 2026, no one-time termination benefits remain payable. As of December 31, 2025, $0.2 million of one-time termination benefits remained payable and were recorded within the accrued liabilities and other liabilities line items on the Company's condensed consolidated balance sheet. The Company paid $0 and $0.2 million of the liability during the three and nine months ended September 30, 2026, respectively. The Company paid $0.4 million and $1.1 million during the three and nine months ended September 30, 2025, respectively. There were no restructuring charges for the three and nine months ended September 30, 2026 and 2025. Restructuring payments commenced in September 2024 and were completed in March 2026.

14. Divestiture of FYARRO

On December 19, 2024, the Company entered into the Divestiture Agreement with KAKEN, KAKEN PHARMACEUTICAL CO., LTD, and Aadi Subsidiary for the sale to KAKEN of 100% of the outstanding shares of capital stock of Aadi Subsidiary and thereby all of the Company's assets related to the FYARRO Business. Per the terms and subject to the conditions of the Divestiture Agreement, KAKEN paid to the Company a cash payment of $102.4 million (following applicable purchase price adjustments under the Divestiture Agreement) at the closing of the FYARRO Divestiture on March 25, 2025.

The Company recorded a net gain on sale of the FYARRO Divestiture of $87.4 million at the closing thereof, which has been recorded on the unaudited condensed consolidated statement of operations and comprehensive (loss) income. The $87.4 million gain represents the aggregate consideration of $102.4 million, less the assets and liabilities transferred, which are listed below (in thousands):

	March 25, 2025
Assets	
Current assets:	
Cash and cash equivalents	$ (1,000)
Accounts receivable, net	(6,903)
Inventory	(5,141)
Prepaid expenses and other current assets	(866)
Total current assets	(13,910)
Property and equipment, net	(6,836)
Operating lease right-of-use assets	(707)
Other assets	(64)
Total assets	$ (21,517)
Current liabilities:	
Accounts payable	$ (852)
Accrued liabilities	(4,951)
Operating lease liabilities, current portion	(201)
Total current liabilities	(6,004)
Operating lease liabilities, net of current portion	(536)
Total liabilities	(6,540)
Net assets disposed of	$ (14,977)

During the three months ended September 30, 2025, the Company recorded a $0.2 million post-closing adjustment related to the March 25, 2025 FYARRO Divestiture as part of the final closing statement in accordance with the Divestiture Agreement. The adjustment was recorded as a reduction to the previously recognized gain on sale.

The Company evaluated various qualitative and quantitative factors related to the disposition of the FYARRO Business and determined the transaction did not meet the criteria for discontinued operations under ASC 205-20, and therefore no reclassification has been made to prior period statements.

15. Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has identified its Chief Executive Officer as the chief operating decision maker (CODM) and the Company views its operations and manages its business in one operating segment, applying advanced technologies to established tumor biology that are intended to efficiently develop improved cancer treatments. The CODM assesses performance for the Company's single operating segment and decides how to allocate resources based on research and development expenses incurred and on net (loss) income as reported on the statement of operations and comprehensive (loss) income. The measure of segment assets is reported on the balance sheet as total assets. Further, segment depreciation expense and segment asset additions are consistent with amounts reported within the statement of cash flows given the Company's operations are aggregated within a single reportable segment. The Company's revenues

relate to sales of FYARRO, which was divested as of March 25, 2025. Refer to Note 2 for further information. All the assets and operations of the Company's sole operating and reportable segment are located in the United States.

Significant segment expenses which are regularly reported to the CODM for purposes of making decisions regarding the allocation of resources are included within the table below and are reconciled to net (loss) income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Total Revenue	$ —	$ —	$ —	$ 7,145
Less:				
ADC assets - research and development expenses	14,705	5,247	35,843	48,701
ADC assets - contract manufacturing	3,433	9,323	12,413	18,199
FYARRO - research and development expenses	—	(225)	7	5,040
FYARRO - commercial and marketing expenses	—	14	—	294
Finance and accounting expenses (1)	1,956	2,099	5,731	7,349
Legal expenses	742	1,108	3,024	4,680
Other segment items (2)	373	180	3,025	(79,773)
Net (loss) income	$ (21,209)	$ (17,746)	$ (60,043)	$ 2,655

(1) Finance and accounting expenses primarily include share-based compensation, insurance, salaries and wages, and other outside consulting services.
(2) Other segment items primarily include other SG&A departmental expenses, cost of sales, other income, and gain on sale of business.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report may include, but are not limited to, statements about:

- our estimates regarding expenses, capital requirements, needs for additional financing and the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements, including our belief that, based on our current plans, our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into the second half of 2028;
- our ability to obtain and maintain regulatory approval for our portfolio of three next generation antibody drug conjugates (the "ADC Therapies") or any other product candidates we may develop, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- the timing, progress and results of preclinical studies and clinical trials for our programs and product candidates (including our anticipated submission of an investigational new drug application for new programs starting in the second half of 2027 in connection with our option agreement with Hangzhou DAC and collaboration agreement with Biocytogen Boston Corp.), the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the anticipated timing of releasing data for current or future clinical trials, including our expected timing of the data readouts for the HWK-007 and HWK-016 Phase 1 clinical trials in the first half of 2027 and for the HWK-206 Phase 1 clinical trial by year-end 2027;
- the anticipated timing of commencement, enrollment, and completion of any current or future clinical trials for the ADC Therapies or any other product candidates we may develop, including our expectation to activate the first clinical sites for our HWK-206 Phase 1 clinical trial in China in the first quarter of 2027;
- our belief that, with the three ADC Therapies, we have the ability to pursue multiple cancer indications with high potential in large addressable patient populations, including and beyond those indications currently expected to be targeted in our ongoing and upcoming Phase 1 trials;
- our belief that the ADC Therapies will be able to target cancers expressing specified tumor markers precisely and deliver the potent, cytotoxic Topoisomerase I ("TOP1") inhibitor at the site of cancer;
- our view that we are positioned to unlock the high potential of the ADC Therapies due to our track record of strong execution of novel drug formulation, research, clinical development, and commercialization in oncology, combined with our deep understanding of antibody drug conjugates ("ADCs");
- our belief that our team is well positioned to execute on our strategy to develop and, if approved, commercialize the ADC Therapies and future pipeline assets to ultimately bring broad benefit to cancer patients worldwide;
- our manufacturing capabilities and strategy;

- the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of the ADC Therapies and any other product candidates that we may develop;
- the implementation of our business model and our strategic plans for our business;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing the ADC Therapies and any other product candidates we may develop;
- the size and growth potential of the markets for the ADC Therapies and any other product candidates we may develop, if approved, and our ability to serve those markets, either alone or in partnership with others;
- our ability to obtain funding for our operations, including funding necessary to complete development, approval and, if approved, commercialization of the ADC Therapies and any other product candidates we may develop;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our financial performance; and
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals.

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory and economic developments. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “intend,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential,” “continue,” “likely,” and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part II, Item 1A (Risk Factors) of this Quarterly Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the “SEC”) completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes thereto appearing elsewhere in this Quarterly Report and our audited financial statements and related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026. Some of the information contained in this discussion and analysis including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report. You should read this Quarterly Report completely, including Part II, Item 1A (Risk Factors) of this Quarterly Report and the "Cautionary Statement Regarding Forward-Looking Statements" sections of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by our forward-looking statements contained in the following discussion and analysis. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

References in the following discussion to "we," "our," "us," or "Whitehawk" refer to Whitehawk Therapeutics, Inc. and its subsidiaries.

Throughout this document we refer to FYARRO (nab-sirolimus, sirolimus protein-bound particles for injectable suspension (albumin-bound)) as FYARRO in the context of commercialization for the treatment of advanced malignant perivascular epithelioid cell tumor (PEComa), investigational use, our historical clinical trials, regulatory matters such as orphan drug designation, and our former agreements with Bristol-Myers Squibb Company, all further discussed throughout this document.

Overview

We are a clinical-stage oncology therapeutics company applying advanced technologies to established tumor biology that are intended to efficiently develop improved cancer treatments. We have deep experience in chemistry, formulation, and drug delivery, as well as research, clinical, and commercial pharmaceutical development, successfully taking product candidates from the clinic to approval, launch, and commercialization.

License Agreement and ADC Therapies

In December 2024, we entered into an intellectual property license agreement (the "License Agreement") with WuXi Biologics (Shanghai FX) Co., Ltd. ("WuXi Biologics") for the development and global commercialization of a portfolio of three next generation antibody drug conjugates ("ADCs") targeting clinically validated, broadly overexpressed tumor antigens in high potential cancer indications with significant unmet need. These ADCs are constructed utilizing an advanced linker-payload platform called CPT113 that has been shown to provide high stability in blood circulation and deliver targeted release of a Topoisomerase I ("TOP1") inhibitor payload into cancer cells.

These in-licensed assets originated through the collaborative efforts of WuXi Biologics, a leading global contract research, development and manufacturing organization ("CRDMO"), and Hangzhou DAC Biotechnology ("Hangzhou DAC"), a global leader in ADC innovation, where Hangzhou DAC's CPT113 linker-payload has been conjugated to novel antibodies developed by WuXi Biologics against three tumor targets: Protein Tyrosine Kinase 7 ("PTK7"), Mucin 16 ("MUC16") and Seizure-related Protein 6 ("SEZ6"). We believe the resulting ADCs will be able to target cancers expressing these respective tumor markers precisely and deliver the potent, cytotoxic TOP1 inhibitor at the site of cancer. Each of these ADCs has demonstrated tumor cell binding, tumor cell line cytotoxicity, and *in vivo* antitumor activity in preclinical models mimicking tumor progression. We refer to these in-licensed ADC assets as the "ADC Therapies" herein.

The U.S. Food and Drug Administration (“FDA”) cleared an investigational new drug application (“IND”) for each of HWK-007, for the treatment of solid tumors, including non-small cell lung cancer (“NSCLC”), ovarian cancer and endometrial cancer, HWK-016, for the treatment of advanced ovarian and endometrial cancers, and HWK-206 for the treatment of small cell lung cancer ("SCLC") and neuroendocrine tumors (“NETs”), in the fourth quarter of 2025, first quarter of 2026 and third quarter of 2026, respectively. The Phase 1 trials for each ADC Therapy are now actively recruiting. We expect data readouts with respect to the clinical trials of HWK-007 and HWK-016 in the first half of 2027 for each trial. With these three assets, we believe we have the ability to pursue multiple cancer indications with high potential in large addressable patient populations, including and beyond those indications currently expected to be targeted in our ongoing and upcoming Phase 1 trials.

Our track record of strong execution of novel drug formulation, research, clinical development, and commercialization in oncology, combined with our deep understanding of ADCs positions us to unlock the high potential of this differentiated ADC portfolio. Our management team has extensive experience in the discovery, development, and commercialization of cancer therapeutics, including in senior roles at leading oncology companies. We are supported by our board of directors and specialized scientific advisors, who contribute their deep understanding of drug discovery and development. Furthermore, our investor base includes top life science investors. We believe that our team is well positioned to execute on our strategy to develop and, if approved, commercialize the ADC Therapies and future pipeline assets to ultimately bring broad benefit to cancer patients worldwide.

Legacy FYARRO Business

For the periods presented and through the FYARRO Divestiture (as defined below), our lead drug product was FYARRO® (sirolimus protein-bound particles for injectable suspension (albumin-bound); nab-sirolimus). Nab-sirolimus is a potent inhibitor of the mTOR biological pathway with demonstrated anti-cancer activity in advanced malignant perivascular epithelioid cell tumor (“PEComa”), a rare cancer. We exclusively licensed FYARRO, previously called ABI-009, nab-sirolimus, from Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company (“BMS”). We refer to the development, production and commercial sale of FYARRO herein as the “FYARRO Business”. On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa and recognized net product sales of $0 for the three and nine months ended September 30, 2026, and $0 and $7.1 million for the three and nine months ended September 30, 2025, respectively. See “Results of Operations” for further discussion of our results.

On December 19, 2024, we entered into a Stock Purchase Agreement (the “Divestiture Agreement”) with KAKEN INVESTMENTS INC., a Delaware corporation (“KAKEN”), KAKEN PHARMACEUTICAL CO., LTD (“Guarantor”), and Aadi Subsidiary, Inc., a Delaware corporation and our former wholly owned subsidiary and the operating company for the FYARRO Business (“Aadi Subsidiary”). Under the Divestiture Agreement, KAKEN acquired 100% of the outstanding shares of capital stock of Aadi Subsidiary from us at the closing for a cash payment of $102.4 million (following applicable purchase price adjustments under the Divestiture Agreement) (the "FYARRO Divestiture"). The divestiture transaction closed on March 25, 2025 and, as a result, we no longer operate the FYARRO Business.

Legacy FYARRO Business Agreements

Former BMS License Agreement. We had exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to ABI-009 (which we refer to as FYARRO) pursuant to an amended and restated license agreement, dated November 15, 2019, as amended August 31, 2021 (the “BMS License Agreement”) with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of BMS. Under the BMS License Agreement, BMS is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. Under the terms of this agreement, we recorded royalties on net product sales of $0 during the three months ended September 30, 2026 and 2025, respectively. For the nine months ended September 30, 2026 and 2025, we recorded royalties on net product sales of $0 and $0.5 million, respectively. No development payments related to milestones were paid during the three and nine months ended

September 30, 2026 and 2025 under the agreement. See Note 7 to the financial statements for more information about the BMS License Agreement.

WuXi Biologics License Agreement

In December 2024, we entered into the License Agreement with WuXi Biologics for exclusive rights to certain patents and know-how pertaining to WuXi Biologics' preclinical ADC Therapies leveraging Hangzhou DAC linker-payload technology targeting each of MUC16, PTK7 and SEZ6. Under the License Agreement, we paid WuXi Biologics a non-refundable, partial upfront payment of $6.0 million in December 2024 and we paid an additional non-refundable, upfront payment of $38.0 million in April 2025, in each case, for the rights and licenses granted to us by WuXi Biologics. In accordance with the License Agreement, WuXi Biologics is eligible to receive from us (a) up to an aggregate of $265.0 million upon the achievement of certain development milestones, and (b) up to an aggregate of $540.0 million upon the achievement of certain commercial milestones, across all ADC Therapies programs. WuXi Biologics is also entitled to running royalties ranging from low-single-digit to upper-single-digit percentages of annual net sales of licensed products in the territory on a product-by-product and region-by-region basis from the first commercial sale of the applicable licensed product in a particular region until the date which is the later of (i) expiration of the last to expire valid claim of a license patent in such region covering the sale of such licensed product in such region or (ii) ten years after the first commercial sale of such licensed product in such region.

Each party may terminate the License Agreement in its entirety, or on a program-by-program basis, as applicable, if the other party remains in material breach of the License Agreement following a cure period to remedy the material breach or if the other party is declared insolvent or in similar financial distress. In addition, WuXi Biologics may terminate the License Agreement on a program-by-program basis if we do not meet certain development due diligence milestones. We may terminate the License Agreement in its entirety, or on a program-by-program basis, as applicable, with or without cause.

Recent Developments

- ***HWK-206 Update.*** In the third quarter of 2026, we filed the IND for HWK-206, our SEZ6-targeted ADC Therapy, which was cleared by the FDA. A Phase 1 trial is now actively recruiting and is initially evaluating activity in HWK-206 for the treatment of SCLC and NETs. In addition, we submitted an IND for HWK-206 in China in the third quarter of 2026 and we anticipate activating our first clinical sites in China in the first quarter of 2027. We expect initial data readout for the HWK-206 Phase 1 clinical trial by year-end 2027.

  In October 2026, the FDA granted Fast Track Designation for HWK-206 for the treatment of patients with extensive-stage small cell lung cancer with disease progression on or after platinum-based chemotherapy.

  In May 2026, we presented real world analysis as part of our collaboration with Tempus AI supporting the therapeutic potential of targeting SEZ6 with a next-generation ADC for the treatment of neuroendocrine tumors, including SCLC. These data were presented in a poster at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, held May 29-June 2, 2026, in Chicago, Illinois. The data showed SEZ6 is highly expressed in SCLC and other tumors of neuroendocrine origin.

