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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

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: 001-37620

KURA ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**61-1547851**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4930 Directors Place, Suite 500, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 500-8800

(Registrant's telephone number, including area code)

12730 High Bluff Drive, Suite 400
San Diego, CA 92130

(Former Name or Former Address, 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, par value $0.0001 per share	KURA	The Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§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 the close of business on October 31, 2025, the registrant had 87,017,518 shares of Common Stock, $0.0001 par value, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

KURA ONCOLOGY, INC.
Condensed Balance Sheets
(In thousands, except par value data)

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 95,287	$ 224,462
Short-term investments	454,378	502,933
Receivable from contracts with collaborators	35,936	2,060
Prepaid expenses and other current assets	35,062	15,374
Total current assets	620,663	744,829
Property and equipment, net	7,397	1,682
Operating lease right-of-use assets	7,539	5,803
Other long-term assets	13,782	7,845
Total assets	$ 649,381	$ 760,159
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 66,788	$ 49,953
Current operating lease liabilities	1,429	1,881
Current portion of long-term debt	4,337	2,607
Current portion of contract liabilities	48,750	24,271
Total current liabilities	121,304	78,712
Long-term debt, net of current portion	5,336	6,916
Long-term operating lease liabilities	8,364	5,190
Other long-term liabilities	2,981	1,795
Long-term contract liabilities	268,854	253,906
Total liabilities	406,839	346,519
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000 shares authorized; 87,016 and 78,229 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	9	8
Additional paid-in capital	1,334,704	1,308,290
Accumulated other comprehensive income	918	764
Accumulated deficit	(1,093,089)	(895,422)
Total stockholders' equity	242,542	413,640
Total liabilities and stockholders' equity	$ 649,381	$ 760,159

See accompanying notes to unaudited condensed financial statements.

KURA ONCOLOGY, INC.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue				
Collaboration revenue	$ 20,750	$ —	$ 50,146	$ —
Total revenue	20,750	—	50,146	—
Operating Expenses				
Research and development	67,908	41,705	186,666	117,700
General and administrative	32,839	18,179	80,843	53,040
Total operating expenses	100,747	59,884	267,509	170,740
Loss from operations	(79,997)	(59,884)	(217,363)	(170,740)
Other Income (Expense)				
Interest and other income	6,274	5,892	21,088	17,190
Interest expense	(393)	(412)	(1,166)	(1,216)
Total other income, net	5,881	5,480	19,922	15,974
Loss before income taxes	(74,116)	(54,404)	(197,441)	(154,766)
Income tax expense	—	—	226	—
Net Loss	$ (74,116)	$ (54,404)	$ (197,667)	$ (154,766)
Net loss per share, basic and diluted	$ (0.85)	$ (0.63)	$ (2.26)	$ (1.80)
Weighted average number of shares used in computing net loss per share, basic and diluted	87,645	86,950	87,550	85,834
Comprehensive Loss				
Net loss	$ (74,116)	$ (54,404)	$ (197,667)	$ (154,766)
Other comprehensive income				
Unrealized gain on short-term investments	207	1,579	154	2,387
Comprehensive Loss	$ (73,909)	$ (52,825)	$ (197,513)	$ (152,379)

See accompanying notes to unaudited condensed financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance as of December 31, 2024	78,229	$ 8	$ 1,308,290	$ 764	$ (895,422)	$ 413,640
Share-based compensation expense	—	—	7,842	—	—	7,842
Issuance of common stock under equity plans	375	—	143	—	—	143
Exercise of pre-funded warrants	2,174	—	—	—	—	—
Other comprehensive income	—	—	—	210	—	210
Net loss	—	—	—	—	(57,429)	(57,429)
Balance as of March 31, 2025	80,778	8	1,316,275	974	(952,851)	364,406
Share-based compensation expense	—	—	6,949	—	—	6,949
Issuance of common stock under equity plans	101	—	515	—	—	515
Exercise of pre-funded warrants	5,918	1	—	—	—	1
Other comprehensive loss	—	—	—	(263)	—	(263)
Net loss	—	—	—	—	(66,122)	(66,122)
Balance as of June 30, 2025	86,797	9	1,323,739	711	(1,018,973)	305,486
Share-based compensation expense	—	—	10,965	—	—	10,965
Issuance of common stock under equity plans	219	—	—	—	—	—
Other comprehensive income	—	—	—	207	—	207
Net loss	—	—	—	—	(74,116)	(74,116)
Balance as of September 30, 2025	87,016	$ 9	$ 1,334,704	$ 918	$ (1,093,089)	$ 242,542

See accompanying notes to unaudited condensed financial statements.

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive		Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Accumulated Deficit	Equity
Balance as of December 31, 2023	74,350	$ 7	$ 1,119,976	$ (1,271)	$ (721,439)	$ 397,273
Issuance of pre-funded warrants to purchase common stock, net of offering costs	—	—	122,726	—	—	122,726
Issuance of common stock, net of offering costs	1,377	1	23,087	—	—	23,088
Share-based compensation expense	—	—	8,512	—	—	8,512
Issuance of common stock under equity plans	454	—	2,555	—	—	2,555
Other comprehensive income	—	—	—	455	—	455
Net loss	—	—	—	—	(49,525)	(49,525)
Balance as of March 31, 2024	76,181	8	1,276,856	(816)	(770,964)	505,084
Share-based compensation expense	—	—	8,430	—	—	8,430
Issuance of common stock under equity plans	241	—	3,040	—	—	3,040
Other comprehensive income	—	—	—	353	—	353
Net loss	—	—	—	—	(50,837)	(50,837)
Balance as of June 30, 2024	76,422	8	1,288,326	(463)	(821,801)	466,070
Exercise of pre-funded warrants	1,000	—	—	—	—	—
Share-based compensation expense	—	—	8,324	—	—	8,324
Issuance of common stock under equity plans	327	—	2,202	—	—	2,202
Other comprehensive income	—	—	—	1,579	—	1,579
Net loss	—	—	—	—	(54,404)	(54,404)
Balance as of September 30, 2024	77,749	$ 8	$ 1,298,852	$ 1,116	$ (876,205)	$ 423,771

See accompanying notes to unaudited condensed financial statements.

KURA ONCOLOGY, INC.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2025	**2024**
Operating Activities		
Net loss	$ (197,667)	$ (154,766)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	25,756	25,266
Depreciation expense	629	644
Non-cash interest expense	412	383
Amortization of premium and accretion of discounts on short-term investments, net	(7,106)	(10,256)
Changes in operating assets and liabilities		
Contract liabilities	39,427	—
Accounts payable and accrued expenses	14,814	2,498
Other long-term liabilities	925	523
Receivable from contracts with collaborators	(33,876)	—
Prepaid expenses and other current assets	(18,840)	632
Operating lease right-of-use and other long-term assets	(5,805)	262
Net cash used in operating activities	(181,331)	(134,814)
Investing Activities		
Maturities of short-term investments	577,628	411,930
Purchases of short-term investments	(521,813)	(418,465)
Purchases of property and equipment	(4,317)	(100)
Net cash provided by (used in) investing activities	51,498	(6,635)
Financing Activities		
Proceeds from issuance of stock under equity plans	658	7,797
Proceeds from issuance of common stock and pre-funded warrants, net of offering costs	—	145,814
Net cash provided by financing activities	658	153,611
Net increase (decrease) in cash and cash equivalents	(129,175)	12,162
Cash and cash equivalents at beginning of period	224,462	37,318
Cash and cash equivalents at end of period	$ 95,287	$ 49,480
Supplemental disclosure of non-cash investing activities		
Unpaid amounts related to purchases of property and equipment	$ 2,027	$ —

See accompanying notes to unaudited condensed financial statements.

1. Organization and Basis of Presentation

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

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

Basis of Presentation

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on February 28, 2025, from which we derived our balance sheet as of December 31, 2024. The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited condensed financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

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

2. Summary of Significant Accounting Policies

Allowance for Credit Losses

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

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

Concentration of Credit Risk

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

Our accounts receivable is derived from contracts with our collaborators. We do not typically require collateral from our collaborators. We continuously monitor payments from collaborators and consider various factors including historical experience, age of the receivable balances, and other current economic conditions or other factors that may affect our collaborators' ability to pay.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets. Computer software and equipment are depreciated over their estimated useful lives of three to five years. Laboratory equipment is depreciated over its estimated useful life of five years. Furniture and fixtures are depreciated over their estimated useful lives of five years. Leasehold improvements are depreciated over the lesser of the term of the related lease or the useful life of the asset.

Leases

We determine if an arrangement is a lease or contains lease components at inception. Short-term leases with an initial term of 12 months or less are not recorded on the unaudited condensed balance sheets. For operating leases with an initial term greater than 12 months, we recognize operating lease right-of-use, or ROU, assets and operating lease liabilities based on the present value of lease payments over the lease term at commencement date. Operating lease ROU assets are comprised of the lease liability plus any lease payments made and exclude lease incentives. Lease terms may include options to extend or terminate when we are reasonably certain that the options will be exercised. We do not separate lease components from non-lease components. For our operating leases, we generally cannot determine the interest rate implicit in the lease, in which case we use our incremental borrowing rate as the discount rate for the lease. We estimate our incremental borrowing rate for our operating leases based on what we would normally pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments. Operating lease expense is recognized on a straight-line basis over the lease term.

If a lease is modified, the modified contract is evaluated to determine whether it is or contains a lease. If a lease continues to exist, the lease modification is determined to be a separate contract when the modification grants the lessee an additional ROU that is not included in the original lease and the lease payments increase commensurate with the standalone price for the additional ROU. A lease modification that results in a separate contract will be accounted for in the same manner as a new lease. For a modification that is not a separate contract, we reassess the lease classification using the modified terms and conditions and the facts and circumstances as of the effective date of the modification and recognize the amount of the remeasurement of the lease liability for the modified lease as an adjustment to the corresponding operating lease ROU asset.

Collaboration Arrangements

We assess whether our licensing and other agreements are collaborative arrangements within the scope of Accounting Standards Codification, or ASC, Topic 808, Collaborative Arrangements, or Topic 808, based on whether they involve joint operating activities wherein both parties actively participate in the arrangement and are exposed to significant risks and rewards of the arrangement. For arrangements that we determine are collaborations under the Scope of Topic 808, we identify each unit of account by determining which promised goods or services are distinct in accordance with ASC Topic 606, Revenue from Contracts with Customers, or Topic 606, and then determine whether a customer relationship exists for that unit of account. If we determine a unit of account within the collaborative arrangement to be with a customer, we apply our revenue recognition accounting policy as further described below. For units of account within the collaborative arrangement under Topic 808 that are not with a customer in its entirety and are not within the scope of other relevant accounting topics, we apply recognition and measurement principles based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. See Note 7, Kyowa Kirin Collaboration and License Agreement, for more details.

Revenue from Collaborations and Licenses

We recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of Topic 606, we perform 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 entity satisfies a performance obligation.

For enforceable contracts with our customers, we evaluate the promises in the contract that are based on goods and services that will be transferred to the customer and determine whether those promises are both (i) capable of being distinct and (ii) distinct in the context of the contract. Arrangements that include rights to additional goods or services that are exercisable at the customer's discretion are generally considered customer options. We assess if these customer options provide a material right to the customer and, if so, these customer options are considered performance obligations.

The transaction price may comprise of payments received under our commercial arrangements, such as licensing technology rights, and may include non-refundable fees at the inception of the arrangements, cost reimbursements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. Profit-sharing payments to our customers are generally not for a distinct good or service and, as such, are included as a reduction of the transaction price. At the inception of arrangements that include variable consideration, we may be required to exercise significant judgment to estimate the amount of variable consideration to include in the transaction price. In making such estimates, we generally use the most likely amount method for milestone payments and the expected value method for other forms of variable consideration and take into account relevant development, regulatory, and other factors that can impact the level of uncertainty associated with these estimates. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate estimated variable consideration included in the transaction price and any related constraint and, as necessary, we adjust our estimate of the overall transaction price. Any adjustments are recorded on a cumulative catch-up basis, which affects revenues and earnings in the period of adjustment.

