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 June 30, 2018

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.)**
3033 Science Park Road, Suite 220, San Diego, CA	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 500-8800
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address or Former Fiscal Year If Changed Since Last Report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark whether 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	☐ (Do not check if a smaller reporting company)	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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of the close of business on August 3, 2018, the registrant had 37,975,302 shares of Common Stock ($0.0001 par value) outstanding.

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ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2018	December 31, 2017 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 17,658	$ 11,433
Short-term investments	108,227	81,712
Accounts receivable, related party	230	216
Prepaid expenses and other current assets	2,420	1,280
Total current assets	128,535	94,641
Property and equipment, net	1	10
Other long-term assets	1,091	1,200
Total assets	$ 129,627	$ 95,851
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 9,330	$ 8,284
Accounts payable and accrued expenses, related party	437	216
Current portion of long-term debt, net	2,813	1,531
Total current liabilities	12,580	10,031
Long-term debt, net	4,150	5,567
Other long-term liabilities	500	388
Total liabilities	17,230	15,986
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; 33,375 and 30,217 shares issued as of June 30, 2018 and December 31, 2017, respectively; and 33,173 and 29,424 shares outstanding as of June 30, 2018 and December 31, 2017, respectively; excluding 202 and 793 shares subject to repurchase as of June 30, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	231,120	169,201
Accumulated other comprehensive loss	(93)	(49)
Accumulated deficit	(118,633)	(89,290)
Total stockholders' equity	112,397	79,865
Total liabilities and stockholders' equity	$ 129,627	$ 95,851

(1) The balance sheet data at December 31, 2017 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to condensed financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Operating Expenses:				
Research and development	$ 11,099	$ 5,158	$ 22,366	$ 10,378
Research and development, related party	377	494	676	787
General and administrative	3,736	2,217	7,102	4,292
General and administrative, related party	64	61	123	126
Total operating expenses	15,276	7,930	30,267	15,583
Other Income (Expense):				
Management fee income, related party	180	195	375	390
Interest income	624	124	1,074	252
Interest expense	(267)	(209)	(525)	(412)
Total other income	537	110	924	230
Net Loss	$ (14,739)	$ (7,820)	$ (29,343)	$ (15,353)
Net loss per share, basic and diluted	$ (0.45)	$ (0.40)	$ (0.91)	$ (0.78)
Weighted average number of shares used in computing net loss per share, basic and diluted	32,971	19,789	32,403	19,627
Comprehensive Loss:				
Net Loss	$ (14,739)	$ (7,820)	$ (29,343)	$ (15,353)
Other comprehensive loss	(25)	(3)	(44)	(4)
Comprehensive Loss	$ (14,764)	$ (7,823)	$ (29,387)	$ (15,357)

See accompanying notes to condensed financial statements.

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

	Six Months Ended June 30,	
	2018	**2017**
Operating Activities		
Net loss	$ (29,343)	$ (15,353)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	4,415	1,924
Non-cash interest expense	114	32
Depreciation expense	9	16
Amortization of premium and accretion of discounts on marketable securities	(703)	3
Changes in operating assets and liabilities:		
Accounts receivable, related party	(14)	(9)
Prepaid expenses and other current assets	(1,026)	(462)
Other long-term assets	(42)	(117)
Accounts payable and accrued expenses	814	(502)
Accounts payable and accrued expenses, related party	221	(373)
Other long-term liabilities	112	109
Net cash used in operating activities	(25,443)	(14,732)
Investing Activities		
Purchases of marketable securities	(106,850)	(19,360)
Maturities of marketable securities	80,993	36,327
Net cash (used in) provided by investing activities	(25,857)	16,967
Financing Activities		
Proceeds from issuance of common stock, net	57,650	159
Proceeds from exercise of stock options	125	35
Repayment of long-term debt	(250)	—
Net cash provided by financing activities	57,525	194
Net increase in cash and cash equivalents	6,225	2,429
Cash and cash equivalents at beginning of period	11,433	9,725
Cash and cash equivalents at end of period	$ 17,658	$ 12,154

See accompanying notes to condensed financial statements.

1. Organization and Basis of Presentation

The Company

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 that target cancer signaling pathways, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We intend to advance our product candidates through a combination of internal development and strategic partnerships and maintain 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, 2017, as filed with the Securities and Exchange Commission on March 12, 2018, from which we derived our balance sheet as of December 31, 2017. The accompanying 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 condensed financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying 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 condensed financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect the amounts reported on our 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

Comprehensive Loss

Comprehensive loss is defined as the change in equity during the period from transactions and other events and non-owner sources. For the periods presented, accumulated other comprehensive loss consists of unrealized gains and losses on marketable securities and foreign currency translation adjustments.