- ***HWK-007 Update.*** In September 2026, we presented two real-world analyses as part of our collaboration with Tempus AI supporting PTK7 as a durable and clinically relevant ADC target in patients with pretreated, epidermal growth factor receptor ("EGFR") wild-type NSCLC. The data were presented at the IASLC 2026 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer, held September 12-15, 2026, in Seoul, Republic of Korea. In the first analysis, the data showed that PTK7 expression remained largely stable following standard-of-care immunotherapy, chemotherapy, chemoimmunotherapy and tyrosine kinase inhibitor treatment, suggesting that the target may remain available for PTK7-directed therapy after prior treatment. In the second analysis, the data demonstrated that PTK7 expression was not independently associated with real-world overall survival or progression-free survival in patients with advanced EGFR wild-type lung adenocarcinoma receiving second- or later-line therapy, supporting

PTK7 as a target-engagement biomarker rather than a marker of prognosis. We are currently evaluating HWK-007, our PTK7 targeted ADC Therapy, in an ongoing Phase 1 clinical trial in patients with non-squamous, EGFR wild-type NSCLC, platinum-resistant ovarian cancer and endometrial cancer.

- ***HWK-016 Update.*** In October 2026, we presented two real-world analyses as part of our collaboration with Tempus AI supporting MUC16 as a durable therapeutic target and potential prognostic biomarker in ovarian cancer. These data were presented at the International Gynecologic Cancer Society (IGCS) Annual Global Meeting held October 1-3, 2026, in Montreal, Canada. MUC16 expression remained largely stable following platinum and non-platinum chemotherapy, bevacizumab-containing regimens, PARP inhibitors and mirvetuximab soravtansine, suggesting that the target may be suitable for MUC16-directed therapy after prior standard of care treatment and in combination with standard early-line platinum-based treatment. We are currently evaluating HWK-016, our MUC16-targeted ADC Therapy, in an ongoing Phase 1 clinical trial in patients with advanced ovarian and endometrial cancers.

- ***Pipeline Update.*** In May 2026, we entered into a new option agreement with Hangzhou DAC for access to CPT113, their core linker-payload technology, for use in up to five additional ADC programs. Per the terms of the option agreement, we will select targets and source antibodies, while retaining global rights and full program control for the new ADC programs.

  In addition, in June 2026, we entered into a global collaboration with Biocytogen Boston Corp. ("Biocytogen") to develop bispecific antibody-drug conjugates ("BsADC"). Biocytogen will provide access to up to five bispecific antibodies using its proprietary RenLite® platform, and we will evaluate these in combination with our ADC linker-payload platform technologies. We then have the option to advance any resulting BsADC candidates as part of our pipeline.

  We anticipate submitting an investigational new drug application for new programs starting in the second half of 2027 in connection with our option agreement with Hangzhou DAC and collaboration agreement with Biocytogen.

- ***New Member of the Board.*** On September 9, 2026, our board of directors appointed Vijay Iyengar, MD, as a new member of the board. Dr. Iyengar brings more than two decades of oncology experience building and scaling global businesses, leading strategic transactions across development-stage and commercial assets and guiding product portfolios from early development through commercialization. During his nine years in senior leadership roles at Incyte Corporation, he helped drive transformative change, including the launch of five brands across eight indications, the company's expansion into more than 20 countries and growth from approximately $1B to more than $4B in annual revenue. Prior to Incyte, Dr. Iyengar held senior leadership positions in oncology at Novartis. Earlier in his career, he was an Engagement Manager in the healthcare practice at McKinsey & Company.

Impact of Negative Global or National Events

Businesses have been and will continue to be impacted by a number of challenging global and national events and circumstances that continue to evolve, including the implementation of tariffs (and, as applicable, their subsequent actual or threatened modification or removal), turmoil in the global banking system, public health epidemics, such as the COVID-19 pandemic, extreme weather conditions, increased economic and regulatory uncertainty, inflation, interest rates, and geopolitical instability, including trade disputes and negotiations and the military conflicts in Ukraine, the Middle East and in other countries. The extent of the impact of these events and circumstances on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on our development activities, third-party manufacturers, and other third parties with whom we do business, as well as their impact on regulatory authorities and our key scientific and management personnel. We continue to actively monitor the potential impacts that these various events and circumstances may have

on our business and we take steps, where warranted, to minimize any potential negative impacts on our business resulting from these events and circumstances.

At this point, the extent to which these global or national events and circumstances may affect our future business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain. We will continue to evaluate the impact that these events could have on our operations, financial position, results of operations and cash flows for the remainder of fiscal year 2026.

Key Trends and Factors Affecting Comparability Between Periods

- We recorded a net gain on sale of $87.3 million for the FYARRO Divestiture in the first quarter of 2025.
- Commercial sale of FYARRO was launched in February 2022, for the treatment of patients with advanced malignant PEComa. We recorded net product sales of $0 for the three months ended September 30, 2026 and 2025, respectively, and $0 and $7.1 million for the nine months ended September 30, 2026 and 2025, respectively. As a result of the FYARRO Divestiture, we no longer commercialize FYARRO as of March 25, 2025. As the commercial sale of FYARRO constituted our sole source of revenue, we do not expect to generate further revenue for the foreseeable future.
- We had built a cross-functional commercial team consisting of marketing, market access and commercial operations. Expenses related to our commercialization of FYARRO, including personnel expenses, sales support, and marketing are included in selling, general and administrative expenses for the nine months ended September 30, 2025. We expect these expenses to decrease, as compared to prior periods, due to the FYARRO Divestiture which closed on March 25, 2025.
- We expect to increase our investment in research and development related to the ADC Therapies. We will continue to incur significant research and development and other expenses related to such ongoing operations. Under the License Agreement, we paid non-refundable license fees of $6.0 million and $38.0 million to WuXi Biologics in the fourth quarter of 2024 and the second quarter of 2025, respectively, plus a 6% VAT fee. Additionally, we recognized $8.5 million of development milestone-related expense for the nine months ended September 30, 2026.

Liquidity and Capital Resources

As of September 30, 2026, we had $169.7 million of cash, cash equivalents and short-term investments. Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into the second half of 2028. As of September 30, 2026, we had an accumulated deficit of $413.3 million. Our net loss was $60.0 million and net income of $2.7 million for the nine months ended September 30, 2026 and 2025, respectively. We have incurred net losses in each year since inception except for the nine months ended September 30, 2025 as we incurred net income due to the sale of a business. These losses have resulted principally from costs incurred in connection with research and development activities, selling, general and administrative costs associated with our operations, costs associated with the Reverse Merger, the FYARRO Divestiture, and the in-licensing of the ADC Therapies. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical and clinical trials of the ADC Therapies and identifying and designing product candidates and the regulatory approval process for any product candidates we may develop.

Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the condensed consolidated balance sheets and condensed consolidated statements of operations and comprehensive (loss) income presented herein. The following

discussion and analysis are based on our financial statements contained in this Quarterly Report, which we have prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

Components of Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income

Revenue

Product Sales, Net

FYARRO was approved by the FDA in November 2021 for treating adult patients with locally advanced unresectable or metastatic malignant PEComa. On February 22, 2022, we launched sales of FYARRO to specialty distributors ("SDs") and a specialty pharmacy ("SP"). We recognize product sales when the SDs and SP obtain control of the product, which occurs upon delivery. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

- *Distribution Fees*: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time the sale is recognized.

- *Rebates*: Allowance for rebates include mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. Our estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

- *Chargebacks:* Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to us the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

- *Co-Payment Assistance:* We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued at the time of product sale to the SDs and SP based on estimated patient participation and average co-pay benefit to be paid per claim. Our estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

- *Product Returns:* Consistent with industry practice, we offer the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SDs and SP and have the ability to control the amount of product that is sold to the SDs and SP, we estimate future potential product returns based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at our estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Revenue and allowances described above were recorded through the FYARRO Divestiture date of March 25, 2025.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including share-based compensation, related to our executive, finance, business development, sales and marketing, and other corporate functions. Other general and administrative expenses include professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and share-based compensation expense for employees engaged in scientific research and development functions; (ii) third-party contract costs relating to research, formulation, manufacturing, nonclinical studies and clinical trial activities; (iii) external costs of outside consultants who assist with technology development, regulatory affairs, clinical development and quality assurance; (iv) payments made under our third-party licensing agreements; and (v) allocated facility-related costs.

Costs for certain activities, such as manufacturing, nonclinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business. We expect to increase our investment in research and development related to the ADC Therapies. We will continue to incur significant research and development and other expenses related to such ongoing operations.

Cost of Goods Sold

Cost of goods sold consist primarily of royalties paid to BMS, costs incurred on sales of FYARRO and costs to manufacture and prepare the product for sales.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash, cash equivalents and short-term investments, and foreign exchange loss for the three and nine months ended September 30, 2026. During the three months ended September 30, 2025, other income includes interest income earned on cash, cash equivalents, and short-term investments, foreign exchange loss, and income received for billable services not part of our ordinary activities provided by our employees to KAKEN under a Transition Services Agreement ("TSA"). The TSA was entered into in connection with the sale of the business on March 25, 2025 and expired September 30, 2025. During the nine months ended September 30, 2025, other income includes interest income earned on cash, cash equivalents, short-term investments, gain on sale of a business, foreign exchange loss, and income received for billable services not part of our ordinary activities provided by our employees to KAKEN under the TSA.

Income Tax Expense

During the three and nine months ended September 30, 2026 and 2025, we recognized no income tax expense on the condensed consolidated statements of operations and comprehensive loss. Since our formation in 2011, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items.

Results of Operations:

The following table presents the results of operations for the periods indicated (in thousands):

	Three Months Ended September 30, 2026	2025	Nine Months Ended September 30, 2026	2025
Revenue				
Product sales, net	$ —	$ —	$ —	$ 7,145
Total revenue	—	—	—	7,145
Operating expenses				
Selling, general and administrative	4,805	5,201	16,311	23,956
Research and development	18,138	14,345	48,263	71,942
Cost of goods sold	—	—	—	760
Total operating expenses	22,943	19,546	64,574	96,658
Loss from operations	(22,943)	(19,546)	(64,574)	(89,513)
Other income (expense), net	1,734	1,800	4,531	92,168
Net (loss) income	$ (21,209)	$ (17,746)	$ (60,043)	$ 2,655

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

Product Sales, Net

Our product sales, net consist of sales of FYARRO. Product sales, net for the three months ended September 30, 2026 and 2025 were $0. Product sales, net for the nine months ended September 30, 2026 and 2025, were $0 and $7.1 million, respectively. As a result of the FYARRO Divestiture, we no longer sell FYARRO as of March 25, 2025.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2026 and 2025, were $4.8 million and $5.2 million, respectively. The decrease of $0.4 million was primarily driven by a decrease of $0.3 million in personnel expenses and $0.1 million in legal and other expenses.

Selling, general and administrative expenses for the nine months ended September 30, 2026 and 2025 were $16.3 million and $24.0 million, respectively. The decrease of $7.7 million was primarily driven by a decrease of $4.8 million in consulting and insurance expenses, $1.4 million in legal and other expenses, $1.2 million in personnel expenses, and $0.3 million in commercial and marketing expenses.

Research and Development Expenses

The following table presents our research and development expenses for the periods indicated (in thousands):

	Three Months Ended September 30, 2026	2025	Nine Months Ended September 30, 2026	2025
Personnel expenses	$ 3,739	$ 2,366	$ 9,862	$ 8,467
Consultants	1,537	853	3,210	1,653
External clinical development	10,401	2,987	25,928	47,154
Clinical drug product manufacturing	2,446	8,118	9,198	14,483
Other expenses	15	21	65	185
Total research and development expenses	$ 18,138	$ 14,345	$ 48,263	$ 71,942

Research and development expenses for the three months ended September 30, 2026 and 2025 were $18.1 million and $14.3 million, respectively. The increase of $3.8 million was primarily driven by an increase of $7.4 million in external clinical development expense primarily related to HWK-007 and HWK-016 clinical studies and includes $3.2 million in development milestone expense to WuXi Biologics upon the acceptance of our IND for HWK-206, $1.4 million in personnel expenses, and $0.7 million in consulting expenses, offset by a $5.7 million decrease in clinical drug manufacturing.

Research and development expenses for the nine months ended September 30, 2026 and 2025 were $48.3 million and $71.9 million, respectively, a decrease of $23.6 million. The decrease was primarily attributable to a $21.2 million decrease in external clinical development expenses, reflecting the $38.0 million upfront license fee recognized in 2025 under the License Agreement with WuXi Biologics. External clinical development expenses in 2026 included $8.5 million of development milestone expenses. Additionally, the overall decrease also reflected decreases of $5.3 million in clinical drug manufacturing expenses and $0.1 million in other expenses, partially offset by increases of $1.6 million in consulting expenses and $1.4 million in personnel expenses.

Cost of Goods Sold

Cost of goods sold was $0 for the three months ended September 30, 2026 and 2025. Cost of goods sold was $0 and $0.8 million for the nine months ended September 30, 2026 and 2025, respectively, primarily reflecting royalties incurred on product sold. The decrease of cost of goods sold was due to the FYARRO Divestiture on March 25, 2025.

Other Income (Expense), Net

Other income (expense), net for the three months ended September 30, 2026 and 2025 was $1.7 million and $1.8 million, respectively. The decrease of $0.1 million was primarily driven by a decrease in short-term investments held.

Other income (expense), net for the nine months ended September 30, 2026 and 2025 was $4.5 million and $92.2 million, respectively. The decrease of $87.7 million was primarily driven by a gain on sale of a business related to the FYARRO Divestiture recognized during the nine months ended September 30, 2025.

Liquidity and Capital Resources

Overview

As of September 30, 2026, we had $169.7 million of cash, cash equivalents and short-term investments. Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into the second half of 2028.

As of September 30, 2026, we had an accumulated deficit of $413.3 million. Our net loss was $60.0 million and net income of $2.7 million for the nine months ended September 30, 2026 and 2025, respectively. We have incurred net losses in each year since inception except for the nine months ended September 30, 2025 as we incurred net income due to the sale of a business. Losses have resulted principally from costs incurred in connection with research and development activities and selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical and clinical trials of the ADC Therapies and identifying and designing product candidates and the regulatory approval process for any product candidates we may develop.

On March 17, 2022, we entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), with respect to an “at the market offering” pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having aggregate gross proceeds of up to $75.0 million through Cowen as our sales agent. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar value

of shares that may be sold in any one trading day and any minimum price below which sales may not be made. We will pay Cowen 3.0% of the aggregate gross proceeds from each sale of shares of common stock under the Sales Agreement. As of September 30, 2026, no shares of common stock had been sold under the Sales Agreement.

The shares of our common stock to be offered and sold under the Sales Agreement will be issued and sold pursuant to our shelf registration statement on the Form S-3 (File No. 333-277018) (the "Shelf Registration Statement"), which was filed with the SEC on February 12, 2024 and which became effective April 30, 2024. No securities have yet been sold under the Shelf Registration Statement. We filed a prospectus supplement with the SEC on April 25, 2025 in connection with the offer and sale of the shares pursuant to the Sales Agreement.

The Shelf Registration Statement allows us to sell from time to time up to $150.0 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings and is intended to provide us flexibility to conduct registered sales of our securities, subject to market conditions and our future capital needs. The terms of any offering thereunder will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

On September 22, 2022, we entered into the purchase agreement for the 2022 PIPE Financing with the 2022 PIPE Investors for the sale of 3,373,526 shares of our common stock for a price of $12.50 per share and Pre-Funded Warrants (the "2022 Pre-funded Warrants") to purchase an aggregate of 2,426,493 shares of our common stock, at a purchase price of $12.4999 per 2022 Pre-Funded Warrant. The 2022 Pre-Funded Warrants are exercisable at an exercise price of $0.0001 and will be exercisable until exercised in full. The 2022 PIPE Financing closed on September 26, 2022. Aggregated net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the securities, were $72.2 million. As of September 30, 2026, all of the 2022 Pre-Funded Warrants have been exercised.