We develop estimates of the stand-alone selling price for each distinct performance obligation, which involve assumptions that may require significant judgment. Our estimates of the stand-alone selling price for license-related performance obligations may include forecasted revenues and expenses, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. Our estimates of the stand-alone selling price for research and development or other service-related performance obligations generally include forecasting the expected costs of satisfying a performance obligation at market rates. We allocate the transaction price, including any unconstrained variable consideration, to the performance obligations within the arrangement based on the relative stand-alone selling prices. When the variable consideration relates specifically to our efforts to satisfy one or more, but not all, performance obligations and allocating the consideration specifically to those performance obligations is consistent with the overall allocation objectives within Topic 606, we allocate the consideration entirely to those performance obligations.

We use judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue related to the performance obligation. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion of over-time performance obligations is based on the nature of the products or services to be provided. Our over-time performance obligations generally involve research and development or other services provided to the customer, and we generally use a cost-to-cost measure of progress because it best depicts the transfer of control to the customer. Under a cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date compared to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). We use judgment to estimate the total cost expected to complete the research and development or other service-related performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

Consideration received or invoices issued as stipulated in contracts prior to revenue recognition are recorded as contract liabilities in the accompanying unaudited condensed balance sheets, classified as either current or long-term contract liabilities based on our best estimate of when such amounts will be recognized. Amounts recognized as revenue, but not yet invoiced are generally recognized as contract assets in other current assets in the accompanying unaudited condensed balance sheets.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, which includes the shares related to outstanding pre-funded warrants, but excludes other potential common stock equivalents. Pre-funded warrants are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little additional consideration, and are fully vested and exercisable. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period. As we have reported net loss for the three and nine months ended September 30, 2025 and 2024, dilutive net loss per common share is the same as basic net loss per common share for those periods. Common stock equivalents outstanding are comprised of stock options, restricted stock units, or RSUs, performance-based restricted stock units, or PSUs, warrants and employee stock purchase plan rights and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. Common stock equivalents outstanding at September 30, 2025 and 2024 totaling approximately 18,559,000 and 15,136,000, respectively, were excluded from the computation of dilutive weighted-average shares outstanding because their effect would be anti-dilutive.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. We operate in a single industry segment which is the discovery and development of precision medicines for the treatment of cancer. Troy E. Wilson, Ph.D., J.D., our president and chief executive officer, who serves as the Chief Operating Decision-Maker, or CODM, reviews the operating results on an aggregate basis and manages the operations as a single operating segment in the United States.

Recent Accounting Pronouncements

Improvements to Income Tax Disclosures

In December 2023, the Financial Accounting Standards Board, or FASB, issued ASU 2023-09 – Improvements to Income Tax Disclosures (Topic 740), which improves the transparency of income tax disclosures by requiring disaggregated information about our effective tax rate reconciliation as well as information on income taxes paid. For each annual period, we will be required to disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued. We plan to adopt the standard on December 31, 2025, and are currently evaluating the effect of the standard on our financial statements.

Disaggregation of Income Statement Expenses

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, which requires disaggregated disclosure of certain costs and expenses on an interim and annual basis. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The disclosure updates are required to be applied prospectively with the option for retrospective application. We are currently evaluating the impact of adopting ASU 2024-03.

3. Investments

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

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

		September 30, 2025			
	Maturities (years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents					
Money market funds	1 or less	$ 39,180	$ —	$ —	$ 39,180
U.S. Treasury securities	1 or less	7,460	—	—	7,460
Total cash equivalents		46,640	—	—	46,640
Short-term investments					
U.S. Treasury securities	2 or less	420,960	915	(1)	421,874
U.S. Agency bonds	3 or less	32,500	9	(5)	32,504
Total short-term investments		453,460	924	(6)	454,378
Total		$ 500,100	$ 924	$ (6)	$ 501,018

		December 31, 2024			
	Maturities (years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents					
Money market funds	1 or less	$ 200,024	$ —	$ —	$ 200,024
Short-term investments					
U.S. Treasury securities	3 or less	497,172	766	—	497,938
U.S. Agency bonds	3 or less	4,997	—	(2)	4,995
Total short-term investments		502,169	766	(2)	502,933
Total		$ 702,193	$ 766	$ (2)	$ 702,957

Short-term investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. As of September 30, 2025 and December 31, 2024, short-term investments of $379.0 million and $393.1 million, respectively, had maturities less than one year, short-term investments of $57.9 million and $97.3 million, respectively, had maturities between one to two years, and short-term investments of $17.5 million and $12.5 million, respectively, had maturities between two to three years. Realized gains and losses were de minimis for the three and nine months ended September 30, 2025 and 2024.

As of September 30, 2025 and December 31, 2024, eight available-for-sale securities with a fair market value of $52.2 million and two available-for-sale securities with a fair market value of $10.0 million, respectively, were in a gross unrealized loss position, none of which were in a continuous unrealized loss position for greater than 12 months. We do not intend to sell such available-for-sale securities, and it is not more likely than not that we will be required to sell such securities prior to recovery of their amortized cost basis. We have no allowance for credit losses as of September 30, 2025 and December 31, 2024. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

Accrued interest receivable on available-for-sale securities as of September 30, 2025 and December 31, 2024 was $3.3 million in both periods. We have not written off any accrued interest receivables for the nine months ended September 30, 2025 and 2024.

4. Fair Value Measurements

As of September 30, 2025 and December 31, 2024, we had cash equivalents and short-term investments measured at fair value on a recurring basis.

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

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

	September 30, 2025			
	Total	Level 1	Level 2	Level 3
Cash equivalents				
Money market funds	$ 39,180	$ 39,180	$ —	$ —
U.S. Treasury securities	7,460	7,460	—	—
Total cash equivalents	46,640	46,640	—	—
Short-term investments				
U.S. Treasury securities	421,874	421,874	—	—
U.S. Agency bonds	32,504	—	32,504	—
Total short-term investments	454,378	421,874	32,504	—
Total	$ 501,018	$ 468,514	$ 32,504	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Cash equivalents				
Money market funds	$ 200,024	$ 200,024	$ —	$ —
Short-term investments				
U.S. Treasury securities	497,938	497,938	—	—
U.S. Agency bonds	4,995	—	4,995	—
Total short-term investments	502,933	497,938	4,995	—
Total	$ 702,957	$ 697,962	$ 4,995	$ —

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

5. Balance Sheet Detail

Property and equipment consisted of the following, in thousands:

	September 30, 2025	December 31, 2024
Leasehold improvements	$ 7,561	$ 1,743
Laboratory and computer equipment	1,946	2,004
Furniture and fixtures	1,758	1,210
Property and equipment, gross	11,265	4,957
Less: accumulated depreciation	(3,868)	(3,275)
Property and equipment, net	$ 7,397	$ 1,682

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

	September 30, 2025	December 31, 2024
Accounts payable	$ 4,671	$ 1,469
Accrued clinical trial research and development expenses	22,800	14,267
Accrued other research and development expenses	18,448	11,938
Accrued compensation and benefits	14,595	17,508
Other accrued expenses	6,274	2,710
Income taxes payable	—	2,061
Total accounts payable and accrued expenses	$ 66,788	$ 49,953

6. Leases

We currently have three operating leases for administrative and research and development office and lab space in San Diego, California and Boston, Massachusetts that expire between November 2025 and May 2033. Under the terms of the operating leases, as each may be amended from time to time, we are required to pay our proportionate share of property taxes, insurance and normal maintenance costs. All of our leases include renewal options for an additional five years, which were not included in the determination of the ROU asset or lease liability as the renewal was not reasonably certain at the inception of the lease. Our Boston lease and former San Diego corporate headquarters lease provided for $1.4 million and $1.3 million, respectively, in reimbursements for allowable tenant improvements and rent credits, which effectively reduced the total lease payments owed. Our San Diego research and development, lab, and principal executive office space lease entered into in January 2025 and amended in June 2025 provides (i) $2.4 million in rent credits, and (ii) a $6.2 million tenant improvement allowance expected to be received during 2025.

Maturities of lease liabilities as of September 30, 2025 are as follows, in thousands:

Year Ending December 31,	
2025 (remaining)	$ 493
2026	1,533
2027	3,658
2028	3,754
2029	3,853
Thereafter	11,169
Total lease payments	24,460
Less: imputed interest	(8,835)
Less: tenant improvement allowance reimbursements yet to be received	(5,832)
Total operating lease liabilities	$ 9,793

As of September 30, 2025 and December 31, 2024, the weighted-average discount rate was 12.3% and 11.4%, respectively, and the weighted-average remaining lease term was 6.4 years and 5.9 years, respectively. Total cash paid for amounts included in the measurement of operating lease liabilities, net of tenant improvement reimbursements, was $0.5 million and $0.3 million for the three months ended September 30, 2025 and 2024, respectively. Total cash paid for amounts included in the measurement of operating lease liabilities, net of tenant improvement reimbursements, was $1.4 million and $1.3 million for the nine months ended September 30, 2025 and 2024, respectively. For the nine months ended September 30, 2025, $2.7 million of operating lease ROU assets were obtained in exchange for operating lease liabilities compared to none for the nine months ended September 30, 2024. Total operating lease and rent expense for the three months ended September 30, 2025 and 2024 were approximately $0.8 million and $0.5 million, respectively. Total operating lease and rent expense for the nine months ended September 30, 2025 and 2024 were approximately $2.4 million and $1.5 million, respectively.

7. Kyowa Kirin Collaboration and License Agreement

On November 20, 2024, we and Kyowa Kirin Co., Ltd. and Kyowa Kirin, Inc., or together Kyowa Kirin, entered into a collaboration and license agreement, or the Kyowa License Agreement, to develop and commercialize globally our product candidate, ziftomenib, a potent, selective oral menin inhibitor, for the treatment, diagnosis and prevention of acute myeloid leukemia, or AML, and other hematologic malignancies, and if Kyowa Kirin exercises the Field Expansion Option (as defined below), the treatment, diagnosis and prevention of all cancers, or collectively the Field.

We have the right and responsibility to lead all development, manufacturing, and regulatory activities and commercial strategy development for ziftomenib in the United States based on a development plan and budget mutually agreed upon with Kyowa Kirin and under the oversight of a joint steering committee and applicable subcommittees. In accordance with the development plan, we are conducting multiple Phase 2 and Phase 3 clinical trials of ziftomenib, as a monotherapy and in combination with other therapies, in AML and other hematologic malignancies to support regulatory approvals of ziftomenib in the United States. We and Kyowa Kirin will continue to conduct the activities required by the development plan as allocated to us by such plan. We are responsible for funding the specified development activities set forth in the initial development plan that are planned to be conducted prior to the end of 2028, and we will share with Kyowa Kirin equally (50/50) all development costs for all other development activities in the United States that are to be included in the development plan, including clinical trials and post-marketing commitments that are reasonably necessary for obtaining or maintaining regulatory approval of ziftomenib in the United States, or Development Services. In addition, we will conduct certain specified development and manufacturing activities outside the scope of the development plan at our sole cost and expense. Following regulatory approval, we will commercialize and record sales of ziftomenib in the United States, and Kyowa Kirin will have the right and responsibility to co-promote ziftomenib for up to a certain percentage of the details in the United States. In collaboration with Kyowa Kirin, we will perform commercialization activities, or Commercialization Services, in accordance with a co-created U.S. territory commercialization plan and budget. The parties will share equally all costs and expenses for, and profits or losses from, the commercialization of ziftomenib in the United States. On June 27, 2025, we entered into a co-promotion and medical affairs agreement with Kyowa Kirin, Inc., or the Kyowa Co-Promotion Agreement, to co-promote and perform medical affairs activities with respect to ziftomenib for the treatment of patients with AML and other hematologic malignancies in the United States, and solely if Kyowa Kirin exercises its field expansion option under the Kyowa License Agreement, all approved indications for ziftomenib in the United States that are licensed under the Kyowa License Agreement. The Kyowa Co-Promotion Agreement was determined to be a separate contract from the Kyowa License Agreement for purposes of revenue recognition and reporting.