Net Loss per Share

Net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of unvested restricted stock awards, outstanding stock options and outstanding warrants.

For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the antidilutive effect of the securities. Because of our net loss, unvested restricted stock awards, outstanding stock options and outstanding warrants are excluded from the calculation of diluted net loss per common share for the periods presented, due to the anti-dilutive effect of the securities.

The following table summarizes the number of potentially dilutive securities that were excluded from our calculation of diluted net loss per share, in thousands:

	Three and Six Months Ended	
	2018	2017
Stock options	3,097	2,214
Unvested restricted stock awards	202	1,387
Warrants	34	34
Total	3,333	3,635

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-02, Leases (Topic 842), which requires lessees to recognize a right-to-use asset and a lease obligation for all leases. Additional qualitative and quantitative disclosures, including significant judgments made by management, will be required. ASU 2016-02 is required to be adopted at the earliest period presented using a modified retrospective approach. In July 2018, the FASB issued ASU 2018-11 to provide another transition method for adoption of the new lease standard by recognizing a cumulative-effect adjustment to the opening balance sheet of retained earnings in the period of adoption. We plan to adopt the lease standard using this alternative transition method on January 1, 2019 and will evaluate existing leases and recognize a right-to-use asset and lease obligation for all leases with terms greater than 12 months on our condensed financial statements. We are currently evaluating the effect the new lease standard will have on our condensed financial statements and related disclosures.

3. Investments

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

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

		As of June 30, 2018			
	Maturities (years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	1 or less	$ 11,317	$ —	$ —	$ 11,317
Commercial paper	1 or less	3,997	—	—	3,997
Total cash equivalents		15,314	—	—	15,314
Short-term investments:					
U.S. Treasury securities	2 or less	49,620	1	(85)	49,536
Commercial paper	1 or less	47,281	—	—	47,281
Corporate debt securities	1 or less	11,424	—	(14)	11,410
Total short-term investments		108,325	1	(99)	108,227
Total		$ 123,639	$ 1	$ (99)	$ 123,541

	Maturities (years)	As of December 31, 2017 Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	1 or less	$ 5,848	$ —	$ —	$ 5,848
Commercial paper	1 or less	2,993	—	—	2,993
Total cash equivalents		8,841	—	—	8,841
Short-term investments:					
U.S. Treasury securities	2 or less	22,929	—	(42)	22,887
Commercial paper	1 or less	50,929	—	—	50,929
Corporate debt securities	1 or less	7,903	—	(7)	7,896
Total short-term investments		81,761	—	(49)	81,712
Total		$ 90,602	$ —	$ (49)	$ 90,553

The available-for-sale 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 June 30, 2018, $93.4 million of our short-term investments had maturities less than one year, and $14.8 million had maturities between one to two years. There were no realized gains or losses for the three and six months ended June 30, 2018. As of June 30, 2018, $51.0 million of our marketable securities were in gross unrealized loss positions, all of which had been in such position for less than 12 months. We reviewed our marketable securities as of June 30, 2018 and determined that the unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that all securities have been in an unrealized loss position for less than 12 months. In addition, we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis. As of June 30, 2018, we did not recognize any such impairment in our condensed financial statements.

4. Fair Value Measurements

As a basis for considering assumptions that market participants would use in pricing an asset or liability, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 - Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3 - Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

Available-for-sale marketable securities consist of U.S. Treasury securities, which were measured at fair value using Level 1 inputs, and corporate debt securities and commercial paper, which were 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. No transfers between levels have occurred during the periods presented.