On December 19, 2024, we entered into the Subscription Agreement (the "Subscription Agreement") with certain investors (the "2024 PIPE Investors"), pursuant to which we agreed to sell to the 2024 PIPE Investors (i) 21,592,000 shares of our common stock, par value $0.0001 per share, at a purchase price of $2.40 per share, and (ii) pre-funded warrants to purchase an aggregate of 20,076,500 shares of our common stock (the "2024 Pre-Funded Warrants"), at a purchase price of $2.3999 per 2024 Pre-Funded Warrant, for aggregate net proceeds of $94.4 million, after deducting certain expenses incurred of $5.6 million related to the issuance of shares. The 2024 PIPE Financing closed on March 4, 2025. As of September 30, 2026, 16,866,574 of the 2024 Pre-Funded Warrants were still outstanding.

On May 13, 2026, we entered into a securities purchase agreement for a private investment in public equity financing (the "2026 PIPE Financing") with certain investors (the "2026 PIPE Investors"), pursuant to which we agreed to sell to the 2026 PIPE Investors (i) 4,330,866 shares of our common stock, par value $0.0001 per share, at a purchase price of $3.92 per share, and (ii) pre-funded warrants to purchase an aggregate of 17,991,021 shares of our common stock (the "2026 Pre-Funded Warrants" and together with the 2022 Pre-Funded Warrants and 2024 Pre-Funded Warrants, the "Pre-Funded Warrants"), at a purchase price of $3.9199 per 2026 Pre-Funded Warrant, for aggregate net proceeds of $81.7 million, after deducting certain expenses incurred of $5.8 million related to the issuance of shares. As of September 30, 2026, all 17,991,021 of the 2026 Pre-Funded Warrants were outstanding.

For each of the 2022 PIPE Financing, 2024 PIPE Financing and 2026 PIPE Financing, the Pre-Funded Warrants have an exercise price of $0.0001 per share of the Company's common stock and are exercisable and will remain exercisable until exercised in full. The holders of such Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% or 9.99%, at the election of the holder, of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. The holders of such Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice.

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30, 2026	2025
Net cash used in operating activities	$ (56,410)	$ (80,199)
Net cash provided by (used in) investing activities	6,169	(4,955)
Net cash provided by financing activities	81,646	94,351
Net increase in cash and cash equivalents	$ 31,405	$ 9,197

Operating Activities

Our cash used in operating activities primarily results from our net loss adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct our clinical programs and employee-related expenditures for research and development and selling, general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to advance our research and development of the ADC Therapies and identifying and designing product candidates and the regulatory approval process for any product candidates we may develop.

For the nine months ended September 30, 2026, cash used in operating activities was $56.4 million and resulted from (i) our net loss of $60.0 million, (ii) a $0.8 million net negative impact on cash used due to changes in net operating assets and liabilities, and (iii) $4.4 million of non-cash adjustments, which were primarily related to share based compensation, depreciation, and discount amortization on short-term investments.

For the nine months ended September 30, 2025, cash used in operating activities was $80.2 million and resulted from (i) our net income of $2.7 million, (ii) a $2.5 million net negative impact on cash used due to changes in net operating assets and liabilities, and (iii) $80.3 million of non-cash adjustments, which were primarily related to gain on sale of a business, share based compensation, discount amortization on short-term investments, lease expense, and depreciation.

Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2026 related to the maturities of short-term investments of $111.6 million, offset by purchases of short-term investments of $105.4 million.

Cash used in investing activities for the nine months ended September 30, 2025 related to proceeds from the sale of business, maturities of short-term investments of $20.1 million, offset by purchases of short-term investments of $125.8 million and purchases of property and equipment of $0.6 million.

Financing Activities

For the nine months ended September 30, 2026 cash provided by financing activities was $81.6 million and resulted from $87.5 million in proceeds received from the sale of common stock and pre-funded warrants as part of the 2026 PIPE Financing, offset by payment of 2026 PIPE Financing related transaction costs of $5.8 million.

For the nine months ended September 30, 2025 cash provided by financing activities was $94.4 million and resulted from $100.0 million of proceeds received in the 2024 PIPE Financing (which closed in March 2025), offset by payment of 2024 PIPE Financing related transaction costs of $5.6 million.

Contractual Obligations and Commitments

In April 2022, we entered into a lease for 10,615 square feet of office space in Morristown, New Jersey. The term of the lease is seventy-three months unless terminated sooner. In connection with the FYARRO Divestiture, KAKEN assumed our sublease for the New Jersey office space, but we agreed to co-inhabit the office with KAKEN. In August 2026, we received landlord and sublandlord consent and our sublease agreement with KAKEN for shared office space became effective. The agreement has a term of twenty-one months and expires in May 2028.

In August 2021, we entered into an amendment to extend the lease of our 2,760 square feet of office space in Pacific Palisades, California. We exercised an option, under our prior lease agreement, to extend the term of the lease for an additional three-year period. Included in the renewal were nine months of rent abatement and a rent escalation clause. The Pacific Palisades lease expired on February 28, 2025.

Rent expense is being recorded on a straight-line basis. Rent expense related to the New Jersey office space was $41 thousand and $34 thousand for the three months ended September 30, 2026 and 2025, respectively. Rent expense was $0.1 million for the nine months ended September 30, 2026 and 2025. See Note 6 to the condensed consolidated financial statements for additional details.

We also have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

On December 19, 2024, we entered into the License Agreement with WuXi Biologics for exclusive rights to certain patents and know-how pertaining to WuXi Biologics' preclinical ADC Therapies leveraging Hangzhou DAC linker-payload technology targeting each of MUC16, PTK7 and SEZ6. Under the License Agreement, we paid $6.0 million and $38.0 million to WuXi Biologics in the fourth quarter of 2024 and the second quarter of 2025, respectively, plus a 6% VAT fee, in each case, for the rights and licenses granted to us by WuXi Biologics. Additionally, we paid $8.5 million of development milestone-related expense under the License Agreement for the nine months ended September 30, 2026.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

For a discussion of our critical accounting estimates, please read Part II, Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026. There have been no material changes to the critical accounting estimates previously disclosed in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2026, the end of the period covered by this Quarterly Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate.

Based on this evaluation, management concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2026.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

For discussion of legal proceedings, see Item 1 of Part I, “Condensed Consolidated Financial Statements - Note 12” in this Quarterly Report.

Item 1A. Risk Factors

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem immaterial may also impair our business operations. Please see the "Cautionary Statement Regarding Forward Looking Statements" section of this Quarterly Report for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. These disclosures reflect our beliefs and opinions as to factors that could materially and adversely affect our company and our securities in the future. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business, including, but not limited to, the following:

- We are a clinical-stage biopharmaceutical company, have a limited operating history and have three clinical product candidates and additional preclinical programs, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of the ADC Therapies and any other product candidates that we may develop.
- We will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- We may be unable to obtain United States or foreign regulatory approval for the ADC Therapies or any other product candidates that we may develop and, as a result, may be unable to commercialize any such product candidates and in such event our business will be substantially harmed.
- We may not be successful in growing our product pipeline through acquisitions and in-licenses.
- We contract with qualified third parties for the production of preclinical and clinical product supplies, and expect to continue to do so for supplies needed for all of our anticipated clinical trials. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of product supplies to meet demand or otherwise or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We are currently dependent on single-source suppliers for our product candidates and their components, including Hangzhou DAC and WuXi Biologics.

- If we cannot replicate the results from our earlier preclinical studies and clinical trials of our product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.
- We have limited resources and are currently focusing our efforts on developing the ADC Therapies for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.
- The market opportunities for the ADC Therapies and other product candidates we may develop, if approved, may be limited to certain smaller patient subsets.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees. If we fail to attract and retain such personnel, we may be unable to continue to successfully develop or commercialize our product or any future product candidates or otherwise implement our business plan, including consummating potential strategic transactions.
- Our success depends on our ability to protect and strengthen our intellectual property and our proprietary technologies, including our ability to obtain patent term extension for our product or any future product candidates.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily.
- Our business is subject to the risks associated with doing business in China. For example, the BIOSECURE Act recently signed into law as part of the 2026 National Defense Authorization Act, among other things, restricts federal government contracts, grants, and loans from being issued to companies that use biotechnology equipment or services produced or provided by select Chinese “biotechnology companies of concern,” and some of our business partners such as WuXi Biologics may be designated as biotechnology companies of concern when applicable implementing regulations, anticipated no later than the third quarter of 2028, come into effect.
- U.S.-China trade relations may adversely impact our supply chain operations and business.
- Litigation and legal proceedings may substantially increase our costs and harm our business, irrespective of outcome, including any securities class action litigation that might occur in connection with potential strategic transactions.
- Our stock price is volatile.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company, have a limited operating history and had a single product approved for commercial sale that we have divested, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We had a single product, FYARRO, approved for commercial sale by the FDA in November 2021 and launched commercially in the United States for treatment of advanced malignant PEComa in February 2022. In March 2025, we divested FYARRO pursuant to a Stock Purchase Agreement (the "Divestiture Agreement"), dated December 19, 2024, with KAKEN INVESTMENTS INC., a Delaware corporation ("KAKEN"), KAKEN PHARMACEUTICAL CO., LTD, and Aadi Subsidiary, Inc., a Delaware corporation and our former wholly owned subsidiary and the operating company for the FYARRO Business ("Aadi Subsidiary"). In December 2024, we entered into an intellectual property license agreement (the "License Agreement") with WuXi Biologics (Shanghai FX) Co., Ltd. ("WuXi Biologics") for the development and global commercialization of the ADC Therapies targeting clinically validated, broadly overexpressed tumor antigens in high potential cancer indications with significant unmet need. Accordingly, we continue to incur significant research and development and other expenses related to such ongoing operations. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

To date, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, the commercialization of FYARRO, hiring personnel, raising capital and providing general and administrative support for these operations.

We just recently commenced clinical trials with the ADC Therapies and have additional programs in the preclinical stage. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields.

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have only generated revenue from product sales for a portion of our operating history (February 2022 through March 2025), and have financed our operations principally through private placements and public offerings of our securities, federal grants and proceeds from licenses. Our net loss was $21.2 million and $17.7 million for the three months ended September 30, 2026 and 2025, respectively. We had an accumulated deficit of $413.3 million as of September 30, 2026, and $353.3 million as of December 31, 2025. These losses have resulted primarily from costs incurred in connection with research and development activities, costs incurred in connection with developing and commercializing FYARRO and general and administrative costs associated with our operations. As a result of our acquisition of the ADC Therapies, we expect to continue to incur significant selling, general and administrative expenses as well as research and development expenses related to our ongoing operations, including, identifying and designing additional product candidates, conducting preclinical studies and clinical trials for our product candidates, and navigating the regulatory approval process for the ADC Therapies and any future product candidates. Although our expenses decreased overall given the divestiture of FYARRO, including related commercial and clinical expenses, and headcount reductions, the amount of our future expenses and potential losses is uncertain.

Even if we succeed in receiving regulatory approval for and commercializing one or more of our current and future product candidates, we expect to continue to incur significant expenses and increase our operating losses over the next several years and for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter

such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital, our ability to fund the development of our product candidates, our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of the ADC Therapies and other product candidates that we may develop.

Our ability to generate product sales depends on our ability, alone or with strategic collaboration partners, to obtain the regulatory and marketing approvals necessary to successfully complete discovery, development and eventual commercialization of one or more of the ADC Therapies or any future product candidates, and commercialize any such product candidates, if approved, in foreign jurisdictions. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including, but not limited to:

- demonstrating the safety and efficacy of the ADC Therapies to the satisfaction of the FDA and obtaining regulatory approval for ADC Therapies and for any other product candidates that we may develop, if any, for which there is a commercial market;
- launching and successfully commercializing the ADC Therapies or any other product candidates that we may develop following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining a commercially viable supply of, 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 the ADC Therapies or any other product candidates that we may develop, if approved;
- completing development activities successfully and on a timely basis;
- our ability to complete IND enabling studies and successfully submit INDs or IND supplements or comparable applications, which become effective without any objections by the FDA or comparable regulatory authorities before commencing a clinical trial for the ADC Therapies and any future product candidates;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the future clinical development of the ADC Therapies and any other future product candidates that we may develop;
- timely receipt of regulatory approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing or contracting for an efficient and scalable manufacturing process for the ADC Therapies and any future product candidates, including obtaining finished products that are appropriately packaged for sale;
- following regulatory approval, negotiating and maintaining an adequate price for the ADC Therapies or any future product candidates, both in the United States and in foreign countries where our products are commercialized;
- a continued acceptable safety profile following any regulatory approval of product candidates;
- commercial acceptance of product candidates by patients, the medical community and third-party payors;
- obtaining coverage and adequate reimbursement by third-party payors for any product candidates;
- satisfying any required post-regulatory approval commitments to applicable regulatory authorities; 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;
- entering into and maintaining, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize the ADC Therapies and any future product candidates; and
- 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 do, 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 would decrease our value and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business or continue our operations and could cause a decline in the value of our common stock.

We will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect this will continue as a result of our ongoing and planned activities, particularly the clinical development of the ADC Therapies. Our expenses could increase beyond our current expectations if we are required by the FDA, the European Medicines Agency (the "EMA") or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical trials or the development of any future product candidates. Other unanticipated costs may also arise. In addition, even if we obtain regulatory approval for the ADC Therapies or any other product candidates that we may develop, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution activities and ongoing compliance activities. We cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and, if approved, commercialize the ADC Therapies or any other product candidates we may develop. In addition, we have incurred, and will continue to incur, additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash, cash equivalents and short-term investments to fund the clinical development of the ADC Therapies, for manufacturing operations and to fund our other research for other product candidates and development activities, as well as for working capital and other general corporate purposes. Advancing the development of the ADC Therapies and any future product candidate will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund all of the activities that are necessary to complete the development of the ADC Therapies and any future product candidates.

We will be required to obtain further funding to support our continuing operations through public or private equity offerings, debt financings, third-party funding, marketing and distribution arrangements, collaborations with third parties and licensing arrangements or other sources or a combination of these approaches, which may dilute our stockholders or restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop the ADC Therapies or any other product candidates we may

develop, if approved. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect stockholder rights and the possibility of such issuance may cause the market price of our shares to decline. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the conduct of our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to certain of our technologies or our product candidates, or grant licenses on terms that are not favorable to us, which may have a material adverse effect on our business, operating results and prospects. 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 resulting from rising inflation and interest rates, monetary policy changes, the implementation of tariffs, the conflicts in Ukraine and the Middle East, and otherwise. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to significantly delay, reduce the scope of, suspend or eliminate one or more of our research or development programs, clinical trials or future commercialization efforts.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Following the FYARRO Divestiture, we do not have any approved products and our pipeline is comprised solely of preclinical and clinical assets. The ADC Therapies are early in clinical development. Going forward, our business will depend on our ability to advance our current and future product candidates through preclinical studies and clinical trials and obtain regulatory approval of our product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Following the FYARRO Divestiture, we do not have any approved products and our pipeline is comprised solely of preclinical and clinical assets. Going forward, our business and future operating results will be dependent on our ability to successfully advance, develop and obtain regulatory approval for and/or commercialize our current and future product candidates and discover or in-license additional preclinical or clinical assets. Our ability to generate product or other revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur.

Prior to initiating clinical trials of our product candidates, we need to complete IND-enabling studies and file an IND or similar application to the FDA or regulatory authorities in other jurisdictions. For example, we completed IND-enabling studies, filed INDs for the ADC Therapies and the FDA cleared the INDs for HWK-007, HWK-016 and HWK-206 in the fourth quarter of 2025, first quarter of 2026 and third quarter of 2026, respectively, but we may not be able to receive such clearance for other product candidates on the timeline we expect. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory clearance for our trials may prevent us from developing product candidates on a timely basis, if at all. A product candidate can unexpectedly fail at any stage of preclinical 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 preclinical studies 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. If we experience failures,

setbacks or delays in our preclinical studies, clinical trials, manufacturing or regulatory efforts, our business may be materially harmed.

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

- generating sufficient preclinical data to support the initiation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct preclinical studies and clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- generating sufficient safety and efficacy data to warrant continued development and which are satisfactory to the FDA or any other regulatory authority for marketing approval.

Even if we successfully advance any of the ADC Therapies or other 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 any product candidates.