Kyowa Kirin has the right and responsibility to lead development, regulatory activities and commercialization for ziftomenib outside of the United States and is solely responsible for the conduct and funding of such activities that are specific to the exploitation of ziftomenib outside of the United States. Following regulatory approval, Kyowa Kirin will be solely responsible for the conduct and funding of commercialization of ziftomenib outside of the United States (including recording sales). Kyowa Kirin is required to use commercially reasonable efforts to conduct the development of ziftomenib outside the United States in accordance with an ex-U.S. territory development plan, to achieve the development milestone events outside the United States that entitle us to receive corresponding development milestone payments, and to commercialize ziftomenib in each country outside of the United States where it has received regulatory approval. Development and commercialization activities outside of the United States will also be under the oversight of the joint steering committee and applicable subcommittees.

We are responsible for the global manufacture and supply of ziftomenib necessary for the development and commercialization activities described above, pursuant to the terms of a clinical supply agreement entered into with Kyowa Kirin Co., Ltd. effective as of March 31, 2025, or the Kyowa Clinical Supply Agreement, which was determined to be a separate contract from the Kyowa License Agreement for purposes of revenue recognition and reporting. Kyowa Kirin has the right to request that we conduct a manufacturing technology transfer and to take over the responsibility of commercial supply of ziftomenib outside the United States.

We granted Kyowa Kirin an exclusive license to enable or allow Kyowa Kirin to develop, manufacture, and commercialize ziftomenib within the Field outside of the United States, or the License. We also granted Kyowa Kirin rights to fulfill their responsibilities related to the Development Services and Commercialization Services as part of the joint development and commercialization of ziftomenib in the United States. In addition, Kyowa Kirin has an option to expand the licensed Field to include the development and commercialization of ziftomenib in gastrointestinal stromal tumors, or GIST, and other solid tumor indications, or Field Expansion Option, which option can be exercised within a specified time period after receipt of clinical data from the planned proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST who are not successfully treated with imatinib. After Kyowa Kirin's exercise of the Field Expansion Option, the Field would include the treatment, diagnosis and prevention of all cancers, including GIST and other solid tumors.

In exchange for the License and Kyowa Kirin's rights to participate in the development and commercialization activities described above, we received an upfront payment of $330.0 million. We are eligible to receive, if Kyowa Kirin exercises the Field Expansion Option, up to an aggregate of $1.161 billion in development, regulatory, commercial milestone and additional upfront payments for the existing Field and the expanded Field, totaling up to $1.491 billion in upfront and milestone payments in the aggregate. We are also eligible to receive tiered double-digit royalties on sales of ziftomenib outside of the United States on a country-by-country basis until the latest of expiration of the last-to-expire valid claim of our patent rights licensed to Kyowa Kirin in such country, expiration of the last-to-expire regulatory exclusivity in such country and ten years after first commercial sale in such country, or the Royalty Term.

The Kyowa License Agreement will remain in effect in the United States until the latest of expiration of all valid claims of our patent rights licensed to Kyowa Kirin, expiration of the last-to-expire regulatory exclusivity or ten years after first commercial sale. The Kyowa License Agreement will remain in effect outside the United States until the expiration of the last-to-expire Royalty Term. Either party may terminate the Kyowa License Agreement for uncured material breach by or insolvency of the other party. Kyowa Kirin may terminate the Agreement for convenience upon twelve months' prior written notice. In addition, Kyowa Kirin has the right to terminate the Kyowa License Agreement with a shorter specified notice period upon the occurrence of a material adverse regulatory event or certain other specified events. We may terminate the Kyowa License Agreement if Kyowa Kirin or any of its affiliates or sublicensees challenges the validity or enforceability of any of the patent rights licensed to Kyowa Kirin by us.

Based on our analysis of the key terms and activities required by the Kyowa License Agreement summarized above and given the involvement by both parties, we assessed the criteria under Topic 808 and concluded that both parties participate in a joint operating activity, are active participants, and are exposed to significant risks and rewards dependent on the commercial success of the activities. Therefore, the Kyowa License Agreement was determined to be within the scope of Topic 808.

We evaluated each of the required promised goods and services and determined the Kyowa License Agreement contains multiple units of account comprised of the License, Development Services related to monotherapy and in combination with other therapies, and Commercialization Services. The License is a unit of account under the scope of Topic 606 as it is reflective of a typical vendor-customer relationship, while the Development Services and Commercialization Services are under the scope of Topic 808 due to the joint participation in the services being performed and these services not being reflective of a typical vendor-customer relationship. However, we determined that Topic 606 was the most appropriate accounting model to apply by analogy to the recognition and measurement of these units of account.

As of September 30, 2025, we determined the transaction price to be $405.0 million, comprised of the upfront fixed payment of $330.0 million and $75.0 million in unconstrained milestones. All other variable consideration related to milestones have been fully constrained due to development, regulatory, or other factors that caused us to determine that it was not probable that a significant reversal of revenue would not occur as of September 30, 2025. We will recognize any royalties or sales-based milestones related to the License granted to Kyowa Kirin when the associated sales occur, and relevant sales-based thresholds are met. As of September 30, 2025, no royalties or sales-based milestones have been recognized.

We allocated the transaction price to each unit of account based on their relative stand-alone selling price. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations, such as certain milestones, is allocated entirely to those performance obligations. Other components of variable consideration that do not relate specifically to our efforts to satisfy specific performance obligations are allocated based on the relative stand-alone selling price. We are entitled to cost-sharing reimbursements from Kyowa Kirin for certain development and commercialization activities we perform and determined that such reimbursements are specifically related to our efforts to satisfy the respective performance obligations while satisfying the overall allocation objective required by Topic 606.

We recognized $49.8 million of revenue allocated to the License at a point in time and upon transfer in November 2024. As of September 30, 2025, consideration allocated to the Development Services for monotherapy and in combination with other therapies was $57.6 million and $120.2 million, respectively, and to Commercialization Services was $177.4 million. The allocated consideration is being recognized over time using a cost-to-cost measure of progress. We estimated the total cost expected to perform the required activities and measured the progress towards completion of each of these obligations at the reporting period. For the three and nine months ended September 30, 2025, we recognized $7.0 million and $19.8 million of revenue from Development Services for monotherapy, respectively, $5.1 million and $10.4 million of revenue from Development Services in combination with other therapies, respectively, and $2.3 million and $5.3 million of revenue from Commercialization Services, respectively. For the three and nine months ended September 30, 2025, we recognized $5.9 million and $14.1 million of revenue, respectively, from cost-share reimbursements related to the sharing of profits and losses, and the related receivable was included in receivable from contracts with collaborators on the unaudited condensed balance sheet as of September 30, 2025. For each of the three and nine months ended September 30, 2025, we also recognized $0.5 million of revenue pursuant to services performed under the Kyowa Clinical Supply Agreement.

As of September 30, 2025, the contract liability amount of $317.6 million represents the aggregate transaction price allocated to performance obligations that are unsatisfied under the Kyowa License Agreement, $48.7 million was classified as current contract liabilities, which represents the portion of the Development Services and Commercialization Services expected to be provided over the next year, and the remaining contract liability balance of $268.9 million was classified as long-term contract liabilities.

8. Stockholders' Equity

In January 2024, we completed a private placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share), or the Private Placement. Net proceeds from the Private Placement, after deducting expenses, were approximately $145.8 million. The common stock and pre-funded warrants met the accounting standards guidance for equity classification, and proceeds were allocated between common stock and pre-funded warrants based on their relative fair value. As of September 30, 2025, pre-funded warrants to purchase 6,478,301 of such shares of common stock from the Private Placement had been exercised and 840,585 remained outstanding.

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

9. Share-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 3,212	$ 3,570	$ 9,253	$ 11,218
General and administrative	7,753	4,754	16,503	14,048
Total share-based compensation expense	$ 10,965	$ 8,324	$ 25,756	$ 25,266

As of September 30, 2025, unrecognized estimated compensation expense related to stock options, RSUs and PSUs was approximately $41.0 million, $12.4 million, and $0.8 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.7 years, 2.7 years, and 1.0 years, respectively. As of September 30, 2025, 969,417 PSUs were outstanding and the vesting of 775,534 PSUs were determined to not be probable and have not been included in share-based compensation expense or unrecognized estimated compensation expense.

10. Segment Reporting

Our CODM manages our operations on an integrated basis for the purpose of allocating resources. When evaluating our financial performance, the CODM regularly reviews total revenues, total expenses, and research and development expenses by project and the CODM makes decisions using this information.

The table below is a summary of the segment profit or loss, including significant expenses, in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 20,750	$ —	$ 50,146	$ —
Less:				
Ziftomenib-related costs	40,320	18,993	107,851	52,335
Darlifarnib (KO-2806)-related costs	8,494	5,178	19,871	13,026
Tipifarnib-related costs	443	721	2,578	3,560
Discovery stage program-related costs	1,744	1,769	5,323	4,950
Research and development personnel costs and other expenses	13,695	11,474	41,790	32,611
Share-based compensation expense	10,965	8,324	25,756	25,266
Other segment expenses[(1)]	25,086	13,425	64,340	38,992
Total operating expenses	100,747	59,884	267,509	170,740
Other income (expenses)				
Interest and other income	6,274	5,892	21,088	17,190
Interest expense	(393)	(412)	(1,166)	(1,216)
Income tax expense	—	—	(226)	—
Segment and net loss	$ (74,116)	$ (54,404)	$ (197,667)	$ (154,766)

(1)Other segment expenses are comprised of general and administrative expenses, excluding share-based compensation expense, which is shown separately.

11. Subsequent Event

On October 25, 2025, we entered into a second amendment to our loan and security agreement with several banks and other financial institutions or entities party thereto and Hercules Capital, Inc., as amended, or Loan Agreement, pursuant to which the repayment of our term loan was extended to be interest only through (a) May 1, 2026 and (b) May 1, 2027, if we satisfy the Approval Milestone (as defined in the Loan Agreement).

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial statements and notes thereto as of and for the fiscal year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the Securities and Exchange Commission, or SEC, on February 28, 2025.

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

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

Overview

We are a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates designed to target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes and, in general, we intend to pair our product candidates with molecular or cellular diagnostics to identify those patients most likely to respond to treatment.

Our lead product candidate is ziftomenib, a selective investigational inhibitor of the menin-KMT2A protein-protein interaction. We are developing ziftomenib for the treatment of genetically defined subsets of acute leukemias, including acute myeloid leukemia, or AML, and acute lymphoblastic leukemia, or ALL. In November 2024, we and Kyowa Kirin Co., Ltd. and Kyowa Kirin, Inc., or together Kyowa Kirin, entered into a collaboration and license agreement, or the Kyowa License Agreement, to develop and commercialize globally ziftomenib for the treatment of patients with AML and other hematologic malignancies, which may be expanded into other indications at the option of Kyowa Kirin, subject to certain conditions. On June 27, 2025, we entered into a co-promotion and medical affairs agreement with Kyowa Kirin, Inc., or the Kyowa Co-Promotion Agreement, to co-promote and perform medical affairs activities with respect to ziftomenib for the treatment of patients with AML and other hematologic malignancies in the United States, and solely if Kyowa Kirin exercises its field expansion option under the Kyowa License Agreement, all approved indications for ziftomenib in the United States that are licensed under the Kyowa License Agreement.

In addition to hematologic malignancies, we are exploring the use of ziftomenib in combination with imatinib for the treatment of gastrointestinal stromal tumors, or GIST, and ziftomenib and our next-generation menin inhibitors for use in other indications, including diabetes and other cardiometabolic disorders and certain solid tumors.

Along with our menin inhibitor program, we are evaluating the ability of farnesyl transferase inhibitors, or FTIs, to address mechanisms of adaptive and innate resistance in the treatment of solid tumors. Our lead FTI product candidate is darlifarnib, which we are evaluating as a monotherapy and in combination with certain targeted therapies in large solid tumor indications, including renal cell carcinoma, or RCC, and $KRAS^{G12C}$-mutated non-small cell lung cancer, or NSCLC. Darlifarnib is the international nonproprietary name for KO-2806.

In addition to darlifarnib, we are evaluating tipifarnib, our first-generation FTI, in combination with alpelisib, a PI3 kinase alpha, or PI3Kalpha, inhibitor, in patients with head and neck squamous cell carcinoma, or HNSCC, whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification.