The ADC Therapies have just recently commenced testing in humans. They are comprised of antibodies that had never previously been tested in humans and linker-payloads that are currently in clinical trials run by independent third parties for other indications.

Our product candidates are next-generation ADCs using the same linker-payload designed by Hangzhou DAC and new antibodies designed by WuXi Biologics. Though ADC-based product candidates have been or are currently being evaluated by others in clinical trials using similar targets or the same linker-payload architectures, our product candidates and their antibody components have never been evaluated in human clinical trials prior to our Phase 1 studies of HWK-007 and HWK-016 that commenced in the first quarter of 2026 and of HWK-206 that commenced in the third quarter of 2026. If our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, such problems could impact the development plans for our other product candidates because all of our product candidates currently use the same linker-payload architecture.

Additionally, if ADCs being developed by other third parties that use the same linker-payload as our product candidates encounter safety or efficacy problems, our product candidates may face challenges from a development, regulatory or commercialization perspective. Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating a similar product candidate or product candidates using the same or similar linkers, payloads or antibodies. Those adverse results can adversely affect the development, approval and commercialization of our product candidates.

Additionally, WuXi Biologics and Hangzhou DAC may enter into other licenses or collaboration partners that allow more third parties to develop and commercialize product candidates with the same or similar components, thereby increasing these risks. Lastly, the linker payloads may use highly potent cytotoxins and payloads that require special manufacturing and handling, which can pose additional risks.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success, which would limit the revenue that we generate from our sales.

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

- 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 a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities or the willingness of patients to pay out-of-pocket in the absence of third-party payor coverage;
- the availability of an approved product candidate for use as a combination therapy;
- the prevalence and severity of any adverse effects associated with any approved product candidate;
- any restrictions on the use of our product candidates together with other medications;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

Even if a product candidate is approved, it may never achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, and we may not generate or derive sufficient revenue from that product and our financial results could be negatively impacted. Before granting reimbursement approval, healthcare payors may require us to demonstrate that any product candidates, in addition to treating target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of any product candidates may require significant resources and may never be successful.

The market opportunities for the ADC Therapies and any other product candidates we may develop, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.) and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes

adequate to cure the cancer or prolong life without a cure. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. There is no guarantee that product candidates that we develop, even if approved, would be approved for first-line or second-line therapy and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Our projections of addressable patient populations that may benefit from treatment with our product or any future product candidates are based on our estimates, which may prove to be incorrect. Additionally, the potentially addressable patient population for any product candidates may be limited or may not be amenable to treatment with such product. Regulatory approval may limit the market of a product candidate to target patient populations when such biomarker-driven identification and/or highly specific criteria related to the stage of disease progression are utilized. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

Even if we obtain significant market share for any future approved product, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Any product candidates for which we may obtain regulatory approval, may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any product candidate that receives regulatory approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidate will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize any product candidates that we may develop. 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 an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain regulatory approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, which would include any product candidate for which we may obtain regulatory approval. Market acceptance and sales of any product candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by healthcare reform measures. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance. Third-party payors decide which drugs they will pay for and establish reimbursement levels. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor’s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors that payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under the health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, any product candidate we may develop may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we may commercialize and, if reimbursement is available, what the level of reimbursement will be.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to prescription drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021 (the "American Rescue Plan"), the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was 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. 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 Inflation Reduction Act of 2022 (the "Inflation Reduction Act"), 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. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. 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 the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. Government agreements with pharmaceutical companies and other measures that use international pricing reference to set drug prices in the United States or increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as future legislative,

executive, and administrative actions and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. 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 laws after obtaining regulatory approval for any of the product candidates that we may develop. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product candidates that we may develop, if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as any product candidates that we may develop, if approved. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives regulatory approval. To obtain favorable reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of any product candidate that we may develop, if approved, to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products 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 any product candidates that we may develop, if approved. Accordingly, in markets outside the United States, the reimbursement for any other products that we may develop and receive regulatory approval for may be unavailable or reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If reimbursement is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates that we may develop, if approved, from third-party payors, the adoption of those other products if approved, the prices of those other products, if approved, and sales revenue from those products if approved will be adversely affected, which, in turn, could adversely affect the ability to market or sell any product candidates that we may develop, if approved. Moreover, coverage policies and third-party payor reimbursement rates, including those of government payors, may change at any time and it is unclear what effect legislative, executive, and administrative actions and any future healthcare measures and agency rules will have on the number of covered individuals. Even if favorable coverage and reimbursement status is attained for one or more product candidates that we may develop for which we receive regulatory approval, it is possible that less favorable coverage policies and reimbursement rates may be implemented in the future.

We may not be able to obtain FDA approval of any future NDA for any other product candidates we may develop.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to any product candidate that we may develop are subject to extensive regulation in the United States. Prior to the approval of our NDA for FYARRO for advanced malignant PEComa, we had not submitted an application for approval or obtained FDA approval for any product.

Approval of an NDA is not guaranteed. The approval process is expensive and uncertain and may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data support that any of our product candidates are safe and effective for the proposed therapeutic use. FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement those goals and their impact on specific clinical programs

and the industry are unclear. The FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to our product candidates, can materially impact our competitive advantage and intellectual property. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including drug product stability data. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the drug.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

Failure to obtain marketing approval in international jurisdictions would prevent any product candidates that we may develop, if approved, from being marketed abroad.

In order to market and sell our products in the European Union and in any other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize any product candidates that we may develop, if approved, in any market.

A variety of risks associated with marketing any product candidates we may develop, if approved, internationally could affect our business.

We may seek regulatory approval for 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;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the United States Foreign Corrupt Practices Act ("FCPA") 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.

In addition, recent conflicts in Ukraine and the Middle East have led to, and could continue to lead to, disruption, instability and volatility in global markets and industries that could negatively impact our operations. For example, the U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

The preclinical studies and clinical trials for the ADC Therapies or any other product candidates that we may develop may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results, which would prevent, delay, or limit the scope of development, regulatory approval and commercialization.

Before obtaining regulatory approval from the FDA, EMA or other foreign regulatory authorities for the sale of product candidates that we may develop, we, among other requirements, may need to complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product candidates. Each product candidate must demonstrate an adequate risk versus benefit profile in our intended patient population and for our intended use. Drug product must also be manufactured and tested in accordance with regional regulatory requirements which may differ from region to region. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is inherently uncertain. A failure of one or more preclinical studies or clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies in the biopharmaceutical industry that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of the ADC Therapies or any other product candidates we may develop.

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

- receipt of feedback from regulatory authorities that require us to modify the design of our clinical trials;

- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- clinical trial sites or our CRO failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- delays due to health epidemics, such as the COVID-19 pandemic, including starting any clinical trials for other indications or programs.

For example, we initiated our PRECISION1 Phase 2 study of FYARRO in malignant solid tumors harboring *TSC1* and *TSC2* inactivating alterations based on exploratory data from our completed Phase 2 registrational study, Advanced Malignant PEComa Trial ("AMPECT trial"), and data for FYARRO in other solid tumors with *TSC1* and *TSC2* inactivating alterations. In August 2024, we had to halt, and subsequently wind-down, the PRECISION1 trial based on interim data and the related analysis by the Independent Data Monitoring Committee, which determined that the study was unlikely to exceed an efficacy threshold necessary to support an accelerated approval, the key goal of the study. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Additionally, we are aware of several other approved and clinical-stage antibody drug conjugates products being developed by multiple other companies, and, as such, the development of the ADC Therapies and our stock price may be impacted by inferences, whether correct or not, that are drawn between the success of our product candidates and those of other companies' antibody drug conjugates products. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety and efficacy results, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our products in clinical trials may have received surgical, radiation and chemotherapy treatments and/or may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our products. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any product candidates we may develop. If we are required to conduct additional clinical trials or other testing of any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of any product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may (i) incur unplanned costs, (ii) be delayed in seeking and obtaining regulatory approval for respective indications, if we receive such approval at all, (iii) receive more limited or restrictive regulatory approval for respective indications, (iv) be subject

to additional post-marketing testing requirements or (v) have the drug removed from the market after obtaining regulatory approval. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use any product candidates, which may also limit their commercial potential.

Any product candidates that we may develop 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 could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If any product candidates that we may develop is associated with serious adverse events or other undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to conduct additional studies to further evaluate their safety, interrupt, delay or abandon their development or halt clinical trials 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 trial or result in a more restrictive label, delay or denial of regulatory approval or potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of any affected product candidate, could substantially increase the costs of commercializing our product(s), and significantly impact our ability to successfully commercialize any product candidates that we may develop, if approved, and generate revenues, and may harm our business, financial condition and prospects significantly.

Any product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. Patients treated with product candidates that we may develop may also be undergoing surgical, radiation and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to the product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If further significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an institutional review board may suspend or terminate clinical research at any time for various reasons, including noncompliance with regulatory requirements or a finding that the participants 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 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 regulatory 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 product candidate that we may develop obtains regulatory 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 (i) conduct additional clinical safety trials, (ii) add additional contraindications, warnings and precautions to the drug label, (iii) significantly restrict the use of the product, (iv) change the way the product is distributed or administered, (v) implement a risk evaluation and mitigation strategy, or create a medication guide outlining the risks of such side effects for distribution to patients, or (vi) suspend or withdraw the product from the market. We cannot predict whether any product candidates that we may develop will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Results from early preclinical studies and clinical trials of the ADC Therapies or any other product candidates that we may develop are not necessarily predictive of the results of later preclinical studies and clinical trials of such product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize any product candidates.

Any results from early preclinical studies and clinical trials of product candidates that we may develop may not necessarily be predictive of the results from later preclinical studies and clinical trials. Similarly, even if we are able to complete preclinical studies and clinical trials according to our current development timeline, the results from such preclinical studies and clinical trials may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

We are subject to risks relating to open-label clinical trials.

Some of our future clinical trials may utilize an open-label study design and may be 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 biases, including 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. The results from an open- label trial may not be predictive of future clinical trial results with any product candidates when studied in a controlled environment with a placebo or active control.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted and are subject to audit, independent radiographic or clinical review, and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. Preliminary data 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 trial. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. 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 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, independent radiographic or clinical review, 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. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any product candidates that we may develop may be harmed, which could harm our business, financial condition, results of operations and prospects.

Adverse results of clinical trials conducted by third parties investigating the same product candidates as us in different territories could adversely affect our development of such product candidate.

Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating our approved product or the same product candidates as us in different territories for the same or different indications. For example, we may in the future enter into collaborations for the development and commercialization of the ADC Therapies or other product candidates that we may develop in certain foreign jurisdictions. As part of these collaborations, we may grant such collaboration partners the right to develop and commercialize the same compounds licensed to us, including the ADC Therapies, in such foreign jurisdictions. As a result, we may not have control over clinical trials or development programs of such third parties that we may collaborate with in the future, and any adverse findings or unexpected side effects from such third party's conduct of clinical trials could adversely affect our development and commercialization of the ADC Therapies, if approved, or the viability of the ADC Therapies as a product candidate. We may be required to report these adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of the ADC Therapies.

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

We may not be able to initiate or continue clinical trials for the ADC Therapies or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to identify and enroll eligible patients for clinical trials may be limited or may result in slower enrollment than we anticipate. In particular, because we are focused on patients with specific genetic alterations for certain of our development programs, our ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic alterations for our clinical trials. If our strategies for patient identification prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for the ADC Therapies or other product candidates.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as the ADC Therapies or any future product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment for one or more of our trials. Patient enrollment and retention for clinical trials may be affected by other factors, including:

- size and nature of the patient population;

- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol or as mandated by regulatory agencies;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- the ability to recruit clinical study investigators with the appropriate competencies and experience;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Furthermore, any negative results we may report in clinical trials of the ADC Therapies or any future product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their ADC drug candidates may negatively affect patient recruitment in our clinical trials. Enrollment delays in our clinical trials may result in increased development costs for the ADC Therapies and any other product candidates that we may develop and jeopardize our ability to obtain regulatory approval for such product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, there is a risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, may not survive the full terms of the clinical trials. As a result, we may have difficulty maintaining participation in our clinical trials through treatment and any follow-up periods. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

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 currently approved or unapproved therapies to treat cancer or other diseases. Patients may not be able to tolerate product candidates in combination with other therapies or dosing of product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates that we develop in the future were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with such products, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for product candidates, the

FDA, EMA or comparable foreign regulatory authorities in other jurisdictions requiring additional clinical trials, or our own products being removed from the market or being less successful commercially.

We may also evaluate product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market a product candidate in combination with any such unapproved therapies that do not ultimately obtain regulatory approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with product candidate, we may be unable to obtain approval of or successfully market product candidates we develop. These unapproved therapies face the same risks described with respect to product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of product candidates that we may develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of product candidates, if approved, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We face substantial competition in oncology and in the ADC field, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

Many companies are active in the oncology market and are developing or marketing products for the specific therapeutic markets that we target, including both antibody- and non-antibody-based therapies. Similarly, we also face competition from other companies and institutions that continue to invest in innovation in the ADC field, including new payload classes, new conjugation approaches and new targeting moieties. Specifically, we are aware of multiple companies with ADC technologies that may be competitive with our products and product candidates, including, but not limited to, AbbVie, Daiichi Sankyo, Day One Biopharmaceuticals, Eli Lilly, Genmab, GlaxoSmithKline, Gilead, Kelun, Mersana, Sanofi, Roche, Pfizer, Zymeworks, Ideaya, and Biocytogen. There are hundreds of ADCs in development, the vast majority of which are being developed for the treatment of cancer.

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition with respect to our current products and product candidates and will face competition with respect to any products and product candidates that we may seek to develop or commercialize in the future. We expect changes to the treatment paradigm, including potential new entrants and new approvals across the lines of therapies. New technologies, procedures or treatments could change the patient population and their eligibility to use our product candidates, raise expectations regarding safety and efficacy results that are necessary for regulatory approval and, if approved, adoption by the medical community, or otherwise render our products and product candidates obsolete and there can be no assurance that our products and product candidates would be able to compete effectively. If we are unable to compete with these new treatment options, physicians may not utilize our products and our future revenues and estimates may be negatively impacted.

Our competitors include large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Any potential competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than us. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in the field before us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop and commercialize. Our competitors also may obtain regulatory approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. The product candidates we may develop which achieve regulatory approval, may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any product candidates we may develop, if approved, could be adversely affected.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical studies and clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such material changes will require regulatory approval before implementation and carry the risk that they will not achieve these intended objectives. Any of these changes could cause any product candidate that we may develop to perform differently and affect the results of clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize any product candidates that we may develop, if approved, and generate revenue.

We may not be successful in growing our product pipeline through acquisitions and in-licenses.

We believe that accessing external innovation and expertise is important to our success; and while we plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio, such as with the in-license of the ADC Therapies, we may not be able to identify suitable licensing or acquisition opportunities, and even if we do, we may not be able to successfully secure such licensing and acquisition opportunities. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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 may also 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 license or acquire additional product candidates to expand our portfolio, our pipeline, competitive position, business, financial condition, results of operations, and prospects may be materially harmed.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have a material adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with any product candidates that we may develop. For example, we may be sued if the ADC Therapies or any other product candidates that we develop allegedly causes injury or is found to be otherwise unsuitable during product 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, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend against them, we could incur substantial liabilities. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our (or third-party) manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. Although we have obtained product liability insurance coverage, our insurance coverage may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain or maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could also cause our stock price to decline.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If the FDA does not conclude that a product candidate and/or new indications satisfy the requirements under the 505(b)(2) regulatory pathway, or if the requirements for such product candidate and/or new indications under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates and/or new indications may take longer, cost more or entail greater complications and risks than anticipated, which may delay or prevent the approval of a product candidate and/or new indications for commercial use.

We submitted a Section 505(b)(2) NDA to the FDA in May 2021 for FYARRO for the treatment of advanced malignant PEComa, and the FDA approved the NDA on November 22, 2021. However, we may not be successful in obtaining FDA approval under 505(b)(2) regulatory pathway for the ADC Therapies or any other product candidates that we may develop.