We also have additional programs that are at a discovery stage. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

Clinical Programs and Pipeline

Ziftomenib

Ziftomenib as a Monotherapy in Relapsed/Refractory AML: KOMET-001 Trial

We received orphan drug designation for ziftomenib for the treatment of AML from the U.S. Food and Drug Administration, or FDA, in July 2019. In September 2019, we initiated the Kura Oncology MEnin-KMT2A Trial, or KOMET-001 trial, a global Phase 1/2 clinical trial designed to assess clinical activity, safety and tolerability of ziftomenib in patients with relapsed or refractory AML with a mutation of the nucleophosmin 1, or NPM1, gene. In April 2024, the FDA granted ziftomenib Breakthrough Therapy Designation for the treatment of patients with relapsed or refractory NPM1-mutated AML based on data from the KOMET-001 trial.

On March 31, 2025, we submitted to the FDA a new drug application, or NDA, for ziftomenib for the treatment of adult patients with relapsed or refractory AML with an NPM1 mutation. The NDA is based on the results from the Phase 2 portion of the KOMET-001 trial. On June 1, 2025, we and Kyowa Kirin announced that the FDA accepted our NDA, granted Priority Review of the NDA and assigned a Prescription Drug User Fee Act, or PDUFA, target action date of November 30, 2025.

On September 25, 2025, the *Journal of Clinical Oncology* published the full results of the KOMET-001 trial. The publication, entitled "Ziftomenib in Relapsed or Refractory NPM1-Mutated AML," includes positive data from 92 adult patients with relapsed or refractory NPM1-mutated AML in the Phase 2 portion of the trial as of the primary data cutoff date of October 28, 2024. As reported in the publication, the KOMET-001 Phase 2 trial met its primary endpoint with a complete remission, or CR, plus CR with full or partial hematologic recovery, or CRh, rate of 22% (95% CI, 14 to 32; P=0.0058), exceeding the historical benchmark of 12%. One additional response of CRh occurred after the primary analysis data cutoff resulting in a cumulative CR/CRh rate of 23% (95% CI, 15 to 33). 61% of evaluable CR/CRh responders were negative for measurable residual disease, or MRD. Overall response rate, or ORR, was 33% (95% CI, 23 to 43), with a median duration of overall response of 4.6 months (95% CI, 2.8 to 7.4).

Median overall survival, or OS, was 6.6 months (95% CI, 3.6 to 8.6). Among ORR responders, median OS was 18.4 months (95% CI, 8.6 to not estimable) compared with 3.5 months (95% CI, 2.7 to 4.2) among non-responders. Two responders received subsequent allogeneic stem cell transplant and both resumed ziftomenib maintenance after transplant. At the time of data cutoff, nine patients (two after transplantation) remained on ziftomenib treatment. Prespecified subgroup analyses showed comparable CR/CRh rates regardless of lines of therapy, prior venetoclax exposure, or presence of co-mutations, including FLT3 or IDH1/2 mutations.

Ziftomenib was well tolerated with a safety profile consistent with previously disclosed data. The most common treatment-emergent adverse events of Grade 3 or higher were febrile neutropenia (26%), anemia (20%), and thrombocytopenia (20%). Differentiation syndrome, or DS, occurred in 25% of patients (15% Grade 3; no Grade 4/5) and was manageable with protocol-defined mitigation. Three patients (3%) discontinued treatment because of ziftomenib-related adverse events.

These findings formed part of the data set used for the NDA for ziftomenib as a potential treatment for adult patients with relapsed or refractory NPM1-mutated AML.

Ziftomenib in Combinations with Venetoclax/Azacitidine and 7+3: KOMET-007 Trial

In addition to evaluating ziftomenib as a monotherapy in relapsed or refractory AML, we have initiated a series of clinical trials to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including patients with NPM1-mutated or KMT2A-rearranged AML.

On October 1, 2025, we and Kyowa Kirin announced dosing of the first patient in a new cohort of the KOMET-007 trial evaluating ziftomenib in combination with cytarabine and daunorubicin induction chemotherapy, or 7+3, plus quizartinib, a FLT3 inhibitor, in patients with newly diagnosed FLT3-ITD/NPM1 co-mutated AML.

The KOMET-007 Phase 1b expansion cohorts, evaluating ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutated or KMT2A-rearranged AML, and ziftomenib in combination with 7+3 in patients with newly diagnosed NPM1-mutated or KMT2A-rearranged AML, continue to progress. Each of these cohorts is expected to enroll at least 20 patients.

Preliminary data from the KOMET-007 Phase 1b expansion cohort evaluating ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed NPM1-mutated AML have been accepted for oral presentation at the American Society for Hematology Annual Meeting and Exposition on December 8, 2025, along with updated safety and clinical activity results from the Phase 1a/b cohorts evaluating ziftomenib in combination with venetoclax and azacitidine in patients with relapsed or refractory NPM1-mutated or KMT2A-rearranged AML.

Ziftomenib in Combinations with Gilteritinib, FLAG-IDA and LDAC: KOMET-008 Trial

Dosing of patients is ongoing in our KOMET-008 trial, which is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutated AML, and in combination with fludarabine, cytarabine, granulocyte-colony stimulating factor, or G-CSF, and idarubicin, or FLAG-IDA, or low-dose cytarabine, or LDAC, in patients with relapsed or refractory NPM1-mutated or KMT2A-rearranged AML. We anticipate presenting preliminary data from the KOMET-008 cohort evaluating ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutated AML in 2026.

Ziftomenib in Combinations with Venetoclax/Azacitidine and 7+3 in Newly Diagnosed AML: KOMET-017 Trials

On September 29, 2025, we and Kyowa Kirin announced the first patient dosed under the KOMET-017 protocol, which is comprised of two independent, global, randomized, double-blind, placebo-controlled Phase 3 trials to evaluate ziftomenib in combination with both intensive and non-intensive regimens in patients with newly diagnosed NPM1-mutated or KMT2A-rearranged AML.

The registrational KOMET-017-IC (Intensive Chemotherapy) trial is evaluating the combination of ziftomenib with induction chemotherapy (7+3) in patients with newly diagnosed NPM1-mutated or KMT2A-rearranged AML. Patients in this trial are randomized to receive ziftomenib or placebo, in combination with standard induction, consolidation chemotherapy and post-consolidation maintenance. The KOMET-017-IC trial will assess MRD-negative CR and event-free survival as dual-primary endpoints to support potential U.S. accelerated approval and full approval, respectively. Based on our current assumptions, we believe we may have topline results from the MRD-negative CR accelerated endpoint in the intensive chemotherapy setting in 2028.

The registrational KOMET-017-NIC (Non-Intensive Chemotherapy) trial is evaluating the combination of ziftomenib with venetoclax plus azacitidine in patients with newly diagnosed NPM1-mutated AML who are unfit to receive intensive chemotherapy. The KOMET-017-NIC trial will assess CR and overall survival as dual-primary endpoints to support potential U.S. accelerated approval and full approval, respectively. Patients in this trial are randomized to receive ziftomenib or placebo, in combination with venetoclax and azacitidine.

Site activation and patient enrollment are progressing in each of the KOMET-017 trials, with patients having been dosed in both trials.

Ziftomenib in Other Acute Leukemia Indications

On April 21, 2025, the Leukemia & Lymphoma Society, or LLS, announced that the first patient has received treatment in a Phase 1 subtrial of LLS's Pediatric Acute Leukemia Master Clinical Trial, or the PedAL Subtrial. The PedAL Subtrial is investigating ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutated acute leukemia. Under the terms of our collaboration agreement with LLS and the Princess Máxima Center for Pediatric Oncology, or Máxima, for the PedAL Subtrial, LLS serves as the coordinating sponsor in North America, Máxima serves as the coordinating sponsor in Europe, and we supply ziftomenib and funding.

Ziftomenib in Gastrointestinal Stromal Tumors

On April 28, 2025, we announced that we dosed the first patients in a Phase 1 trial evaluating ziftomenib in combination with imatinib in patients with advanced GIST after imatinib failure, which we refer to as the KOMET-015 trial. Enrollment in the KOMET-015 trial is ongoing.

Next-Generation Menin Inhibitors

We continue to make progress toward multiple next-generation menin inhibitor drug candidates. We have nominated a next-generation menin inhibitor for evaluation in diabetes.

Darlifarnib (KO-2806)

We are evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of darlifarnib, our next-generation FTI, when administered as a monotherapy and in combination with other targeted therapies in a Phase 1 first-in-human trial, which we call the FIT-001 trial.

Preliminary data from the FIT-001 trial for darlifarnib as a monotherapy in RAS-altered advanced solid tumors were presented at the European Society for Medical Oncology, or ESMO, Congress in Berlin, Germany in October 2025. The data presented at the ESMO Congress indicate that darlifarnib has a manageable safety and tolerability profile when administered at doses from 3 to 10 mg per day. Encouraging antitumor activity was observed in advanced HRAS-mutated solid tumors across multiple dose levels, demonstrating on-target activity and a broad therapeutic window.

The FIT-001 trial includes multiple cohorts to evaluate darlifarnib in combination with other targeted therapies in large solid tumor indications, including cabozantinib in RCC and adagrasib in $KRAS^{G12C}$-mutated NSCLC, colorectal cancer, or CRC, and pancreatic ductal adenocarcinoma, or PDAC.

Under the terms of a clinical collaboration agreement with Mirati Therapeutics, Inc., or Mirati, a wholly owned subsidiary of Bristol Myers Squibb, Mirati supplies us with adagrasib, a $KRAS^{G12C}$ inhibitor, for the adagrasib combination cohort of the FIT-001 trial, and we sponsor the trial. We anticipate the presentation of preliminary clinical data from the combination of darlifarnib and adagrasib in 2026.

Preliminary data from the evaluation of darlifarnib in combination with cabozantinib in patients with RCC were presented at the ESMO Congress in October 2025. The data from this cohort, which includes patients with clear cell RCC, or ccRCC, and patients with non-clear cell RCC, reflect a manageable safety profile across multiple doses, including at the full label dose of cabozantinib. Antitumor activity was observed across all doses, including in patients with prior exposure to cabozantinib. As of the data cutoff date, the objective response rate, or ORR, was 33-50% in ccRCC, and 17-50% in patients with prior cabozantinib exposure, and the disease control rate was 80-100% in ccRCC. We expect to initiate Phase 1b expansion cohorts of darlifarnib and cabozantinib in patients with advanced RCC in the first half of 2026 and to present updated dose-escalation data from the combination in 2026.

Tipifarnib

We have completed enrollment and dose escalation in our Phase 1/2 trial of tipifarnib and alpelisib in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification, or the KURRENT-HN trial. Data from the KURRENT-HN trial were presented at the ESMO Congress in October 2025. The combination of tipifarnib and alpelisib demonstrated a manageable safety profile in HNSCC patients across multiple doses. Robust antitumor activity was observed in heavily pretreated patients with relapsed or metastatic HNSCC with PIK3CA alterations. An ORR of 47% was observed at a daily dose of tipifarnib 1200 mg with alpelisib 250 mg.

Based on the data from the KURRENT-HN trial, we are evaluating data generation options for the combination of darlifarnib and a PI3Kalpha inhibitor in HNSCC and other PI3Kalpha-driven solid tumors.

Liquidity Overview

As of September 30, 2025, we had cash, cash equivalents and short-term investments of $549.7 million.

In November 2024, we entered into the Kyowa License Agreement to develop and commercialize globally ziftomenib for the treatment of patients with AML and other hematologic malignancies, which may be expanded into other indications at the option of Kyowa Kirin, subject to certain conditions. In exchange for the licenses and rights granted to Kyowa Kirin to participate in the development and commercialization of ziftomenib, we received an upfront payment of $330.0 million. As of September 30, 2025, $75.0 million in development milestone payments were achieved under the Kyowa License Agreement. In November 2025, an additional $30.0 million in development milestone payments was achieved under the Kyowa License Agreement.

In January 2024, we completed a private placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share), or the Private Placement. Net proceeds from the Private Placement, after deducting expenses, were approximately $145.8 million. As of September 30, 2025, pre-funded warrants to purchase 6,478,301 of such shares of common stock from the Private Placement had been exercised and 840,585 remained outstanding.