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously

approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA is not required to meet the PDUFA goal date, and the FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. Moreover, even if any new indication or product candidate is approved under the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which we may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We may be unable to obtain United States approval for product candidates that we may develop or foreign regulatory approval for product candidates that we may develop and, as a result, may be unable to commercialize any product candidates and in such event our business will be substantially harmed.

The ADC Therapies and other product candidates that we may develop are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. we cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon numerous factors, including the type, complexity and novelty of the product candidate. The standards that the FDA and our foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Under the new leadership at the HHS under the current administration, agency reorganization, mass layoffs due to the reduction in force initiative and other measures implemented by the Department of Government Efficiency may impact the normal operations of the FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. In January 2025, an executive order entitled “Unleashing Prosperity Through Deregulation”, was issued which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the new administration and FDA commissioner, or other executive orders. Recent developments at the FDA include implementation of Elsa, a generative AI tool, across all centers at the agency, announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, and the announcement of a new Commissioner’s National Priority Voucher program to companies supporting certain U.S. national health priorities and interests. FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other sensitive data of American patients to parties located in China. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the new administration. To the extent the agency reorganization and other agency changes lead to disruptions in FDA’s operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or

indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for product candidates that we may develop, we will be unable to generate product revenue, and our business will be substantially harmed.

Obtaining approval by the FDA, EMA 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. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Even if we eventually complete clinical testing and receive approval for any product candidates that we may develop, the FDA, EMA 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. Other than FYARRO, we have not obtained regulatory approval for any product candidate, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Further, regulatory approval may be delayed for reasons beyond our control. For example, events such as a United States federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018, 2019, 2025, and 2026 or the diversion of resources to handle the COVID-19 public health emergency and pandemic, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to obtain regulatory approval for our product candidates. Finally, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us from obtaining regulatory 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, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may find deficiencies with or 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;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests for our product candidates, if required; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Our clinical trials have been and may in the future be undertaken in the United States. We may choose to conduct additional clinical trials internationally as well. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for regulatory approval in foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We are subject to risks relating to regulatory uncertainty in foreign jurisdictions.

Brexit and uncertainty in the regulatory framework as well as future legislation in the United Kingdom, European Union, and other jurisdictions can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for future clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

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 or EMA grants regulatory 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 preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The regulatory approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States, as well as other risks. 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.

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 regulatory approvals, our target market will be reduced and our ability to realize the full market potential of a product candidate will be harmed.

Following Brexit, to the extent we conduct any operations in the United Kingdom, we will be subject to applicable regulatory requirements in the United Kingdom. Although the United Kingdom is no longer a member of the European Union, European Union law remains applicable in Northern Ireland, as set forth in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework, which was implemented in Northern Ireland on January 1, 2025. There are a number of new marketing authorization routes available in the United Kingdom, Great Britain (England, Scotland and Wales) or Northern Ireland, in addition to the national procedure. As with the European Union position, a company can only start to market a medicine in the United Kingdom once it has received a marketing authorization. The main legislation that applies to clinical trials in the United Kingdom is the UK Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the Clinical Trials Directive into domestic law. Consequently, the requirements and obligations that relate to the conduct of clinical trials in the United Kingdom currently remain largely aligned with the European Union position. It is unclear how future regulatory regime in the United Kingdom will impact regulations of products, manufacturers, and approval of product candidates in the United Kingdom. In the immediately foreseeable future, the United Kingdom regulatory approval process is likely to remain similar to that applicable in the European Union, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the European Union.

The ADC Therapies and any other product candidate we may develop for which we obtain marketing approval for could be, subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with any product candidate we may develop when and if any of them are approved.

The ADC Therapies and any other product candidate we may develop for which we obtain marketing approval could be, subject to a comprehensive regulatory scheme, which includes the regulation of manufacturing processes, post-approval clinical data, labeling, advertising, marketing, distribution and promotional activities for such product, by the FDA and other regulatory authorities. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. For example, the FDA may require the submission of a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. In addition, if the FDA or foreign regulatory authorities approve 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 on-going compliance with current good manufacturing practices ("cGMPs"), good laboratory practices ("GLPs") and good clinical practices ("GCPs") for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

If marketing approval of the ADC Therapies and any other product candidate we may develop is granted, such product candidates may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. We may be required, as a condition of approval of an NDA for a product candidate, to conduct certain post-marketing requirements ("PMR") and/or post-marketing commitments ("PMC"). If we fail to comply with the PMR and/or PMC, the FDA may take enforcement actions, which may include, among other things, the issuance of a Warning Letter and assessing civil monetary penalties. The product may also be deemed misbranded.

If any product candidate that we may develop receives marketing approval they may, have a label that limits their approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, 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, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing.

Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may have negative consequences, including:

- adverse inspection findings;
- additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- restrictions on a product, distribution, manufacturers or manufacturing processes;

- issuance of warning letters, safety alerts, dear-healthcare-provider letters, press releases or other communications containing warnings regarding the product that would result in adverse publicity;
- voluntary or mandatory product recalls and publicity requirements or withdrawal of a product from the market;
- suspension or withdrawal of marketing or regulatory approvals or other permits or voluntary;
- product seizures, detentions or import bans;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- requirement to establish or modify a REMS;
- requirement to conduct post-marketing studies or surveillance;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit and other delays;
- delays in or the rejection of approvals of additional indications for a product;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on, or the suspension or termination of, future trials;
- fines, restitution or disgorgement of profits or revenue;
- reputational harm;
- refusal of government contracts or future orders under existing contracts, exclusion from participation in federal health care programs; or
- injunctions or the imposition of civil or criminal penalties, including False Claims Act liability.

The holder of an approved NDA or comparable regulatory approval must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve pending applications or supplements to approved applications filed by us.

The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates that we may develop, if approved, and generate revenue. If regulatory sanctions are applied or if regulatory approval is withdrawn, our value and operating results will be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of FYARRO prior to its divestiture or any product candidate that we may develop, including the ADC Therapies, if approved, we may become subject to significant liability. The FDA and other regulatory agencies, including the U.S. Department of Justice, strictly regulate the post-approval marketing and promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies 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. As such, we may not promote our products for indications or uses for which they do not have approval. For example, physicians may, in their practice of medicine, use drug products for their patients in a manner that is inconsistent with the approved label. If we, or any of our contractors or agents acting on behalf of us, are found to have promoted such off-label uses, we may become subject to significant liability. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any product candidate that we may develop, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic product in connection with approval of any future product candidates or new indication that we may develop, and if we fail to obtain or face delays in obtaining FDA approval of such companion diagnostic product, we will not be able to commercialize such product candidate intended for use with such companion diagnostic product and our ability to generate revenue from such product candidate will be materially impaired.

In connection with the development of any future product candidates or new indications we may develop or work with collaborators to develop or obtain access to companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our programs. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of any future product candidates or new indication we may develop. To be successful in developing and commercializing such product candidate in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any future product candidate or new indication that we may develop, whether before or concurrently with approval of such product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. In June 2023, FDA announced a new voluntary pilot program through which drug manufacturers can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests, or LDTs, and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In 2025, the U.S. District Court for the Eastern District of Texas vacated FDA's LDT Final Rule, declaring that LDTs are not devices regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and instead are professional services regulated by the CMS under the Clinical Laboratory Improvement Amendments of 1988. In January 2024, FDA announced its plans to reclassify certain high-risk in vitro diagnostics, including companion

diagnostics, as Class II (or moderate risk) devices. We will continue to evaluate the impact of FDA guidance and other developments in the diagnostic space. This guidance and future issuances from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for any future product candidate or new indication, or experience delays in doing so, the development of such product candidate may be adversely affected, the product candidate may not obtain marketing approval, and we may not realize the full commercial potential of such product candidate after obtaining marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of any such future product candidate or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of any such future product or new indication. or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of any such future product candidate we may develop.

A Fast Track designation for HWK-206 may not lead to a faster development or review process, or we may be unable to maintain or effectively utilize such a designation. We may seek Fast Track designations from the FDA for other product candidates. Even if one or more of our product candidates receive Fast Track designation, we may not lead to a faster development or review process, or we may be unable to maintain or effectively utilize such a designation.

In November 2026, we announced that the FDA granted Fast Track designation for HWK-206 for the treatment of patients with extensive-stage small cell lung cancer with disease progression on or after platinum-based chemotherapy. We may seek Fast Track designation for other product candidates, and we may not be successful in securing such additional designation or in expediting development if such designations were received. Even if we receive Fast Track designation for product candidates, the FDA may withdraw such Fast Track designation if it believes that the Fast Track designation is no longer supported by data from our clinical development program.

Fast Track designation is designed to facilitate the development and expedite the review of therapies intended for the treatment of a serious or life-threatening condition which demonstrates the potential to address unmet medical needs for the condition. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any product candidates that we may develop that receives Fast Track designation does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. The FDA may withdraw any Fast Track Designation at any time. Furthermore, Fast Track designation does not change the standards for

approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

Breakthrough Therapy designation is for a product candidate that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request the FDA to designate our product candidate as a Breakthrough Therapy at the time of, or any time after, the submission of an IND for the product candidate. For product candidates that have been designated as a Breakthrough Therapy, the FDA may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the product candidate; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

The FDA has broad discretion in determining whether to grant a Fast Track or Breakthrough Therapy designation for a drug. Obtaining a Fast Track or Breakthrough Therapy designation does not change the standards for product approval but may expedite the development or approval process. There is no assurance that the FDA will grant either such designation for any other indication or product candidate that we may pursue. Even if the FDA does grant either such designation, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that a product candidate will receive regulatory approval in the United States in other indications.

We may not be able to obtain or maintain orphan drug designation or obtain or maintain orphan drug exclusivity for any product candidates and, even if we do, such exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for any product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. On January 24, 2023, the FDA published a

notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order - that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations.

Even if orphan drug designation is granted, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain regulatory approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, that the orphan drug exclusivity may not effectively protect an approved product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review. Further, changes in the leadership of the FDA and other federal agencies under the current administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans. In April 2025, the President issued an executive order and an accompanying fact sheet focused on lowering drug prices, but it is unclear what actions will be implemented by the Department of Health and Human Services, CMS, and FDA under the new leadership, and how those actions will impact our industry and our business.

We may be unable to obtain orphan drug designation or orphan drug exclusivity for any other product candidate, or we may be unable to successfully commercialize a product candidate for such orphan population due to risks that include:

- the orphan patient populations may change in size;
- there may be changes in the treatment options for patients that may provide alternative treatments;
- the development costs may be greater than projected revenue of drug sales for the orphan indications;
- the regulatory agencies may disagree with the design or implementation of our clinical trials;
- there may be difficulties in enrolling patients for clinical trials;
- the product candidate may not prove to be efficacious in the respective orphan patient populations;
- clinical trial results may not meet the level of statistical significance required by the regulatory agencies; and
- the product candidate may not have a favorable risk/benefit assessment in the respective orphan indication.

If we are unable to obtain regulatory approval for a product candidate in any other orphan population for which we obtain orphan drug designation or we are unable to successfully commercialize a product candidate, if approved, for such orphan population, it could harm our business prospects, financial condition and results of operations.

Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory 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 PMRs, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for future product candidates. Under the accelerated approval provisions in the FDA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that generally provides a 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, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. 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. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The Food and Drug Omnibus Reform Act 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. In March 2023, the FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such 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 under another expedited regulatory designation (e.g., breakthrough therapy designation), 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 a 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.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any product candidates that we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. Some of the provisions of the ACA have been subject to judicial and Congressional challenges, and in June 2021, the 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.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan 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 a pharmaceutical manufacturer to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, 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 Inflation Reduction Act of 2022 (the "Inflation Reduction Act"), 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. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. In June 2026, the CMS issued a proposed rule that would codify policies established in guidance documents for the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and beyond. CMS plans to release guidance to implement policies related to the effectuation of the MFP for the Medicare Drug Price Negotiation Program for 2028, consistent with the Inflation Reduction Act. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. If HHS begins to set most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, that can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the

current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. 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 laws after obtaining regulatory approval for any of the product candidates that we may develop. 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. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, unless additional congressional action is taken. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for any product candidates that we may develop, if approved, and accordingly, our financial operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, 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. Additionally, FDA has authorized the state of Florida to develop a program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Implementation of cost containment measures or other healthcare reforms that affect the pricing and/or availability of drug products may impact our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act"), was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we 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 whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory 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 regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Further, in view of the Supreme Court decision in

Loper Bright Enterprises v. Raimondo, this landmark decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, including market exclusivities, which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the current administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other jurisdictions. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Additionally, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions and may impose substantial obligations upon companies and new rights for individuals. Failure to comply with the GDPR and the applicable national data protection laws of European Union member states may result in fines up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Additionally, the UK has implemented legislation that substantially implements the GDPR, the UK GDPR, which provides for similar obligations and provides for penalties for noncompliance of up to the greater of £17.5 million or four percent of worldwide revenues. The UK enacted the UK Data (Use and Access) Act 2025 on June 19, 2025, which made targeted amendments to the UK GDPR and the UK Data Protection Act. The European Union also has enacted numerous laws and regulations addressing cybersecurity. Similar laws have been proposed, and in certain cases enacted, in other foreign jurisdictions. For example, on August 20, 2021, the Personal Information Protection Law ("PIPL") of the People's Republic of China was adopted and went into effect on November 1, 2021. The PIPL allows for fines of up to 50 million renminbi or 5% of a covered company's revenue in the prior year.

The PIPL shares similarities with the GDPR, including extraterritorial application, data minimization, data localization, and purpose limitation requirements, and limitations on cross-border data transfers. These developments and regimes and other regulatory regimes, guidance, or developments may impose additional obligations with respect to cross-border data transfers, all of which could restrict our activities in certain jurisdictions, limit our ability to provide our products and services or engage in other activities in certain jurisdictions, require us to modify our policies and practices, and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data across borders. Any of these events, if occurring, could adversely affect the manner in which we conduct our business and thus materially affect our operations and financial results.

More generally, state and foreign laws addressing privacy, data protection and cybersecurity may apply to the privacy, protection, security, and collection, use, transfer, retention, and other processing of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (the "CCPA"), which took effect on January 1, 2020, and subsequently was amended and supplemented by the CPRA, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. Numerous other states in the U.S. have proposed or enacted similar legislation. While the CCPA and many other similar state laws exempt some data regulated by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and certain clinical trials data, the CCPA and such other laws, to the extent applicable to our business and operations, may increase our compliance costs and potential liability. Further, some states have enacted more specific legislation, such as Washington's enactment of the My Health, My Data Act, which includes a private right of action. The U.S. federal government is also contemplating federal privacy legislation, and the U.S. Department of Justice has issued rules regarding certain bulk sensitive personal data transfers. The evolving trend toward more stringent laws and regulations in the United States relating to privacy, data protection and

cybersecurity, including the foregoing laws and regulations and the potential for future laws and regulations, could increase our compliance costs and potential liability and adversely affect our business.

It is possible that the GDPR, UK GDPR, CCPA, CPRA, or other laws and regulations relating to privacy, data protection and cybersecurity may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our policies and practices. We cannot guarantee that we are in compliance with all such laws and regulations, and we cannot be sure how these laws and regulations will be interpreted, enforced or applied to our operations.

Furthermore, various jurisdictions are introducing or enhancing laws, rules, and regulations relating to privacy, data protection and cybersecurity, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, and our efforts to comply with the evolving data protection rules may be unsuccessful. Our actual or alleged non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level in various jurisdictions may be costly and require ongoing modifications to our policies, procedures, and systems. The GDPR, UK GDPR, and other laws and regulations addressing privacy, data protection and cybersecurity may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with them.

Our actual or perceived failure to adequately comply with applicable laws and regulations or other actual or asserted obligations relating to privacy, data protection and cybersecurity, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect our business, financial condition, results of operations, and growth prospects.