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

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

Financial Operations Overview

Revenue from Collaborations and Licenses

We generate revenue primarily through collaboration and license agreements, such as the Kyowa License Agreement. Such agreements may require us to deliver various rights and/or services, including intellectual property rights or licenses and research, development and other services. Under such agreements, we are generally eligible to receive non-refundable upfront payments, funding for research, development and other services, milestone payments, and royalties.

Our collaboration agreements fall under the scope of Accounting Standards Codification, or ASC, Topic 808, Collaborative Arrangements, or Topic 808, when there is a joint operating activity and when both parties are active participants in the arrangement and are exposed to significant risks and rewards. For our arrangements under the scope of Topic 808, we evaluate each promised good or service that is distinct in accordance with ASC Topic 606, Revenue from Contracts with Customers, or Topic 606 (i.e., a unit of account), and apply Topic 606 to those units of account that are determined to be with a customer. For all other units of account that are not within the scope of other relevant accounting topics, we analogize to other authoritative accounting literature, such as Topic 606.

Topic 606 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers under a five-step model: (i) identify 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 a performance obligation is satisfied.

In contracts where we have more than one promise to provide the customer with goods or services, each promise is evaluated to determine whether it is a distinct performance obligation based on whether (i) the customer can benefit from the good or service on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The evaluation of whether a promised good or service is a distinct performance obligation may require significant judgment and is based on the facts and circumstances surrounding each contract and the nature of the promised goods and services within each contract.

We are required to make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of arrangements that include variable consideration, we may be required to exercise significant judgment to estimate the amount of variable consideration to include in the transaction price. In making such estimates, we generally use the most likely amount method for milestone payments and the expected value method for other forms of variable consideration and take into account relevant development, regulatory, and other factors that can impact the level of uncertainty associated with these estimates. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. These estimates are re-assessed each reporting period and we adjust our estimate of the overall transaction price as necessary.

The consideration under the contract is allocated between the distinct performance obligations based on their respective relative stand-alone selling prices. The estimated stand-alone selling price of each performance obligation reflects our best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis and is determined by reference to market rates for the good or service when sold to others or by using an adjusted market assessment approach if the selling price on a stand-alone basis is not available. The determination of the stand-alone selling price often requires significant judgment. Our estimates of the stand-alone selling price for license-related performance obligations may include forecasted revenues and expenses, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. Our estimates of the stand-alone selling price for research and development or other service-related performance obligations generally include forecasting the expected costs of satisfying a performance obligation at market rates. We also exercise significant judgment in allocating variable consideration that relates specifically to our efforts to satisfy one or more, but not all, performance obligations and determining whether such allocation is consistent with the overall allocation objectives within Topic 606.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred to the customer for the related goods or services. For performance obligations satisfied over time, we determine the measure of progress that best represents the transfer of goods or services to the customer. Revenue is recognized by measuring the progress towards complete satisfaction of the performance obligation using an input-based measure. Estimating the progress of the performance obligation requires significant management estimates, such as forecasting costs necessary to satisfy the performance obligation.

Sales-based royalties received in connection with licenses of intellectual property are subject to a specific exception in Topic 606, whereby the consideration is not included in the transaction price and recognized in revenue until the customer's subsequent sales or usages occur. We may also be entitled to cost-share reimbursements or may be required to share profits related to our collaboration and license agreements.

Research and Development Expenses

We focus on the research and development of our pipeline programs. Our research and development expenses consist of costs associated with our research and development activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of September 30, 2025, we had no in-licensed technologies that had alternative future uses in research and development projects or otherwise.

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

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

- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of doses that patients receive;

•the number of patients that participate in the clinical trials;

•the drop-out or discontinuation rates of patients;

•the duration of patient follow-up;

•potential additional safety monitoring or other studies requested by regulatory agencies;

•the number and complexity of analyses and tests performed during the clinical trial;

•the phase of development of the product candidate; and

•the efficacy and safety profile of the product candidate.

General and Administrative Expenses

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

Other Income, Net

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

Results of Operations

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
Collaboration revenue	$ 20,750	$ —	$ 20,750	$ 50,146	$ —	$ 50,146
Research and development expenses	67,908	41,705	26,203	186,666	117,700	68,966
General and administrative expenses	32,839	18,179	14,660	80,843	53,040	27,803
Other income, net	5,881	5,480	401	19,922	15,974	3,948

Comparison of the Three Months Ended September 30, 2025 and 2024

Collaboration Revenue. We recognized collaboration revenue of $20.8 million for the three months ended September 30, 2025, $20.3 million of which related to services performed under the Kyowa License Agreement, and $0.5 million related to services performed under the clinical supply agreement entered into with Kyowa Kirin Co., Ltd. effective as of March 31, 2025, or the Kyowa Clinical Supply Agreement.

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

	Three Months Ended September 30,		
	2025	2024	Change
Ziftomenib-related costs	$ 40,320	$ 18,993	$ 21,327
Darlifarnib-related costs	8,494	5,178	3,316
Tipifarnib-related costs	443	721	(278)
Discovery stage program-related costs	1,744	1,769	(25)
Personnel costs and other expenses	13,695	11,474	2,221
Share-based compensation expense	3,212	3,570	(358)
Total research and development expenses	$ 67,908	$ 41,705	$ 26,203

The increase in ziftomenib-related research and development expenses for the three months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in costs related to our registration-directed clinical trial of ziftomenib and the ziftomenib combination trials. The increase in darlifarnib-related research and development expenses for the three months ended September 30, 2025 compared to the same period in 2024 was primarily due to increased costs related to our Phase 1 clinical trial. The increase in personnel costs and other expenses for the three months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in headcount costs to support our ongoing clinical trials. We expect our research and development expenses to increase in future periods as we continue clinical development activities for our ziftomenib and FTI programs.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in personnel costs and pre-commercial planning expenses. We expect our general and administrative expenses to increase in future periods to support our planned increase in research and development and pre-commercial activities.

Other income, net. The increase in other income, net for the three months ended September 30, 2025 compared to the same period in 2024 was primarily due to an increase in interest income.

Comparison of the Nine Months Ended September 30, 2025 and 2024

Collaboration Revenue. We recognized collaboration revenue of $50.1 million for the nine months ended September 30, 2025, $49.6 million of which related to services performed under the Kyowa License Agreement, and $0.5 million related to services performed under the Kyowa Clinical Supply Agreement.

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

	Nine Months Ended September 30,		
	2025	2024	Change
Ziftomenib-related costs	$ 107,851	$ 52,335	$ 55,516
Darlifarnib-related costs	19,871	13,026	6,845
Tipifarnib-related costs	2,578	3,560	(982)
Discovery stage program-related costs	5,323	4,950	373
Personnel costs and other expenses	41,790	32,611	9,179
Share-based compensation expense	9,253	11,218	(1,965)
Total research and development expenses	$ 186,666	$ 117,700	$ 68,966

The increase in ziftomenib-related research and development expenses for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in costs related to our registration-directed clinical trial of ziftomenib and the ziftomenib combination trials. The increase in darlifarnib-related research and development expenses for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to increased costs related to our Phase 1 clinical trial. The increase in personnel costs and other expenses for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in headcount costs to support our ongoing clinical trials.

General and Administrative Expenses. The increase in general and administrative expenses for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to increases in personnel costs and pre-commercial planning expenses.

Other income, net. The increase in other income, net for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to an increase in interest income.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through equity and debt financings and payments received under the Kyowa License Agreement. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities and, more recently, to building out our commercial capabilities and infrastructure.

In November 2024, we entered into the Kyowa License Agreement to develop and commercialize globally ziftomenib for the treatment of patients with AML and other hematologic malignancies, or the Field. In exchange for the licenses and rights granted to Kyowa Kirin to participate in the development and commercialization of ziftomenib, we received an upfront payment of $330.0 million and are eligible to receive up to an additional $933.0 million in development, regulatory and commercial milestone payments for the Field. As of September 30, 2025, $75.0 million in development milestone payments were achieved under the Kyowa License Agreement. In November 2025, an additional $30.0 million in development milestone payments was achieved under the Kyowa License Agreement.

In January 2024, we completed the Private Placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share). Net proceeds from the Private Placement, after deducting expenses, were approximately $145.8 million. As of September 30, 2025, pre-funded warrants to purchase 6,478,301 of such shares of common stock from the Private Placement had been exercised and 840,585 remained outstanding.

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

In November 2022, we entered into a loan and security agreement with several banks and other financial institutions or entities party thereto, or collectively the Lenders, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, which was amended in October 2023 and October 2025, or the Loan Agreement, providing for up to $125.0 million in a series of term loans, or Term Loans. Under the terms of the Loan Agreement, we borrowed $10.0 million of an initial $25.0 million tranche of Term Loans. The remaining tranches of Term Loans expired without us drawing down such additional loans. The Term Loans have a maturity date of November 2, 2027, or the Maturity Date. Repayment of the Term Loans is interest only through (a) May 1, 2026 and (b) May 1, 2027, if we satisfy the Approval Milestone (as defined in the Loan Agreement). After the interest-only payment period, borrowings under the Loan Agreement are repayable in monthly payments of principal and accrued interest until the Maturity Date. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%.

At our option, we may prepay all or any portion of the outstanding Term Loans at any time. We paid a facility charge of approximately $0.1 million upon closing and an additional approximately $0.2 million of facility charges in November 2023 due to the availability of the second tranche of the Term Loans. The Loan Agreement also contains an end of term fee in an amount equal to approximately $1.5 million (which is 6.05% of the maximum amount of the first tranche of loans), which is due and payable on the earliest to occur of (i) the Maturity Date, (ii) the date we prepay the outstanding loans in full, and (iii) the date that the secured obligations become due and payable. Our obligations under the Loan Agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. As part of the Loan Agreement, we are subject to certain negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

We have incurred operating losses and negative cash flows from operating activities since inception. As of September 30, 2025, we had an accumulated deficit of $1.1 billion. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of collaborators or potential collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of September 30, 2025, we had cash, cash equivalents and short-term investments of $549.7 million. Based on our current plans, we believe that our cash, cash equivalents and short-term investments as of September 30, 2025 will be sufficient to enable us to fund our current operating expenses into 2027, and combined with anticipated collaboration funding under the Kyowa License Agreement, should support our ziftomenib AML program through topline results from KOMET-017, our clinical trials in the frontline combination setting. Our future capital requirements will depend on many factors, including:

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

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

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

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

	Nine Months Ended September 30,		
	2025	2024	Change
Net cash used in operating activities	$ (181,331)	$ (134,814)	$ (46,517)
Net cash provided by (used in) investing activities	51,498	(6,635)	58,133
Net cash provided by financing activities	658	153,611	(152,953)

Operating Activities. The increase of $46.5 million in net cash used in operating activities for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to an increase of $42.9 million in net loss and changes in operating assets and liabilities of $7.3 million, offset by a decrease of $3.2 million in non-cash net accretion of discounts on short-term investments.

Investing Activities. The increase of $58.1 million in net cash provided by investing activities for the nine months ended September 30, 2025 compared to the same period in 2024 was primarily due to an increase of $165.7 million in maturities of short-term investments, offset by increases of $103.4 million in purchases of short-term investments and increases of $4.2 million in purchases of property and equipment.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2025 related to proceeds of $0.7 million from the issuance of shares of common stock under our equity plans. Net cash provided by financing activities for the nine months ended September 30, 2024 primarily related to net proceeds of approximately $145.8 million from the sale of shares of our common stock and pre-funded warrants to purchase shares of our common stock in our Private Placement and proceeds of $7.8 million from the issuance of shares of common stock under our equity plans.

Contractual Obligations and Commitments

We have borrowed $10.0 million of Term Loans under our Loan Agreement, which requires us to make principal and interest payments. The Term Loans are subject to variable changes in the per annum interest rate, which is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%. In addition, an end of term fee will be due in an amount equal to approximately $1.5 million (which is 6.05% of the maximum amount of the first tranche of loans), payable on the earliest of the Maturity Date, acceleration or prepayment of the Term Loans.

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

We enter into short-term and cancellable agreements in the normal course of operations with clinical sites and contract research organizations, or CROs, for clinical research studies, professional consultants and various third parties for preclinical research studies, clinical supply manufacturing and other services through purchase orders or other documentation. Such short-term agreements are generally outstanding for periods less than one year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice of 90 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

Pursuant to our in-license agreements, we have milestone or contractual payment obligations contingent upon the achievement of certain milestones or events. We may be required to pay up to approximately $78.8 million in milestone payments, plus additional sales royalties and sublicense fees, in the event that regulatory and commercial milestones under the in-license agreements are achieved. Our in-license agreements are cancelable by us with written notice within 180 days or less.

Under the Kyowa License Agreement, we are responsible for funding the specified development activities included in the development plan that are planned to be conducted prior to the end of 2028, and we will share equally (50/50) with Kyowa Kirin all development costs for all other development activities in the United States included in the development plan (including the costs of future trials conducted under the development plan in the United States). We will share equally with Kyowa Kirin in any potential profits and losses arising from the commercialization of ziftomenib in the United States for the existing Field and, if Kyowa Kirin exercises its option to expand the licensed Field, the expanded Field.

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed financial statements required estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the unaudited condensed financial statements. On an ongoing basis, we evaluate our critical accounting estimates and judgments, including those related to revenue from collaborations and licenses, and clinical trial costs and accruals. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Management Estimates," included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the short-term investments to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in U.S. Treasury securities, money market funds and U.S. Agency bonds. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our short-term investments without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For our short-term investments, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the unaudited condensed statements of operations and comprehensive loss. We believe that should a 10.0% change in interest rates were to have occurred on September 30, 2025, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Any changes would only be realized if we sold the investments prior to maturity.

We are also subject to interest expense fluctuations through our Term Loans which, as of September 30, 2025, bear interest at a rate equal to the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%, and are therefore exposed to changes in interest rates through their maturity date in November 2027. For interest expense, we do not believe that an increase or decrease in the interest rate would have a significant impact on the unaudited condensed statements of operations and comprehensive loss. We believe that should a 10.0% change in the interest rate were to have occurred on September 30, 2025, this change would not have had a material effect on interest expense as of that date.

Inflation Risk

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

ITEM 4. CONTROLS AND PROCEDURES

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

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

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with management's evaluation of such internal control that occurred during our most recent quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Risk Factor Summary

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

- We are highly dependent on the success of our lead product candidate, ziftomenib, which is still in clinical development, and we cannot give any assurance that ziftomenib or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized. Even if our product candidates receive regulatory approval and are commercialized, they may be less competitive and generate less revenue than we anticipate.
- Our discovery, preclinical and clinical development activities are primarily focused on the development of targeted therapeutics for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs may never lead to marketable products.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.
- Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.
- Failure by us or our third-party collaborators to develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.
- We have incurred losses since our inception, expect to incur losses over the next several years and may never achieve or maintain profitability.
- We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and operating results will vary significantly from period to period.
- We may need to obtain substantial additional capital in connection with our continuing operations. If we are required to raise additional capital, doing so may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.
- Our collaboration with Kyowa Kirin is important to our business. If Kyowa Kirin ceases development efforts under the Kyowa License Agreement, or if the Kyowa License Agreement is terminated, we may not receive future milestone payments or royalties under the Kyowa License Agreement and our business could be adversely affected. If Kyowa Kirin does not fulfill its obligations under the Kyowa Co-Promotion Agreement, our business could be adversely affected.
- We rely on third-party contractors and organizations to conduct, and/or to supply materials to conduct, our clinical trials and provide commercial supply, and those third parties may not perform satisfactorily, including failing to meet deadlines for the supply of materials and/or the completion of such clinical trials or to meet the demands of our commercial supply.

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

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

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

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

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

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

•If we are unable to maintain the confidentiality of our trade secrets or other confidential information, our business and competitive position would be harmed.

•Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

•We have built a limited marketing, sales and distribution infrastructure. If our sales capabilities are inadequate, or we are unable to enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

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

•We are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

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

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

Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the information included or incorporated by reference in this Quarterly Report and in our other public filings, you should carefully consider the risks described below in evaluating our company. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 28, 2025.

Risks Related to the Discovery and Development of Our Product Candidates

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

Our future success is highly dependent on obtaining regulatory approval for, and then successfully commercializing, our lead product candidate, ziftomenib. Our business depends entirely on the successful development and commercialization of our product candidates. We have not completed the development of any product candidates; we currently generate no revenues from sales of any product, and we have not demonstrated that we can successfully develop a marketable product. Although we submitted, and the FDA has accepted, our NDA seeking approval for ziftomenib for the treatment of adult patients with relapsed or refractory AML with an NPM1 mutation, there can be no assurance that the FDA will approve the NDA. We may receive a complete response letter rather than approval of the NDA at the conclusion of the FDA's review.

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

There is no guarantee that our clinical trials will be completed on time or at all. Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote any product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals. Although the scope of regulatory approval is similar in other countries, in some countries there are additional regulatory requirements and potential regulatory risks and we cannot predict success in these jurisdictions.

Prior to receiving approval, if any, to commercialize a product candidate in the United States or internationally, we or our collaborators must demonstrate to the satisfaction of the FDA and other regulatory authorities that such product candidate is safe and effective for its intended use. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of a product candidate may not be replicated in subsequent clinical trials. Even if we believe the preclinical or clinical data are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. We maintain frequent, ongoing dialogue with the FDA and other regulatory bodies regarding our clinical trial designs, including the patient selection criteria, dosing plans and statistical analysis plans. There is a risk that the FDA or other regulatory agencies could at any time raise objections to the design or conduct of our clinical trials. Any such objections could delay the initiation or completion of our registration-directed clinical trials.

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

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

We have not previously received marketing approval for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval for any indication. Although we submitted an NDA to the FDA for ziftomenib for the treatment of relapsed or refractory NPM1-mutated AML in the first quarter of 2025, and the FDA accepted such NDA in the second quarter of 2025, we cannot anticipate whether or when we will seek regulatory review of a product candidate for any other indications. If we do not receive regulatory approvals for and successfully commercialize any of our product candidates on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one of our product candidates, our revenues may be dependent, in part, on our third-party collaborator's ability to co-commercialize such product candidate or to commercialize the companion diagnostic for such product candidate, as applicable. Further, our revenues may be dependent on the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the market opportunities for the indications we pursue are not as significant as we estimate, our business and prospects may be harmed.

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

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

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

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

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

Results from clinical trials conducted at a single clinical site or a small number of clinical sites may not be predictive of results from additional clinical sites or from subsequent clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict with certainty if or when any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

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

- failure to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a clinical trial;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow-up;
- delay or failure in determining an acceptable dose and schedule for a product candidate in a clinical trial;
- clinical sites and investigators deviating from clinical trial protocol, failing to conduct the clinical trial in accordance with regulatory requirements or dropping out of a clinical trial;

•lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our CROs and other third parties;

•clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to redesign or modify our clinical trial protocols, conduct additional clinical trials or abandon product development programs;

•the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

•we may experience delays or difficulties in the enrollment of patients whose tumors harbor the specific genetic alterations that our product candidates are designed to target;

•our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•we may have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;

•regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

•the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or

•there may be changes in governmental regulations or administrative actions.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these clinical trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

•be delayed in obtaining marketing approval for our product candidates;

•not obtain marketing approval at all;

•obtain approval for indications or patient populations that are not as broad as intended or desired;

•obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that could reduce the potential market for our products or inhibit our ability to successfully commercialize our products;

•be subject to additional post-approval restrictions and/or testing requirements; or

•have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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

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

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

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

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

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

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

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

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

We have observed serious adverse events in conducting clinical trials of our product candidates. The most common treatment-related serious adverse event observed to date with ziftomenib, occurring in more than 10% of patients, is DS. While no Grade 4/5 treatment-related DS has been observed in patients with NPM1-mutated AML treated with ziftomenib, we note that during its review of the NDA for ziftomenib for the treatment of adult patients with NPM1-mutated AML, the FDA has adjudicated two cases with fatal outcomes where DS could not be ruled out as a contributing factor, although the investigators who reported such cases suspected alternate etiologies. Other treatment-related serious adverse events observed with ziftomenib, occurring in fewer than 10% of patients, include febrile neutropenia, leukocytosis, dyspnea, pulmonary embolism, nausea, diarrhea and increased white blood cell count.

Our FIT-001 trial represents the first time our darlifarnib compound has been tested in humans. To date, treatment-related serious adverse events have been reported in fewer than 10% of patients treated with darlifarnib, and have been limited to neutropenia, febrile neutropenia and thrombocytopenia.

Tipifarnib has been studied in more than 5,000 oncology patients and generally has been well tolerated and exhibited a manageable side effect profile. The most common treatment-related serious adverse event observed in our clinical trials of tipifarnib has been nausea, reported in approximately 5% of patients.

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

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

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

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. The FDA generally will require either approval or clearance of the diagnostic at the same time the FDA approves the therapeutic product, or as a post-marketing commitment at the time of the therapeutic product's approval. For example, we anticipate that if the FDA approves our NDA for ziftomenib, such approval will be subject to a post-marketing commitment to conduct a study to support the availability of an in vitro diagnostic device (companion diagnostic) to identify susceptible NPM1 mutations in patients with AML for the safe and effective use of ziftomenib. We presently anticipate that approved companion diagnostics will be required in order to obtain approval for our other product candidates for the treatment of patients with other molecular or genetic alterations.

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

Any delay or failure by us or third-party collaborators to develop, validate or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

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

- may not perform their obligations as expected;
- may not pursue commercialization of companion diagnostics for our therapeutic product candidates that achieve regulatory approval;

•may not commit sufficient resources to the marketing and distribution of such companion diagnostics;

•may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; and

•may terminate their relationship with us.

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

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

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

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

In addition to the potentially small populations for our clinical trials, the eligibility criteria of our clinical trials will further limit the pool of available trial participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a trial. Additionally, the process of finding and diagnosing patients may prove costly. For example, certain genetic alterations are not included in existing diagnostic panels, have unknown prognostic significance and/or are not targeted by any FDA-approved treatment, and as a result, biomarker testing for such alterations is not routinely performed. To seek to address these limitations, we have contracted with third-party laboratories to facilitate the genetic screening of patients for our clinical sites. However, there is no guarantee that these efforts will be effective.

We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials because of the perceived risks and benefits of the product candidate under trial including the number and frequency of trial required procedures and tests, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. Further, if patients do not comply with clinical trial process and procedure and, for example, drop out, miss scheduled doses or follow-up visits, or fail to follow trial protocols, then the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities.

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

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

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

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

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

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred losses since our inception, expect to incur losses over the next several years and may never achieve or maintain profitability.*

To date, we have financed our operations primarily through equity and debt financings and payments received under the Kyowa License Agreement. We have incurred losses since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Losses have resulted principally from costs incurred in connection with our research and development activities, and from general and administrative costs associated with our operations. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially if and as we:

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

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, successfully developing companion diagnostics, obtaining marketing approval from the FDA and other global regulatory authorities for these product candidates, and the manufacturing, marketing and selling of these products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or even sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease our value and could impair our ability to raise capital, maintain our research, development and planned future commercialization efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We expect our actual financial condition and operating results to fluctuate significantly from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

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

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

We may need to obtain substantial additional capital in connection with our continuing operations. If we are required to raise additional capital, doing so may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.*

If we need to raise additional capital in connection with our continuing operations, we would expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships or licensing arrangements. Additional capital may not be available on reasonable terms, if at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of our stockholders as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, such as our Kyowa License Agreement, we may have to relinquish valuable rights to our product candidates, other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. As a result of the global pandemics, bank failures, actual or perceived changes in interest rates, current or future tariffs, and economic inflation, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive.