Inadequate funding, layoffs, and other policies impacting the normal operations of the FDA, the Securities and Exchange Commission ("SEC") and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of fees, and statutory, regulatory, and policy changes. Changes in the leadership of the FDA and other federal agencies under the current administration, including return-to-office policy, hiring freeze, layoffs, and other policies implemented by the Department of Government Efficiency, may lead to changes in the operations of the FDA and other agencies, which may have a material impact on the industry and our clinical development plans. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

If a prolonged government shutdown occurs or if the FDA's normal operations are disrupted, 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, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with other United States healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. Further, our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities 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 significant losses, including, 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 regulatory 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 regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it 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 federal False Claims Act or federal civil money penalties;

- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act 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 federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;

- the federal HIPAA, which created new federal criminal statutes that prohibit a person from 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, fictitious, or fraudulent statements or representations 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 does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. 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 requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value made to covered recipients in the previously year, 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; our failure to submit required information timely, accurately, and completely may result in significant civil monetary penalties and may increase our liability under other federal laws or regulations; and

- additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including, for example, the GDPR, the UK GDPR, and state laws and regulations, including general legislation such as the CCPA, and sector- or subject matter-specific laws and regulations, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways. Many state laws in the U.S. are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state and other laws and regulations and if we fail or are alleged to comply with an applicable requirement of any of these laws or regulations, we could be subject to claims, demands, and litigation initiated by private individuals or entities, regulatory investigations and other proceedings, and fines, penalties, and other liabilities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions or safe harbors, it is possible that some of our activities, including those of our contractors or agents who conduct business for or on behalf of us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are alleged or found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant consequences, 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. Any of the foregoing consequences could seriously harm our business and our financial results. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraud, misconduct or other improper activities. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with federal and state health care fraud and abuse laws and regulations and similar foreign fraudulent misconduct laws; and accurately report financial information or data or disclose unauthorized activities to us. In particular, research, 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, certain 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. We have adopted a code of conduct, but 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 our self 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, or any contract manufacturers and suppliers we engage, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures, the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes, the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. The operations of our contractors may involve the use of hazardous and flammable materials, including chemicals and biological materials, and accordingly may 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, including any contamination at our current or past facilities and at third-party facilities, 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 hazardous and flammable materials, including chemicals and biological 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.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees are employed by the government and would be considered foreign officials under the FCPA, and often the purchasers of pharmaceuticals are government entities; therefore, our dealings with these doctors, hospital employees and purchasers are subject to regulation under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, collaborators, or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries

and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Our business activities may be subject to United States and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. For example, the U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls in connection with the conflict in Ukraine. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

If we fail to comply with export and import regulations, and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs that result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the United States. Tariffs, trade restrictions or sanctions imposed by the United States or other countries, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China, escalation in conflicts in Ukraine and the Middle East, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in Russia, could increase the prices of our and our collaboration partners' drug products, affect our and our collaboration partners' ability to commercialize such drug products, or create adverse tax consequences in the United States or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the United States or other countries could materially adversely affect our results of operations and financial condition.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been recently implemented that will limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Risks Related to Our Reliance on Third Parties

Our product candidates are complex and can be difficult to manufacture.

Our product candidates are complex and can be difficult to manufacture due to the advanced linker-payload architecture. Problems with the manufacturing process, including even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, and insufficient inventory, negative impact on our sales and results of operations and make us a less attractive collaborator for potential partners or subject us to liability for any contamination or injury or failure to comply with applicable laws. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs. There can be no assurance that manufacturing issues will not occur in the future.

We are currently dependent on single-source suppliers for our product candidates and their components, any issues with any such suppliers, including increases in costs or expenses or delays in supply, could harm our business.

We currently rely on third parties to manufacture or supply our product candidates and their components and raw materials, many of which are sole source manufacturers and suppliers. For the near term, Hangzhou DAC will continue to manufacture the CPT113 linker-payload and WuXi Biologics and its subsidiary will continue to manufacture the antibodies underlying our ADC Therapies, including antibody development, bioconjugation and fill and finish.

Although we have arrangements in place for the manufacture and supply of our product candidates and its key components, our manufacturers or suppliers could discontinue the manufacturing or supply at any time. Our manufacturers or suppliers may not be able to meet our demand whether because of acts of nature, the nature of our agreements with those manufacturers or suppliers or our relative importance to them as a customer, and our manufacturers and suppliers may decide in the future to discontinue or reduce the level of business they conduct with us either entirely or for a particular territory. The loss of any of the foregoing would require significant time and effort to locate and qualify an alternative source of supply, including efforts involved in the technology transfer. These third parties could also seek to renegotiate our arrangements and require that we pay more for the manufacture or supply. Any contractual disputes between us and our manufacturers or suppliers, or the loss of manufacturing ability by such parties could similarly require significant time, effort and expense and materially harm our business.

In addition, we might not be able to identify and qualify additional or replacement suppliers for our product candidates, its key components or the key raw materials used in the manufacture of our product candidates on a timely basis or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We may also face delays in our clinical trials or regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers.

Furthermore, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce products and product candidates on schedule and could cause reputational damage. Some of the raw materials could be difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction in the manufacture of any product candidates could adversely impact or disrupt the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies that were previously conducted for our product candidates.

We have relied on third parties, including WuXi Biologics and its affiliates, to conduct certain preclinical studies and clinical trials. We are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates

that we may acquire or in-license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected.

We rely on third parties to conduct preclinical studies and clinical trials and for the manufacture, production, storage and distribution of our products and product candidates and certain commercialization activities for our products.

We rely on, and expect that we will continue to rely on, third parties to assist in managing, monitoring and otherwise carrying out preclinical studies and clinical trials of our ADC Therapies and other product candidates that we may develop and other third parties for the manufacture, production, storage and distribution of our ADC Therapies and other product candidates that we may develop and certain commercialization activities for our product candidates, if approved, including government pricing, reporting and chargeback and rebate processing, pharmacovigilance and adverse event reporting. We have less control over the activities of third parties than we would otherwise have if we relied entirely upon our own staff and we are exposed to different risks, including all the risks associated with such third parties' businesses and financial condition, than if we performed such functions ourselves. There can be no assurance that these third parties will perform services for us in accordance with our timelines, standards and expectations. If these third parties do not successfully carry out their duties under their agreements or otherwise fail to comply with regulatory requirements, we may experience delays in our research and development activities, be unable to obtain and maintain regulatory approval, be unable to commercialize our products and be required to issue product recalls. In addition, if any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements on a timely basis or on commercially reasonable terms, and even if successful in entering into alternative arrangements, we may experience significant delays during the transition. This risk may be heightened by our use of single-source supplier arrangements. Furthermore, if a third-party manufacturer cannot maintain a compliance status acceptable to the FDA, or if the EMA or a comparable regulatory authority in another jurisdiction does not approve these facilities for the manufacture of our products and product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would be time-consuming, costly and uncertain and significantly impact our ability to develop, obtain regulatory approval for, source adequate supply of or market our products and product candidates.

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

We rely on third-party license agreements pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our development programs and product candidates. For example, under our License Agreement with WuXi Biologics, we have been granted worldwide development and commercialization rights to the ADC Therapies, which includes rights to use the linker-payloads that WuXi Biologics has licensed from Hangzhou DAC. These license agreements impose diligence, milestone payment, royalty payment and other obligations on us.

Termination of the License Agreement or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms or to cease all development and commercialization of our current product candidates. In addition, delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business for that period. If any such events were to occur, they could have a material adverse effect on our business prospects, financial condition and results of operations.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third-party intellectual property, technology and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable

terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

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

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

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct all of our preclinical studies and clinical trials. We have relied and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct, supervise and monitor our preclinical studies and clinical trials of our ADC Therapies and any other product candidates we may develop. We enter into agreements with third parties that have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the conduct of such third party, the amount or timing of resources that any such third party will devote to our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. The third parties we rely on for these services may also (i) have staffing difficulties, (ii) fail to comply with contractual obligations, (iii) experience regulatory compliance issues, (iv) undergo changes in priorities or become financially distressed, or (v) have relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies and clinical trials being delayed or unsuccessful. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, this would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and legal, regulatory, and scientific requirements and standards. Moreover, the FDA requires us and our third parties to comply with applicable GLP and GCP standards, regulations for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to assure that the data and reported results are reliable and

accurate and for clinical trials that the rights, integrity and confidentiality of trial participants are protected and that they are adequately informed of the potential risks of participating in clinical trials. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies and clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under current cGMP regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. We are also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not successfully carry out their contractual duties or perform preclinical studies and clinical trials in a satisfactory manner, meet expected deadlines or conduct our preclinical studies and clinical trials in accordance with legal and regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for product candidates that we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates, if approved.

We may form or seek strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.

We may form or seek strategic alliances, joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to any product candidates that we may develop. We are at risk that any such future collaborations may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their efforts under their collaboration agreement with us;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

In addition, any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances without cause subject to a specified notice period. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may not receive additional milestones or royalties under those collaborations. In addition, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us.

Future efforts for additional alliances or collaborations may also require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our

management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Furthermore, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

If we cannot maintain successful collaborations, our business, financial condition, and operating results may be adversely affected.

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 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 transaction;
- 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 regulatory approvals; and
- our inability to generate revenue from acquired technology and/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.

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

Our drug development programs and the potential commercialization of any product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. 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 would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for

the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for 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 them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

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 our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to 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 the ADC Therapies or any future product candidates or bring them to market, if approved, and generate product revenue.

We may enter into collaborations with third parties for the development and commercialization for any product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving any product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than us;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of any product candidate that we may develop, if approved, relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in 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;
- collaboration agreements may not lead to development or commercialization of any product candidates that we may develop in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of any product candidates that we may develop;
- collaborators may own or co-own intellectual property covering our products that results from us collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements. For example, on June 27, 2022, EOC Pharma (Hong Kong) Limited ("EOC") elected to terminate our license agreement with EOC ("EOC License Agreement"), effective immediately, due to alleged material breaches by us. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us. As a result, we became party to a lengthy arbitration process and, although we were found not liable for any damages to EOC in the arbitration panel's final award in September 2024, we nevertheless experienced management distraction and incurred significant legal fees to defend ourselves.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to our Business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers or key scientific personnel could be detrimental to us if we cannot recruit suitable replacements in a timely manner. Any leadership transitions, as well as future other senior management changes, could disrupt and have a detrimental effect on our business. We may need to hire additional personnel in connection with future clinical development and commercial activities. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than us. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with these advisors or they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

If we are unable to successfully establish and maintain sales or marketing capabilities or enter into agreements with third parties to sell or market product candidates that we may develop, when approved, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

In order to commercialize any product candidate that we may develop, when approved, we must build and maintain marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product(s). There are risks involved with establishing and maintaining both our own commercial capabilities and entering into arrangements with third parties to perform these services and we may not be successful in accomplishing these required tasks, which may negatively impact the successful commercialization of our product(s).

Establishing and maintaining an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates that we obtain approval to market will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market or if we do not have arrangements in place with third parties to provide such services on our behalf. If the commercial launch of a product candidate for which we recruit a sales team and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our

investment would be lost if we cannot retain or reposition our commercialization personnel. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on its own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product sales will suffer, and we may incur significant additional losses.

In order to successfully implement our plans and strategies, from time to time we may need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 5, 2026, we had 37 full-time or part-time employees. In order to successfully implement our plans and strategies, from time to time we may need additional managerial, operational, development, financial and other personnel. In order to successfully implement our plans and strategies, from time to time we may need additional managerial, operational, development, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for any product candidates we may develop, while complying with any contractual obligations to contractors and other third parties that we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of any product candidates that we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to develop product candidates that we may develop and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, or use or other processing of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on and processed by our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of systems and information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. These risks may be heightened due to the increasing number of our and our vendors' and contractors' personnel working remotely. Additionally, new and evolving technologies, including artificial intelligence technologies that facilitate the identification and exploitation of security vulnerabilities, may increase cybersecurity risks. Further geopolitical events such as wars and conflicts may increase the cybersecurity threats we and the third parties we work with face. Any disruption or security breach or incident resulting in a loss, destruction, unavailability, or unauthorized alteration, dissemination, or other processing of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, have prevented or will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, or unauthorized alteration, dissemination, or other processing of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, any such event that were to occur and cause interruptions in our operations could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss, unauthorized alteration, or unavailability of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, interruptions or other disruptions of our internal information technology systems or security breaches or incidents could result in the loss, misappropriation, and/or unauthorized access, use, disclosure, or other processing of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information or individually identifiable health information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads or is perceived to lead to unauthorized access, use, disclosure, or other processing of individually identifiable health information or personal information, including such information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of such information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Some federal, state and foreign governmental requirements include obligations of companies to notify individuals of security breaches involving particular information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have relationships. Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems

could also have a material adverse effect on our business. Any disruption or security incident resulting or perceived to result, in any loss, destruction, or unauthorized alteration or other processing of, or damage to, our data (including personal information and other information relating to individuals, and our confidential or proprietary information or that of third parties), we could be exposed to claims, demands, litigation and governmental investigations and other proceedings, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties, and other liabilities.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach of, or security incident of, or impacting, our systems or third-party systems where information important to our business operations or commercial development is stored or otherwise processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our ability to utilize our net operating loss ("NOL") carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under United States federal or state tax law. Our U.S. federal NOLs generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 taxable years under applicable United States federal tax law, and therefore could expire unused. Our U.S. federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs is generally limited to 80% of our current year taxable income.

As of December 31, 2025, after consideration of the NOLs that have been estimated to expire unused under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), we had U.S. federal NOL carryforwards of approximately $118.9 million, $40.6 million of which will begin to expire in 2030, and the remaining $78.3 million do not expire. We also have state NOL carryforwards of approximately $22.2 million available as of December 31, 2025, of which $21.3 million will begin to expire in 2037.

Following the FYARRO Divestiture, the portion of our NOLs and other tax attributes that were allocable to Aadi Subsidiary generally remain with Aadi Subsidiary and no longer constitute our tax attributes.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent stockholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. Similar rules may apply under state tax laws. We have experienced such ownership changes in the past and we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside our control. To the extent such limitations will cause NOL and research and development credit carryforwards to expire unused, these tax attributes have been removed from our deferred tax assets. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. Moreover, due to suspensions on the use of NOLs or other regulatory changes by certain jurisdictions, our NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For example, in June 2024, California enacted legislation that limits the use of state NOLs for tax years beginning on or after January 1, 2024, and before January 1, 2027.

Changes in tax laws could materially adversely affect our financial condition.

Legislation or other changes in United States and international tax laws could increase our tax liability and adversely affect after-tax profitability. For example, in August 2022, the United States enacted the Inflation Reduction Act, which implemented a number of changes, including a 1% excise tax on stock buybacks and an alternative minimum tax on adjusted financial statement income. Further, legislation commonly known as the "One Big Beautiful Bill Act" enacted

in July 2025, eliminates capitalization of domestic research and experimental expenditures for taxable years beginning January 1, 2025, but retains the requirement to amortize foreign research and experimental expenditure over 15 years. Such enacted and other proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may have significant impacts on our effective tax rate, cash tax expenses and net deferred tax assets in future periods.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect and strengthen our intellectual property and our proprietary technologies, including our ability to obtain patent term extension for our product or any future product candidates.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries for our product and product candidates, proprietary technologies and their uses, and know-how related to our business, as well as our ability to operate without infringing upon the valid and enforceable patents and 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 and product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our patent portfolio covering the ADC Therapies is at an early stage and includes provisional applications and applications under the Patent Cooperation Treaty ("PCT"). We do not currently own or in-license any issued patents covering the ADC Therapies, and our ability to obtain patent protection and to exclude competitors is therefore uncertain. 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 our licensors will result in patents being issued in any particular jurisdiction 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 or invalidated by third parties.

A provisional patent application is not examined and cannot itself issue as a patent. To claim the benefit of a provisional application's filing date, a corresponding non-provisional or PCT application generally must be filed within twelve months, and failure to do so would result in the loss of that priority date. We cannot assure you that we or our licensors will file such applications in a timely manner, or that the applications, if filed, will be sufficient to support the priority claim.