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

In November 2022, we entered into the Loan Agreement with the Lenders and Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, pursuant to which we borrowed $10.0 million of Term Loans. No further Term Loans may be drawn under the Loan Agreement. On June 1, 2024, a minimum cash covenant commenced requiring us to hold cash in the United States and subject to a first-priority perfected security interest in favor of the Lenders in an amount greater than or equal to (x) 55.0% of the outstanding loan obligations if we have not received FDA approval for ziftomenib, or (y) 35.0% of the outstanding loan obligations if we have received FDA approval for ziftomenib, provided that neither (x) nor (y) will apply at any time our market capitalization is equal to or greater than $1,250.0 million. Since June 1, 2024, our market capitalization has not always exceeded $1,250.0 million, however, we have met the minimum cash covenant. While any amounts are outstanding under our term loan facility, we are subject to affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness, transactions with affiliates and a minimum cash covenant, among other customary covenants. If we default under our term loan facility, the Lenders may accelerate our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the Lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could accelerate our obligations under the Loan Agreement upon the occurrence of an event of default, which includes, among other things, our failure to satisfy our payment obligations under the Loan Agreement, the breach of certain of our other covenants under the Loan Agreement or the occurrence of a material adverse change, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

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

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

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

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

Events involving limitations to liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market-wide liquidity problems. We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, standard insurance limit, with balances concentrated at a small number of financial institutions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or with which we do business, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. In addition, if any of our partners or parties with whom we conduct business are unable to access funds due to the status of their financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

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

Risks Related to Our Dependence on Third Parties

Our collaboration with Kyowa Kirin is important to our business. If Kyowa Kirin ceases development efforts under the Kyowa License Agreement, or if the Kyowa License Agreement is terminated, we may not receive future milestone payments or royalties under the Kyowa License Agreement and our business could be adversely affected. If Kyowa Kirin does not fulfill its obligations under the Kyowa Co-Promotion Agreement, our business could be adversely affected.*

We are dependent upon Kyowa Kirin for the development of, and the regulatory activities and commercial strategy for, ziftomenib outside the United States. Additionally, Kyowa Kirin is responsible for half of all costs and expenses for the commercialization of ziftomenib in the United States. Under the Kyowa Co-Promotion Agreement, Kyowa Kirin has the right and responsibility to co-promote ziftomenib in the United States and is obligated to meet minimum detailing requirements using sales representatives meeting specific qualifications. If Kyowa Kirin does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval, and commercialization efforts related to ziftomenib could be delayed or terminated.

Disagreements between us and Kyowa Kirin regarding clinical development and commercialization matters could lead to delays in the development or commercialization of ziftomenib and, in some cases, termination of the Kyowa License Agreement and the Kyowa Co-Promotion Agreement. Kyowa Kirin may terminate the Kyowa License Agreement for convenience upon 12 months' prior written notice. In addition, Kyowa Kirin has the right to terminate the Kyowa License Agreement with a shorter specified notice period upon the occurrence of a material adverse regulatory event or certain other specified events. The Kyowa Co-Promotion Agreement will automatically terminate upon termination of the Kyowa License Agreement.

If our collaboration does not result in the successful development and commercialization of ziftomenib, or if Kyowa Kirin terminates the Kyowa License Agreement, we may not receive any future milestone or royalty payments under the Kyowa License Agreement. In addition, any termination of the Kyowa License Agreement or the Kyowa Co-Promotion Agreement by Kyowa Kirin could affect our ability to further develop ziftomenib or adversely affect how we are perceived in scientific and financial communities. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

We rely, and expect to continue to rely, on third-party contractors, CROs, clinical data management organizations, independent contractors, medical institutions and clinical investigators to support our preclinical development activities and conduct our clinical trials.

We compete with many other companies, some of which may be our business competitors, for the resources of these third parties. Large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours.

Our agreements with third-party contractors may terminate for a variety of reasons, including a failure to perform by the third parties. The third parties on whom we rely may have the right to terminate their engagements with us at any time. The termination of these agreements or engagements may cause delay in the development and commercialization of our product candidates. If any such third-party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which could result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the services performed by such third parties.

Our reliance on third parties to conduct our clinical trials reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA and other regulatory authorities require us to comply with good clinical practice guidelines for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, such as ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

In addition to relying upon third-party service providers, we depend on our collaborators and other third-party suppliers to supply certain therapies for our combination trials. For example, we depend on Mirati to supply adagrasib for the NSCLC, CRC and PDAC combination cohort of our FIT-001 trial. If Mirati does not perform in accordance with our collaboration agreement, or the agreement is terminated, the adagrasib combination cohort of our FIT-001 trial, and our development plans for darlifarnib in combination with adagrasib, could be materially adversely impacted. Similarly, for our KURRENT-HN trial, we depend upon Novartis Pharma AG, or Novartis, to supply alpelisib in accordance with the terms of our collaboration agreement. If Novartis does not perform in accordance with the agreement, or the agreement is terminated, the KURRENT-HN trial, and our development plans for tipifarnib in combination with alpelisib, could be materially adversely impacted.

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

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

We depend on third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.*

We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of clinical supplies of ziftomenib, darlifarnib, tipifarnib and our other product candidates for preclinical and clinical testing. We expect to rely on third parties as well for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We also expect to rely on other third parties to package and label the drug product as well as to store and distribute drug supplies for our clinical trials.

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

Some of our manufacturers and suppliers are located in China. Recent developments in international trade policies, including restrictions and tariffs, may restrict our ability to work with certain of our manufacturers and suppliers or otherwise disrupt our supply chain, and we expect to experience increased costs and expenses, which may have adverse effects on the development of our product candidates and our business operations. For further information regarding impacts to our business as a result of trade policy developments, see the risk factor titled "*International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects*."

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

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- catastrophic events at the third-party organization;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that may be conducted after an NDA is submitted to the FDA. We are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of both the active drug substances and finished drug product for ziftomenib, darlifarnib, tipifarnib and our other product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture our products, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

To the extent our third-party manufacturers and supply chain suppliers are negatively impacted by geopolitical events such as actual or potential conflicts in the Middle East, Europe or Asia, as well as actual or threatened public health epidemics or outbreaks, we may not be able to provide continuous drug supply to our clinical sites and our clinical trials may be delayed or may not be completed, which would have a material adverse effect on our business operations and performance.

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

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

Our product candidates must be approved by the FDA pursuant to an NDA in the United States, by the European Medicines Agency, or the EMA, in Europe, and by similar regulatory authorities outside the United States prior to commercialization.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our product candidates may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel. Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to FDA and other related government agencies. For example, government shutdowns, furlough of employees and reduced federal government employee headcount and the size of the federal government. The reductions in the FDA's workforce and budgetary pressures could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the marketing of our products which could have a material adverse effect on our business. In addition, public health epidemics or outbreaks could also potentially affect the business of the FDA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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

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

The FDA may also impose requirements for costly post-approval studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-approval studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

We have received Breakthrough Therapy Designation from the FDA on ziftomenib for the treatment of patients with relapsed or refractory NPM1-mutated AML and tipifarnib for the treatment of patients with recurrent or metastatic HRAS-mutated HNSCC with variant allele frequency ≥ 20% after disease progression on platinum-based chemotherapy. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs that have been designated as Breakthrough Therapies are eligible for Priority Review by the FDA, rolling submission of portions of the NDA and FDA's organizational commitment involving senior management to provide guidance to the company to help determine the most efficient route to approval. Such interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. However, the reduced timelines may introduce significant chemistry, manufacturing and controls challenges for product development.

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

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens, on behalf of the government, through whistleblower actions, and civil monetary penalties laws which prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information on covered entities which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;

•the federal Physician Payments Sunshine Act, which requires applicable manufacturers of certain drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians or their immediate family; and

•analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, and/or drug pricing. Some state and local laws also require the registration of pharmaceutical sales representatives.

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

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations (or such failure by the third parties with whom we work) could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.*

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

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer health data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or collectively CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA and other state laws exempt some data processed in the context of clinical trials, these developments may increase compliance costs and potential liability. Similar laws are being considered in several other states. In addition, data privacy and security laws have been proposed at the federal and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union, or EU, General Data Protection Regulation (EU) 2016/679, or GDPR, and the United Kingdom's GDPR, or UK GDPR (collectively, GDPR), and Australia's Privacy Act impose strict requirements for processing personal data. For example, under GDPR, companies may face temporary or definitive bans on data processing, and other corrective actions, fines of up to 20 million Euros under the EU GDPR/17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, whichever is greater, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, apply to clinical trials conducted in Canada. Clinical trials conducted in Asia are and may in the future be subject to existing, new and emerging data privacy regimes in that region.

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

If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are bound by certain contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, materials, and other statements regarding data privacy and security. Regulators in the United States have scrutinized and are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and has in the past and may in the future necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences including, but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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

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

For example, in March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, improve quality, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit.

There have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. We cannot predict the ultimate content, timing or effect of healthcare reform legislation or regulation or the impact of potential legislation or regulation on us.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, signed into law on July 4, 2025, is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, that due to subsequent legislative amendments, will stay in effect until 2032. Additionally, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. These laws and other potential legislation may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. As a result, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. For example, in August 2022, former President Biden signed the Inflation Reduction Act, or IRA, into law. The IRA, among other things, (1) extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, (2) directs the U.S. Department of Health and Human Services, or HHS, to negotiate, subject to a specified cap, the price of a set number of certain high-expenditure, single-source drugs covered under Medicare that have been on the market for at least seven years, or Medicare Drug Price Negotiation Program, (3) imposes rebates under Medicare Part B and Medicare Part D to penalize manufacturers for price increases that outpace inflation, and (4) makes several changes to the Medicare Part D benefit, including by significantly lowering the beneficiary maximum annual out-of-pocket costs, and through a change in manufacturer liability under the program. These provisions began to take effect progressively in fiscal year 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. In August 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued, and will continue to issue and update, guidance as these programs are implemented. On January 17, 2025, HHS selected 15 additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. In December 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, in January 2024, the FDA approved Florida's SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Future legislation could potentially change drug pricing dynamics. We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business, particularly in light of the current U.S. presidential administration.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, on September 30, 2025, the current administration announced the first agreement with a major pharmaceutical company that requires the drug manufacturer to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions and proposals include, for example, (1) directives to reduce agency workforce and cut programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration's executive order that directed HHS to establishing an artificial intelligence, or AI, task force and developing a strategic plan; (4) directing HHS to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs of imported pharmaceutical products; (6) directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans; and (7) as part of the Make America Healthy Again (MAHA) Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, trademarks, confidentiality agreements, and license agreements to protect the intellectual property related to our current product candidates and development programs.

Threats to the duration, breadth or strength of protection provided by any patents, patent applications or future patents we may own, license, or pursue with respect to any of our current or future product candidates or products could hinder our ability to commercialize any of our current or future product candidates or products. For example, our patent rights may not protect our products and product candidates if competitors devise products that compete with us without legally infringing our patent rights. Further, if we encounter delays in our development efforts, the length of time during which we could market any of our current or future product candidates or products under any patent protection we obtain would be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates or products, patents protecting such candidates might expire before or shortly after such product candidates or products are commercialized.

Ziftomenib

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

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

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

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

Darlifarnib (KO-2806)

We have filed patent applications in the United States, Europe, China, Japan and other foreign jurisdictions covering the composition of matter of darlifarnib and certain structurally related compounds and methods of using darlifarnib for treating

cancers. However, there is no guarantee that patents will be granted from such applications or that any granted patents would provide protection against third parties.

Tipifarnib

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

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

While patent term extension may be available for a patent that covers an approved tipifarnib product, the applicable authorities, including the U.S. PTO and the FDA, and any equivalent patent or regulatory authorities in other countries, may disagree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, for example, for our tipifarnib method of use patents, our competitors who obtain the requisite regulatory approval could offer tipifarnib products for the same indication(s) as our tipifarnib product earlier than expected, so long as the competitors do not infringe any other patents that we may hold. Competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

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

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

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

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

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

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

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we are unable to maintain the confidentiality of our trade secrets or other confidential information, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants; however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, to third parties, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent the competitor, or those to whom the competitor communicates the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Certain inventions that are patentable in the United States may not be patentable in other countries and vice versa. Further, our ability to enforce our patent rights in foreign jurisdictions may not be as effective as in the United States. For example, some foreign countries, such as India and China, may not allow or enforce patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection or eliminate our patent protection completely.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO or third-party preissuance observations to the European Patent Office, or EPO, or become involved in patent office post-grant proceedings, such as opposition, derivation, reexamination, inter partes review, or post-grant review proceedings, challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding, or in litigation, could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, threats to the duration, breadth or strength of protection provided by our patents and patent applications is threatened could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Even if our owned and licensed patents might provide such protection or competitive advantage, we may not have the resources to effectively enforce our rights under such patents, which can be expensive and time-consuming. Further, our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

For instance, under the Unitary Patent Court system that has been implemented in Europe, patent applicants have the option, upon grant of a patent by the EPO, of electing grant of a Unitary Patent, which will be subject to the jurisdiction of the Unified Patent Court, or UPC. This is a significant change in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation.

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

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

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

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

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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

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 use of U.S.-based manufacturing companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

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

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

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

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like immunotherapy, chemotherapy, targeted therapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- our ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the acceptance and utilization of diagnostics to identify appropriate patients;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

We have built a limited marketing, sales and distribution infrastructure. If our sales capabilities are inadequate, or we are unable to enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.*

In preparation for potential FDA approval of ziftomenib in patients with relapsed or refractory NPM1-mutated AML, we have built, on a territory-by-territory basis sales, marketing, market access, distribution, managerial and other non-technical capabilities, or have made arrangements with third parties to perform these services. We have hired and trained our sales, marketing, analytics and market access teams with expertise to commercialize ziftomenib. The training and ongoing management of these teams, and the development of our commercial capabilities and infrastructure with respect to our other product candidates, is expensive and time consuming and requires significant attention of our executive officers to oversee. Any failure or delay in the development of our commercial capabilities and infrastructure would adversely impact the commercialization of any of our products that we obtain approval to market. Additionally, if the commercial launch of any product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition such sales and marketing personnel. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. For example, under the Kyowa License Agreement and the Kyowa Co-Promotion Agreement, we are collaborating with Kyowa Kirin for the potential commercialization of ziftomenib in certain indications. If we are unable to enter into similar arrangements for ziftomenib in indications outside the Kyowa License Agreement or for other product candidates when needed on acceptable terms or at all, we may not be able to successfully commercialize such product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies, which may directly compete with ziftomenib, darlifarnib, tipifarnib and any other future product candidates. If any competitor is able to advance their clinical program more quickly than ours, the commercial opportunity for our product candidates could be reduced. In the case of ziftomenib, in November 2024, Syndax Pharmaceuticals, Inc., or Syndax, announced the FDA's approval of revumenib (Revuforj®), another menin inhibitor, in relapsed or refractory KMT2A-rearranged acute leukemia in adult and pediatric patients one year and older, and in October 2025, Syndax announced the FDA's approval of their supplemental NDA for Revuforj for the treatment of relapsed or refractory AML with a susceptible NPM1 mutation in adult and pediatric patients one year and older who have no satisfactory alternative treatment options.

Our commercial opportunity also could be reduced or eliminated if our competitors develop and commercialize products that are safer, are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop alone or in combination with other drugs or biologics. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or slow our regulatory approval and ability to sell our products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products or prioritize the use of other branded products over our products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The insurance coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain coverage and adequate reimbursement for any product candidates for which we receive marketing approval could limit our ability to market those products and decrease our ability to generate revenue.*

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

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

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

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

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

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently have product liability and clinical trial liability insurance coverage that we believe is adequate, but such coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we commence or expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

We are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.*

We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and market access personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees, and recruiting additional key employees, may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We have expanded our development, regulatory, operations, medical affairs, market access, marketing and sales capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

We have experienced significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, manufacturing and supply chain, regulatory affairs, operations, medical affairs, sales, marketing and market access. To manage our growth, we must continue to implement and improve our managerial, operational and financial systems and recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to effectively manage growth could delay the execution of our business plans, disrupt our operations, or result in operational mistakes or shortcomings, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

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

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

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

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, and, as a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents.

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

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to produce and develop our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, information technology systems, cloud-based infrastructure, applications, websites, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business. Our business, including our ability to manufacture drug products and conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, as they have in the past and may in the future, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations require us to implement and maintain specific security measures designed to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We (or third parties with whom we work) have in the past experienced, and may in the future experience or be perceived to have experienced, a security incident. For example, in July 2024, we were notified of a cybersecurity incident experienced by a former clinical trial service provider. The incident was investigated by our Incident Review Team and evaluated by our Materiality Assessment Team, which concluded that the incident was not material to our business. Adverse consequences of a security incident may include government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention, interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent patients from participating, or cause patients to cease participation, in our clinical trials, and negatively impact our ability to grow and operate our business.

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

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

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

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

Interruptions in our operations due to system failures, accidents, security breaches or other events could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

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

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

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

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

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.*

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties, including manufacturers and suppliers located in China, for the manufacture of clinical supplies of ziftomenib and darlifarnib for preclinical and clinical testing. We also expect to rely on third parties outside of the United States for commercial manufacture if any of our product candidates receives marketing approval. In addition, we rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, developments in trade and other regulations may restrict our ability to work with partners in China, thereby potentially disrupting our supply chain. In the event any of our product candidates is approved, tariffs and trade restrictions could hinder our ability to establish cost-effective commercial production and distribution capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report.

Risks Related to Ownership of our Common Stock

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

Our common stock has been listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol "KURA" since November 5, 2015. The high and low price per share of our common stock as reported by Nasdaq during the period from November 5, 2015 through September 30, 2025, were $43.00 and $2.50, respectively. We cannot predict the extent to which investor interest in our company will sustain an active trading market on Nasdaq or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if an active trading market is not sustained or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

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

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

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- changes in the structure of healthcare payment systems;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- our dependence on third parties, including CROs as well as our partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results, liquidity or other indicators of our financial condition;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- market conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of September 30, 2025, we had 8,245,876 shares of common stock available for grant under the 2014 Plan, options to purchase up to an aggregate of 13,702,920 shares of common stock outstanding, 1,467,525 unvested restricted stock units outstanding and 969,417 unvested performance-based restricted stock units outstanding. Also, pursuant to our 2023 Inducement Option Plan, as amended, or Inducement Plan, we are authorized to grant nonstatutory stock options to individuals that were not previously our employees or directors (or following a bona fide period of non-employment), as an inducement material to the individuals' entry into employment with us, pursuant to Nasdaq Listing Rule 5635(c)(4). As of September 30, 2025, we had 251,925 shares of common stock available for grant under the Inducement Plan and options to purchase up to an aggregate of 2,248,075 shares of common stock outstanding.

In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2015 Employee Stock Purchase Plan, or ESPP. As of September 30, 2025, we had 457,851 shares of common stock reserved for future issuance under the ESPP.

Further, as of September 30, 2025, (i) warrants to purchase up to (a) 33,988 shares of our common stock at an exercise price of $3.31 per share and (b) 26,078 shares of our common stock at an exercise price of $14.38 per share and (ii) pre-funded warrants to purchase up to 840,585 shares of our common stock at an exercise price of $0.0001 per share were outstanding.

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

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

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

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- division of our board of directors into three classes;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66$^{2}/_{3}$% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 66$^{2}/_{3}$% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation;
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock; and
- a requirement that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders;

•any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; and

•any action asserting a claim against us governed by the internal affairs doctrine.

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

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. The OBBBA enacted in 2025, the IRA enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and legislation informally titled the Tax Cuts and Jobs Act enacted in 2017, made significant changes to the U.S. tax laws. For example, the Tax Cuts and Jobs Act required taxpayers to capitalize and amortize U.S.-based and non-U.S.-based research and experimental, or R&E, expenditures over five and fifteen years, respectively. The OBBBA restored the deductibility of domestic R&E expenditures in the year incurred for tax years beginning after December 31, 2024, but retained the capitalization and amortization requirement for foreign R&E expenditures. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a year is limited to 80% of taxable income in such year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, on June 27, 2024, California Senate Bill 167, or SB 167, was enacted into law. SB 167 provides for a three-year suspension of net operating losses under the California Personal Income Tax and Corporation Tax and a three-year cap on the use of business incentive tax credits to offset no more than $5 million of tax per year. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our state net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

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

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

General Risk Factors

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

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

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

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

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

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

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

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

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

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

ITEM 5. OTHER INFORMATION

On November 3, 2025, we announced receipt of a $30.0 million milestone payment under the Kyowa License Agreement in connection with the dosing of the first patient in the second of two KOMET-017 Phase 3 registrational trials of ziftomenib.

Trading Plans

During the three months ended September 30, 2025, certain of our directors and officers adopted, modified or terminated contracts, instructions or written plans for the purchase or sale of our securities as noted below:

			Trading Arrangement			
Name and Position	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares to be Sold**	**Expiration Date**
Kathleen Ford, Chief Operating Officer	Termination***	August 28, 2025	X		74,438, and ESPP net shares to be purchased	September 15, 2025
Kathleen Ford, Chief Operating Officer	Adoption***	August 29, 2025	X		79,696, PSUs and RSUs net shares to be received, and ESPP net shares to be purchased	August 31, 2026
Teresa Bair, Chief Legal Officer	Adoption	September 4, 2025	X		218,021, and ESPP net shares to be purchased	December 5, 2026
Mollie Leoni, M.D., Chief Medical Officer	Adoption	September 9, 2025	X		99,531, and RSUs net shares to be received	December 31, 2026
Brian Powl, Chief Commercial Officer	Adoption	September 19, 2025	X		90,116, Options net shares unsold, RSUs net shares to be received, and ESPP net shares to be purchased	December 31, 2026
Faheem Hasnain, Lead Independent Director	Adoption	September 9, 2025	X		20,000	June 9, 2027

* Intended to satisfy the affirmative defense of Rule 10b5-1(c)

** Not intended to satisfy the affirmative defense of Rule 10b5-1(c)

*** Represents the modification, as described in Rule 10b5-1(c)(1)(iv) under the Exchange Act, of a written plan adopted on June 10, 2024 that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

In addition, our officers (as defined in Rule 16a-1(f) under the Exchange Act) have entered into sell-to-cover arrangements adopted pursuant to Rule 10b5-1 authorizing the pre-arranged sale of shares to satisfy our tax withholding obligations arising exclusively from the vesting of shares of restricted stock. The amount of shares to be sold to satisfy our tax withholding obligations under these arrangements is dependent on future events which cannot be known at this time, including the future trading price of our shares. The expiration date relating to these arrangements is dependent on future events which cannot be known at this time, including the final vesting date of the applicable shares of restricted stock and the officer's termination of service.

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.		8-K (Exhibit 3.1)	6/14/2017	001-37620
3.2	Amended and Restated Bylaws of the Registrant.		8-K (Exhibit 3.2)	6/14/2017	001-37620
4.1	Form of Common Stock certificate.		8-K (Exhibit 4.1)	3/12/2015	000-53058
4.2	Warrant to Purchase Stock issued by the Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
4.3	Form of Warrant Agreement issued by the Registrant on November 2, 2022 to certain Lenders.		10-K (Exhibit 4.3)	2/23/2023	001-37620
4.4	Amended and Restated Warrant Agreement, dated November 29, 2022, by and between the Registrant and Hercules Capital, Inc.		10-K (Exhibit 4.4)	2/23/2023	001-37620
4.5	Warrant Agreement, dated November 29, 2022, by and between the Registrant and Hercules Capital IV, L.P.		10-K (Exhibit 4.5)	2/23/2023	001-37620
4.6	Form of Pre-Funded Warrant.		8-K (Exhibit 4.1)	1/26/2024	001-37620
4.7**	Registration Rights Agreement, dated January 26, 2024, by and among the Registrant and the persons party thereto.		8-K (Exhibit 10.2)	1/26/2024	001-37620
10.1	Kura Oncology, Inc. 2023 Inducement Option Plan, as amended, and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder.		8-K (Exhibit 99.1)	10/16/2025	001-37620
10.2	Second Amendment to Loan and Security Agreement, dated as of October 25, 2025, by and among the Registrant, Hercules Capital, Inc. and other banks thereto.	X			
31.1	Certification of Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certifications of Principal Executive and Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.	X			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101.INS).	X			

* The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
** Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

SIGNATURES

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

Kura Oncology, Inc.

Date: November 4, 2025

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