A PCT application does not itself result in an issued patent. To obtain patent protection, national or regional phase applications must be filed in each jurisdiction of interest within the deadlines applicable in that jurisdiction, which are measured from the earliest priority date. Pursuing protection in every jurisdiction would be prohibitively expensive, so we and our licensors will elect to pursue protection in only a subset of jurisdictions, and the claims that issue may differ from jurisdiction to jurisdiction. We cannot assure you that national or regional phase applications will be filed in a timely manner or in all jurisdictions that may be commercially important to us.

Even if patents issue from our or our licensors' applications, the claims granted may be significantly narrower than those originally filed, may not cover the ADC Therapies as ultimately developed and commercialized, and may be challenged, narrowed, circumvented, or invalidated. If we are unable to obtain and maintain meaningful patent protection for the ADC Therapies, we may be unable to exclude competitors from developing and marketing the same or similar products; the perceived value of our product candidates, and of our company, may be reduced; and we may be unable to assert infringement claims or counterclaims against third parties or to negotiate favorable settlements. In addition, if we experience delays in our clinical trials or in obtaining regulatory approval, the period during which we could market our product candidates under patent protection would be shortened.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for us and our 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 and/or limitations in our ability to properly protect the intellectual property rights relating to our ADC Therapies or any future products or 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 owned or licensed United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, will be considered patentable by the United States Patent and Trademark Office (the "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 issued patent 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 current or 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;
- if clinical trials encounter delays, the period of time during which we could market our current or future product candidates under patent protection would be reduced;
- patents may be challenged, invalidated, modified, narrowed, revoked, circumvented, found to be unenforceable, found to be not infringed or otherwise may not provide any competitive advantage;
- 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 could limit, interfere with or eliminate our ability to make, use and sell our product or potential product candidates or design around any of our owned, co-owned, or licensed patents;
- since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product; or (ii) invent any of the inventions claimed in our patents or patent applications;
- even when laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing products or product candidates.

The patent prosecution process is also expensive, complex, and time-consuming, and we and our 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 and our licensors will fail to identify patentable aspects of our (or such licensor's) research and development output before it is too late to obtain patent protection. If we are unable to obtain or maintain patent protection with respect to any of our proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

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, thereby jeopardizing 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 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 our products.

Patent term is generally measured from the earliest non-provisional or PCT filing date to which a patent claims priority, and does not include the period during which a provisional application is pending. Because of the time required for clinical development and regulatory review, any such patents may expire before or shortly after our product candidates, if approved, are commercialized.

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 products 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. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our pending and future patent applications and those of our licensors may not result in patents being issued that protect our ADC Therapies or future products or product candidates or effectively prevent others from commercializing competitive products.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in-licenses 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-licenses may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our ADC Therapies or any future products or 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 our 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 our 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 ("PGR"), and *inter partes* review ("IPR"), or other similar proceedings challenging our owned 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 or put our patent applications at risk of not

issuing, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. 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 or identical technology and products, or limit the duration of the patent protection of our products. 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 patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. If any of our patents, if and when issued, covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. We may not prevail in any lawsuits that we or any third-party initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

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 any product candidates but that are not covered by the claims of the patents that we own or license;
- we or our 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 our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- 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, financial condition, results of operations and prospects.

Our 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 success depends in part on avoiding infringement or misappropriation of the patents, intellectual property 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 products or products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings, and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party United States 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 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 ADC Therapies, if approved, or any future products 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 that may be infringed by commercialization of our ADC Therapies or any future products, and we cannot be certain that we were the first to file a patent application related to a product or technology. Moreover, because patent applications can take many years to issue, and because patent claims can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our ADC Therapies may infringe or which such third parties claim are infringed by our technologies. 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 products 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. If a patent holder believes one or more of our products or product candidates infringes such holder's patent rights, the patent holder may sue us even if we have received patent protection. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. Any 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 Quarterly Report, others may hold proprietary rights that could prevent our product candidates that we may develop from being marketed. For example, various patent offices periodically grant mode of action patents and a third party may have or obtain a patent with claims covering modes of action relevant to our product candidates. While these mode of action patents may be difficult to enforce, the third party may assert a claim of patent infringement directed at any product candidates we may develop. Any patent-related legal action or any claim relating to intellectual property infringement that is successfully asserted against us claiming damages and seeking to enjoin commercial activities relating to our products or processes could subject us to significant liability for damages, including treble damages and attorney's fees if it was determined that we willfully infringed, and require us to obtain a license to manufacture or market our products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. 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 our current or future strategic partners 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 products 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 or delay 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 our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

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 ADC Therapies or any future products or product candidates that we may develop 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 ADC Therapies or any future products or 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. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We may also be unable to license or acquire third-party intellectual property rights on terms that would be favorable to us or allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant

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 or other proceedings to protect or enforce our patents or intellectual property or our licensors' patents or intellectual property, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our patents and other intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the attention of our management and key personnel from our business operations. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/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 products or product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, 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 withheld relevant information from the USPTO or made a misleading statement during prosecution of the patent application.

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 our licensors' patents in such a way that such patents no longer cover our technology or platform, product or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we 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, product 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 and/or unenforceability is unpredictable, and prior art could render our patents or our 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 our 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 our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or 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 technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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.

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 may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our ADC Therapies or any future products or 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 our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. 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 any future products to market.

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

On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be 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 files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. 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 our licensors are the first to either file any patent application related to

our ADC Therapies or any future products or product candidates or invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including 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 that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect any future products.

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

For example, the United States 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 United States Congress, the United States 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 patents and the patents we might obtain or license in the future.

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 our former employees or our licensors or other third parties have an ownership interest in our patents or other intellectual property. Confidentiality and intellectual property assignment agreements may not be honored and may not effectively assign intellectual property rights to us. The assignment of intellectual property rights under these agreements may not be automatic upon the creation of the intellectual property or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against it, to determine the ownership of what we regard as our 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 ADC Therapies or any future products or 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 United States non-provisional effective 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 ADC Therapies or any future products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to us.

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

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates that we may develop, one or more of our United States patents or those of our licensors may also be eligible for limited patent term restoration under the 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 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. 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 or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, our competitors may obtain approval of competing 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 trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, the statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications and we may not timely file foreign patent applications.

Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which significantly impacts European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the “UPC”). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and

remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of these changes.

Competitors may use our technologies in jurisdictions where we do not pursue or 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 any of our future products, and our patents, the patents of our licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain 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 our 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 our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our 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 third parties, including 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.

Government actions in certain jurisdictions, including sanctions-related measures and decrees directed at patent owners from countries such as the United States, may prevent us from obtaining, maintaining, or enforcing patent rights, or may allow third parties to use our patented inventions without compensation.

Governments may take actions that limit or eliminate patent protection or increase its cost. For example, in March 2022, the Russian government issued Decree No. 299, which provides that where the Russian government authorizes the use of a patented invention without the owner's consent, the compensation payable to owners from countries that Russia considers "unfriendly," which include the United States, is set at zero. As a result, we may be unable to obtain compensation for, or to enforce otherwise valid patent rights against, certain uses of our inventions in Russia, and we may not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions into Russia.

Sanctions imposed by the United States and other governments on Russia, and Russia's countermeasures, may also impede our ability to file, prosecute, maintain, and enforce patents in Russia. Although the U.S. Treasury Department's Office of Foreign Assets Control has authorized certain intellectual property-related transactions in Russia, including filing and prosecuting patent applications and paying maintenance fees, sanctions-related restrictions and the reluctance of financial institutions to process Russia-related payments may make it difficult or impossible to pay local counsel and other intermediaries, which could result in the abandonment or lapse of patent applications or patents. These actions could result in the partial or complete loss of patent rights in Russia.

Other jurisdictions, including China and Brazil, also have laws under which patented inventions may be exploited without the patent owner's consent in certain circumstances, such as compulsory licensing. More generally, geopolitical developments in the United States and abroad, including sanctions, export controls, and trade measures, could increase the uncertainty and cost of prosecuting and maintaining patent applications and of maintaining, enforcing, or defending patents. Any of these developments could impair our competitive position in the affected jurisdictions and adversely affect our business, financial condition, results of operations, and prospects. See also our risk factors regarding security and data privacy breaches and regarding doing business in China.

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 our owned and in-licensed patents and/or applications will be due to be paid to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors and any patent rights we may own or license in the future. We have systems in place to remind us to pay these fees, and, in certain instances, we rely on our licensor partners 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 and over the lifetime of our owned patents and applications. 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, competitors or other third parties might be able to enter the market earlier than would otherwise have been the case and it could have a material adverse effect on our business, financial condition, results of operations and prospects.

Defects of form may also exist in the preparation or filing of our and our licensors' patents and patent applications, or may arise in the future, including with respect to priority claims, inventorship listings, ownership, claim scope, timely responses to official actions, and timely requests for patent term adjustment. If there are material defects, an issued patent may be invalid or unenforceable, and we may lose patent rights or the ability to exclude others.

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. 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 secrets, 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.

We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. 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. However, trade secrets are difficult to protect. For example, we may be required to share our trade secrets with third-party licensees, collaborators, consultants, contractors, or other advisors and we have limited control over the protection of trade secrets used by such third parties. Although we have taken steps to protect our trade secrets and unpatented know-how, including by entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed or that they have been obtained in all circumstances, and it is possible that any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Enforcing a claim that a party illegally obtained, disclosed, used 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. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. If any of these events occurs or if we otherwise lose protection for our trade secrets or confidential or proprietary information, the value of this information may be greatly reduced, and our competitive position in the marketplace, business, financial condition, results of operations and prospects may be materially adversely affected. 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 share, and expect to continue to share, trade secrets and other confidential information with third parties located in jurisdictions that present a heightened risk of misappropriation, including through cybersecurity intrusions, and our ability to restrict former personnel from joining competitors may be limited.

Because we may rely on third parties to manufacture our product candidates and to conduct preclinical studies and clinical trials, we share, and expect to continue to share, trade secrets, know-how, and other confidential information with those parties, many of which are located outside the United States, including in China. Sharing proprietary information increases the risk of unintended disclosure or misappropriation. Any disclosure, whether intentional or unintentional, by our employees, by the employees of third parties with whom we share facilities, or by third-party consultants and vendors, or any misappropriation by third parties, including through a cybersecurity breach, could enable competitors to duplicate or surpass our technological achievements and erode our competitive position.

We may need to share proprietary information, including trade secrets, with business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or by state actors and those affiliated with or controlled by state actors. Our confidentiality agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure, and the legal protections available for trade secrets, and the practical ability to enforce them, vary by jurisdiction. Monitoring unauthorized disclosure is difficult, and enforcing a trade secret claim is expensive, time-consuming, and unpredictable. Competitors may also purchase our products, if approved, and attempt to reverse engineer

or replicate some or all of the competitive advantages we derive from our development efforts, or design around our protected technologies. See also our risk factors regarding security and data privacy breaches and regarding doing business in China.

In addition, the laws of many jurisdictions limit the enforceability of non-compete provisions in employment agreements. If such provisions are unenforceable, former employees may be free to join our competitors or to form competing businesses, potentially using know-how they gained while working for us.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and will 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, and other third parties. We may become subject to litigation where a third party asserts that we or our employees, consultants or advisors inadvertently or otherwise breached the agreements and used or disclosed 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 ADC Therapies, if approved, or any future products or product candidates, if approved, and technology. 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.

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 pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product or any future 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 pharmaceutical companies including competitors or our 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 technology and product candidates that we may develop 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 or allow commercialization of our ADC Therapies or any future products or product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

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 the technology 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 our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we had licensed may be reduced or eliminated, and our rights to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our 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-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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 technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product, 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 or product candidate, 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 technology, manufacturing methods, product or future methods or product candidates resulting in either an injunction prohibiting our manufacture, sales or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Our rights to the linker-payload used in all of our product candidates are held through a sublicense from WuXi Biologics, which in turn licenses the technology from Hangzhou DAC. If WuXi Biologics' license from Hangzhou DAC is terminated, or if WuXi Biologics fails to comply with its obligations under that license, our rights could be terminated or impaired.

Under the License Agreement, we have been granted worldwide development and commercialization rights to the ADC Therapies, which include rights to use linker-payloads that WuXi Biologics has licensed from Hangzhou DAC. If WuXi Biologics were to breach or otherwise fail to comply with its obligations under the Upstream License, including payment, diligence, or other obligations, Hangzhou DAC may have the right to terminate the Upstream License, which could result in the termination of our sublicense. The same could occur if the Upstream License expires or terminates for any other reason, including the insolvency or a change of control of either party.

We may have limited visibility into WuXi Biologics' compliance with the Upstream License and limited ability to cure any breach on its behalf. The Upstream License may be complex and susceptible to multiple interpretations, and disputes could arise among us, WuXi Biologics, and Hangzhou DAC regarding, among other things, the scope of the rights granted, sublicensing rights, financial and diligence obligations, whether our technology infringes intellectual property of Hangzhou DAC that is not covered by the license, and the ownership of jointly created inventions. The resolution of any such dispute could narrow our rights or increase our financial obligations.

Because many of our product candidates currently use the same linker-payload architecture, the termination or impairment of our rights to the linker-payload would affect our pipeline, and we may be unable to develop, manufacture, or commercialize our product candidates. In that event, competitors, including parties to which WuXi Biologics or Hangzhou DAC may license the same or similar technology, could gain the freedom to develop and market competing products. See also our risk factors regarding security and data privacy breaches and regarding doing business in China.

If we fail to comply with our obligations in the agreements under which we license intellectual property 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 licensors regarding intellectual property 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 technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patents and other rights 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 us and our licensors and partners; and
- the priority of invention of patented technology.

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

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology 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 conditions, results of operations, and prospects.

The patent protection and patent prosecution for our product candidates that we may develop in the future may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our ADC Therapies or any future products or product candidates, there may be times when the filing and prosecution activities for patents are controlled by our licensors or collaboration partners, including those licensed to us under our license agreements. If any of our licensors or collaboration partners fail 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 patents covering our ADC Therapies or any future products or 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 our product or those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any invention that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. 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.

Third parties, including our contract research and manufacturing organizations and other collaborators, may own or claim rights in inventions relating to our product candidates, and co-owners of patent rights may be able to license those rights to our competitors or impede our enforcement efforts.

We rely on third parties, including WuXi Biologics and its subsidiaries, contract research organizations, and contract development and manufacturing organizations, to conduct testing, process development, and manufacturing for our product candidates. Agreements with these parties may provide that improvements or inventions made in the course of their work are owned solely by the third party or jointly with us. If we determine that rights to such an improvement are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from the third party. We may not be able to obtain a license on commercially reasonable terms, or at all, and any license may be non-exclusive, giving our competitors access to the same technology. Failure to obtain a necessary license could prevent us from commercializing our product candidates or force us to cease some of our business operations.

Certain patents or patent applications relating to our product candidates may be co-owned with third parties. Our rights in such patents may depend on agreements among the co-owners to which we are not a party. Under United States law, absent agreement to the contrary, each co-owner of a patent generally may make, use, offer to sell, and sell the patented invention, and license it to others, without the consent of, or any obligation to account to, the other co-owners. Co-owners of patents relating to our product candidates could therefore license their interests to our competitors. In addition, all co-owners generally must join as plaintiffs in an infringement action, so we may need the cooperation of any co-owner to enforce such patents, and that cooperation may not be provided.

Disputes regarding inventorship and ownership may also arise from conflicting views about the contributions of different individuals, from the effects of foreign laws where foreign nationals or foreign entities are involved in developing the subject matter of a patent, or from conflicting obligations of third parties involved in developing our product candidates. Our product candidates incorporate antibodies designed by WuXi Biologics and a linker-payload designed by Hangzhou DAC, each of which is located in China. The failure to name the proper inventors on a patent can result in the patent being invalid or unenforceable. Litigation may be necessary to resolve such disputes, and if we fail to defend against such claims, we could lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, intellectual property that is important to our product candidates. Even if we are successful, litigation could result in substantial costs and distraction to our management and other employees.

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

Our licensed patent applications may have been or may be in the future supported through the use of United States government funding awarded by the National Institute of Health or the FDA Office of Orphan Products Development and the Army Medical Research and Development Command. Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we have licensed, or may acquire or license in the future, intellectual property rights that have been generated through the use of United States government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. These United States government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States 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 ("march-in rights"). The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States 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 United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

The use of artificial intelligence and other new and evolving technologies in our operations, or by our collaborators and service providers, may present risks to our intellectual property and confidential information and may subject us to evolving legal requirements.

We and our third-party collaborators and service providers may use artificial intelligence, machine learning, and other automated or computational technologies (collectively, "AI") in connection with our research, development, regulatory, and operational activities. The use of AI can give rise to intellectual property risks, including uncertainty regarding the patentability and ownership of AI-assisted inventions, the compromise of proprietary or confidential information, inaccurate or biased outputs, data privacy and cybersecurity issues, disputes regarding the provenance of data used to train or operate AI systems, and claims of infringement or misappropriation.

The legal framework governing inventorship of AI-assisted inventions is evolving. In November 2025, the USPTO rescinded the guidance it issued in February 2024 and issued revised guidance stating that AI systems cannot be named as inventors, that the same legal standard for inventorship applies to all inventions regardless of whether AI was used, and that the factors set forth in *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998), apply only in determining whether multiple natural persons qualify as joint inventors. Further changes in USPTO guidance, court decisions, or legislation in the United States or abroad could affect our ability to obtain, maintain, or enforce patents covering inventions developed with the assistance of AI. If we or our licensors are unable to establish that a natural person conceived each claimed invention, patents covering those inventions could be challenged as invalid or unenforceable on inventorship grounds.

Information that we or our service providers input into third-party AI tools may be retained, used to train models, or disclosed to others, which could compromise trade secrets or, in some circumstances, patentability. AI may have errors or inadequacies that are not easily detectable, and if the data used to train AI, or the content that AI applications assist in producing, are deficient, inaccurate, or biased, our business may be adversely affected. We also expect increasing government regulation of AI, including the European Union's Artificial Intelligence Act, which entered into force on August 1, 2024 and imposes obligations on providers and deployers of AI systems, and which may increase our compliance costs. Our employees, collaborators, or third-party service providers may incorporate AI tools into their work in ways that do not meet evolving regulatory or industry standards.

General Risks

Our business is subject to the risks associated with doing business in China.

As a result of our reliance on WuXi Biologics and Hangzhou DAC, both located in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we rely on an entity located in China, our business is subject to the risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;

- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;
- changes and volatility in currency exchange rates;
- unexpected or unfavorable changes in regulatory requirements; and
- difficulties in managing foreign relationships and operations generally.

For example, the BIOSECURE Act was signed into law as a part of the 2026 National Defense Authorization Act, which includes Section 851 regarding a "[p]rohibition on contracting with certain biotechnology providers." This law restricts federal government contracts, grants, and loans from being issued to companies that use biotechnology equipment or services produced or provided by select Chinese biotechnology companies (each, a "biotechnology company of concern"), as part of such companies' performance of those agreements with the U.S. government. This legislation, including its implementing regulations, or similar legislation in the future, could adversely impact our current or future third-party arrangements with certain companies, including those in China or Chinese-owned U.S. companies, which could delay or impact our clinical trials and consequently delay or obstruct successful commercialization of our product candidates. Foreign CMOs may be a target of U.S. legislation, including the BIOSECURE Act, and trade restrictions and other foreign regulatory requirements could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, restrict or even prohibit our ability to work with such CMOs, or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies. Once the implementing regulations of Section 851 come into effect, which will be no later than the third quarter of 2028, some of our business partners like WuXi Biologics may be designated as biotechnology companies of concern through the criteria and process established by the implementing regulations. Even if we do not seek any covered federal government contracts, grants, or loans, it is possible that commercial partners, government agencies, or other third parties may view our business less favorably if we contract with entities that ultimately become biotechnology companies of concern.

In addition, other U.S. national security laws and regulations could also affect the transfer of certain types of data abroad, including to China. For example, the Department of Justice issued a final rule which took effect in April 2025 that places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China and other designated countries, or with other specified links to China and other designated countries. These rules also may broadly require us to extract promises from other third-party service providers that they will not transfer data we share with them onward to parties linked to countries of concern.

Moreover, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partners, licensors, suppliers, manufacturers or collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. Furthermore, if one or more of our manufacturers or suppliers in China, including WuXi Biologics, is deemed to be a biotechnology company of concern, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such third parties. In addition, while we

may work to establish relationships with CROs and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into the development program.

U.S.-China trade relations may adversely impact our supply chain operations and business.

The U.S. and Chinese governments have taken certain actions that change trade policies, including tariffs that affect certain products which are manufactured in China and mutual exchange of certain types of data. Due to our reliance on WuXi Biologics and Hangzhou DAC to supply and manufacture our product candidates and their components, we are reliant on collaborating with a company with significant operations in China. It is unknown whether and to what extent new tariffs, laws or regulations will be adopted that increase the cost or feasibility of importing and/or exporting products, components and information from China to the United States and vice versa. Further, the effect of any such new tariffs or actions on our industry and customers is unknown and difficult to predict. As additional new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or if China or other affected countries take retaliatory trade actions, such changes could have a material adverse effect on our clinical development plans, business, financial condition, results of operations or cash flows.

Litigation and legal proceedings may substantially increase our costs and harm our business.

As described in Note 12 (Commitments and contingencies) to the financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q, we have been and may in the future become, party to lawsuits and legal proceedings including, without limitation, actions and proceedings in the ordinary course of business relating to our collaboration partners, directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. For example, in June 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us. In the Request for Arbitration, EOC claimed that we breached certain provisions of the EOC License Agreement, including failing to provide certain manufacturing information to EOC. As a result, we became party to a lengthy arbitration process and, although we were found not liable for any damages to EOC in the arbitration panel's final award in September 2024, we nevertheless experienced management distraction and incurred significant legal fees to defend ourselves.

The expense of defending against litigation and legal proceedings may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits or legal proceedings is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation and legal proceedings are subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition.

Our stock price is volatile.

The market price of our common stock could be subject to significant fluctuations. From the completion of our reverse merger with Aerpio Pharmaceuticals, Inc. on August 26, 2021 through November 5, 2026, the closing price for our common stock ranged from a low of $1.32 to a high of $33.00 per share. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the results of current, and any future, nonclinical or clinical trials of the ADC Therapies or any of our product candidates that we may develop;

- our ability to obtain regulatory approvals for ADC Therapies or for any other product candidates that we may develop, and delays or failures to obtain such approvals;
- the failure of the ADC Therapies or any product candidates that we may develop, if approved, for marketing and commercialization, to achieve commercial success;
- any inability to obtain adequate supply of the ADC Therapies or any of our product candidates that we may develop or the inability to do so at acceptable prices;
- the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements;
- adverse regulatory authority decisions;
- the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- changes in laws or regulations applicable to the ADC Therapies or any of our product candidates that we may develop;
- announcements by commercial partners or competitors, including, without limitation, with respect to new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including turmoil in the global banking system, deteriorating market conditions due to investor concerns regarding inflation and conflicts in Ukraine and the Middle East;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our products and potential products;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the hiring or loss of key employees;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;

- sales of our common stock by us or our stockholders in the future, or the anticipation thereof;
- trading volume of our common stock;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management's attention and resources, which could significantly harm our profitability and reputation.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We rely heavily on direct management oversight of transactions, along with the use of legal and outsourced accounting professionals. Although we may implement, document, and modify policies and procedures to maintain effective internal controls, we may identify significant deficiencies and material weaknesses or fail to remediate previously identified deficiencies in our internal controls.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company. If we fail to staff our accounting, finance and information technology functions adequately or maintain internal control over financial reporting adequate to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and

judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of new and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

On February 12, 2024, we filed a universal shelf registration statement on Form S-3 (File No. 333-277018) (the "Shelf Registration Statement"), which became effective on April 30, 2024. No securities have yet been sold under the Shelf Registration Statement. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. Further, pursuant to the (i) Registration Rights Agreement dated March 4, 2025, we filed a registration statement on Form S-3 to register the shares of common stock (including those subject to pre-funded warrants) issued and sold in the 2024 PIPE Financing that closed on March 4, 2025, which registration statement was declared effective on April 8, 2025, and (ii) Registration Rights Agreement dated May 14, 2026, we filed a registration statement on Form S-3 to register the shares of common stock (including those subject to pre-funded warrants) issued and sold in the 2026 PIPE Financing that closed on May 14, 2026, which registration statement was declared effective on June 9, 2026.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our officers, directors, holders of 5% or more of our capital stock and their respective affiliates, and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our outstanding voting stock.

These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact the elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholder and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Unfavorable market and global economic conditions as a result of multiple global events, adverse developments affecting the financial services industry, the conflicts in Ukraine and the Middle East, potential uncertainty related to Taiwan and its relationship to China, fluctuations in interest rates, the implementation and suspension of tariffs, and general economic downturns, could adversely affect our business, financial condition or results of operations.

While the potential economic impact brought by multiple adverse global circumstances, such as conflicts in Ukraine and the Middle East, potential uncertainty related to Taiwan and its relationship with China, fluctuations in interest rates, the implementation of tariffs, adverse developments affecting the financial services industry and general economic downturns are difficult to assess or predict, both as to magnitude and duration, these events have resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for any of our future product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in the Middle East, Russia, Belarus or Ukraine, but we do not and cannot know if the current uncertainties in these geopolitical areas may escalate and result in broad economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials outside the United States or result in material implications for our business. In addition, our insurance policies typically contain a war exclusion of some description and we do not know how our insurers are likely to respond in the event of a loss alleged to have been caused by geopolitical uncertainties. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other 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 (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the “FDIC”), as receiver, and on March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVB’s customer deposits and certain other liabilities and acquired substantially all of SVB’s loans and certain other assets from the FDIC. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. While we only had a minimal amount of our cash directly at SVB and, since that date, the FDIC has stated that all depositors of SVB would be made whole, and First-Citizens Bank & Trust Company has assumed our deposits from SVB, there is no guarantee that the federal government would guarantee all depositors as they did with SVB depositors in the event of further bank closures and continued instability in the global banking system may adversely impact our business and financial condition.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements

directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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

Our operations and performance may be affected by political or civil unrest or military action, including the current conflicts in Ukraine and the Middle East, terrorist activity, unstable governments and legal systems. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. Our ability to conduct clinical trials in regions experiencing political or civil unrest could negatively affect clinical trial enrollment or the timely completion of a clinical trial. We believe the aforementioned economic conditions could lead to reduced demand for our drug products, which could have a material adverse effect on our business and results of operations.

Additionally, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the "debt ceiling." Any U.S. government default on its debt could have broad macroeconomic effects that could, among other things, disrupt access to capital markets and deepen recessionary conditions. Further, as of September 30, 2026, we had cash, cash equivalents and short-term investments of $169.7 million consisting of U.S. government treasury bills, commercial paper, and corporate debt securities. Any default by the U.S. government or credit downgrade of the securities we hold could impact the liquidity or valuation of our investments.

We, or the third parties upon whom we depend, may be adversely affected by earthquakes, wildfires (such as the Pacific Palisades fire, which burned near but did not reach our former headquarters) and other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 pandemic, power shortage, telecommunication failure, cyberattacks, geopolitical tensions, including those related to the conflicts in Ukraine and the Middle East or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidate or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs

may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds.

We are a "smaller reporting company" under applicable securities regulations. A smaller reporting company is a company that (i) as of the last business day of its most recently completed second fiscal quarter has an aggregate market value of the company's voting stock held by non-affiliates, or public float, of less than $250 million or (ii) for the most recently completed fiscal year has less than $100 million in revenue and as of the last business day of its most recently completed second fiscal quarter has less than $700 million in public float. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings and has certain other reduced disclosure obligations in our SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future.

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

The trading market for our common stock will be influenced by the research and reports that industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

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

Our bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the DGCL, or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, our amended and restated certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision 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. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above.

The use of new and evolving technologies, such as AI, in our operations may require us to expend material resources and may present risks and challenges that can impact our business, including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We may integrate AI, including generative artificial intelligence ("Gen AI"), machine learning, and automated decision-making technologies into our operations. The use of AI technology, including Gen AI, can give rise to intellectual property risks, including uncertainty regarding ownership of AI-generated inventions, compromises to proprietary IP, inaccuracy, bias, data privacy and cybersecurity issues, data provenance disputes, and infringement or misappropriation claims. The legal landscape for AI-generated inventions remains uncertain, and development of the law in the U.S. and abroad could impact our ability to enforce proprietary rights or protect against infringing uses. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents. For example, on February 13, 2024, the USPTO issued AI Inventorship guidance entitled "Inventorship Guidance for AI-assisted Inventions" which indicated that the three-part test articulated in *Pannu v. Iolab Corp.* 155 F.3d 1344 (Fed. Cir. 1998) was relevant to the inventorship analysis of AI-assisted inventions. However, the USPTO rescinded the February 13, 2024, guidance and issued a new guidance document entitled "Revised Inventorship Guidance for AI-Assisted Inventions" on November 28, 2025, which treats AI systems as tools, applies the same inventorship standard regardless of AI assistance, and provides that the Pannu factors only apply when determining whether multiple natural persons qualify as joint inventors. Although this guidance reduces certain uncertainty, it is not binding on courts, and its application to specific AI-assisted inventions is thus highly uncertain and subject to fact-dependent, and the standards applied in other jurisdictions may differ and may change based on USPTO guidance and law.

Our employees may use AI including Gen AI in certain circumstances to perform portions of their work. There can be no assurance that employees will not inadvertently or improperly input information that is proprietary, confidential, or sensitive information, including trade secrets, into AI systems in a manner that results in unauthorized disclosure or loss of confidentiality. Many AI tools are provided by third-party vendors, and we may have limited ability to control or verify how information submitted by employees is processed, stored, retained, or used by such providers, including whether such information may be incorporated into model training or otherwise accessed or disclosed. Any failure to adequately prevent the disclosure or misuse of our proprietary or confidential information, whether due to employee error, inadequate controls, evolving AI system functionality, or third-party practices, could result in the loss of trade secret protection and

the disclosure of confidential information related to our inventions and product candidates, which could preclude us from obtaining patents covering disclosed inventions and product candidates, all of which could impair or preclude our ability to obtain patent protection covering the disclosed subject matter, or result in breaches of confidentiality obligations to our collaborators and other third parties, or violations of privacy laws. Any of these outcomes could adversely affect our business.

AI is a rapidly evolving field, and we cannot predict how AI technologies and their adoption will develop or how those developments will affect our business. AI, including Gen AI, may have errors or inadequacies that are not easily detectable. If the data used to train AI or the content AI applications assist in producing are deficient, inaccurate, or biased, our business may be adversely affected. We expect increasing government regulation of AI use (including the EU's AI Act which entered into force on August 1, 2024), which may significantly increase compliance costs. This legislation may impose significant obligations on providers and deployers of AI systems. The legal and regulatory landscape for AI-related intellectual property remains uncertain and continues to evolve, and developments in the law in the U.S. and abroad could increase our compliance costs or affect our ability to enforce and protect our proprietary rights.

The rapid evolution of AI (including Gen AI) may, to the extent we decide to integrate such technologies with our products and services, require the application of significant resources to design, develop, test and maintain such products and services to help ensure that any such AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. We also may need to expend further resources to adjust our business practices, as these laws and regulations evolve, especially where requirements across jurisdictions are inconsistent. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our vendors may in turn incorporate AI tools (including Gen AI) into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world could use increasingly sophisticated methods, including the use of Gen AI, to engage in illegal activities involving the theft and misuse of personal information, financial and other confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Securities Trading Plans of Directors and Executive Officers

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on March 18, 2025).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on March 18, 2025).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	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.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

* Filed herewith.

** The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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.

WHITEHAWK THERAPEUTICS, INC.

Date: November 9, 2026

By: */s/ Scott Giacobello*

Scott Giacobello
Chief Financial Officer
(Principal Financial Officer and Duly Authorized Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Lennon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Whitehawk Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2026

By: /s/ David Lennon, Ph.D.

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Giacobello, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Whitehawk Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2026

By: /s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Whitehawk Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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) 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: November 9, 2026

By: /s/ David Lennon

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

Exhibit 32.2

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

In connection with the Quarterly Report of Whitehawk Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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) 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: November 9, 2026

By: /s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial Officer)