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:

	As of June 30, 2018		
	Balance	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 11,317	$ 11,317	$ —
Commercial paper	3,997	—	3,997
Total cash equivalents	15,314	11,317	3,997
Short-term investments:			
U.S. Treasury securities	49,536	49,536	—
Commercial paper	47,281	—	47,281
Corporate debt securities	11,410	—	11,410
Total short-term investments	108,227	49,536	58,691
Total	$ 123,541	$ 60,853	$ 62,688

	As of December 31, 2017		
	Balance	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 5,848	$ 5,848	$ —
Commercial paper	2,993	—	2,993
Total cash equivalents	8,841	5,848	2,993
Short-term investments:			
U.S. Treasury securities	22,887	22,887	—
Commercial paper	50,929	—	50,929
Corporate debt securities	7,896	—	7,896
Total short-term investments	81,712	22,887	58,825
Total	$ 90,553	$ 28,735	$ 61,818

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. Accounts Payable and Accrued Liabilities

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

	June 30, 2018	December 31, 2017
Accounts payable	$ 1,755	$ 1,248
Accrued research and development expenses	5,242	3,852
Accrued compensation and benefits	1,563	2,345
Other accrued expenses	770	839
Total accounts payable and accrued expenses	$ 9,330	$ 8,284

6. Stockholders' Equity

In January 2018, we sold an aggregate of 3,136,722 shares of our common stock under our at-the-market issuance sales agreement with Cowen and Company, LLC, or ATM facility, at a weighted average price per share of $18.85 for net proceeds of approximately $57.7 million. In March 2018, we amended the ATM facility to increase the maximum aggregate offering price under the ATM facility from up to $100.0 million to up to $160.0 million, which amount included the shares of our common stock previously sold under the ATM facility for gross proceeds of approximately $59.3 million. In July 2018, we terminated the ATM facility.

In July 2018, we completed a public offering in which we sold an aggregate of 4,600,000 shares of common stock at a price of $16.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately $74.5 million.

7. Equity Incentive Plan

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	$ 1,369	$ 678	$ 2,808	$ 1,266
General and administrative	867	352	1,607	658
Total share-based compensation expense	$ 2,236	$ 1,030	$ 4,415	$ 1,924
Restricted stock awards:				
Employee	$ 33	$ 33	$ 66	$ 66
Nonemployee	798	445	1,799	828
Total	$ 831	$ 478	$ 1,865	$ 894
Stock options:				
Employee	$ 1,349	$ 530	$ 2,429	$ 989
Nonemployee	50	22	115	41
Total	$ 1,399	$ 552	$ 2,544	$ 1,030
Employee stock purchase plan:				
Employee	$ 6	$ —	$ 6	$ —
Total	$ 6	$ —	$ 6	$ —

Pursuant to our 2015 Employee Stock Purchase Plan, we commenced the first purchase period in the second quarter of 2018. As of June 30, 2018, unrecognized compensation costs related to employee stock options and restricted stock awards were approximately $15.6 million and $0.1 million, respectively, which are expected to be recognized over a weighted average period of approximately 2.7 years and 0.2 years, respectively.

8. Related Party Transactions

Our president and chief executive officer is also the sole managing member of Araxes Pharma LLC, or Araxes, and is a significant stockholder of each of us and Araxes. The following is a summary of transactions with Araxes for the three and six months ended June 30, 2018 and 2017:

- *Asset Purchase Agreement*

  Under our asset purchase agreement with Araxes, in the three and six months ended June 30, 2017, we paid a milestone payment of $0.2 million to Araxes following dosing of the first patient in the first KO-947 Phase 1 clinical trial in April 2017.

- *Facility Sublease*

  We subleased office space in La Jolla, California from Wellspring Biosciences, Inc., or Wellspring, a wholly owned subsidiary of Araxes pursuant to a sublease agreement that expired in June 2017. In December 2016, we entered into a new sublease agreement with Wellspring for office space in San Diego, California, or New Sublease. The New Sublease will expire on October 31, 2019. For both the three months ended June 30, 2018 and 2017, rent expense, including operating costs, related to our subleases was approximately $0.1 million. For the six months ended June 30, 2018 and 2017, rent expense, including operating costs, related to our subleases was approximately $0.2 million and $0.1 million, respectively.

- *Management Fees*

  Effective April 2018, we amended our management services agreement with Araxes. Under the amendment, Araxes pays us a fixed fee of $60,000 per month for management services, which is reduced from the fixed fee of $65,000 per month. In addition, the agreement allows for Araxes to reimburse us an amount equal to the number of full time equivalents, or FTE, performing research and development services for Araxes, at an annual FTE rate of approximately $367,000, plus actual expenses as reasonably incurred. The initial term of this agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the three months ended June 30, 2018 and 2017, we recorded reimbursements of approximately $0.1 million in each period, and for the six months ended June 30, 2018 and 2017, we recorded reimbursements of approximately $0.1 million and $0.2 million, respectively, for research and development services provided to Araxes, which was recorded as a reduction to research and development expenses on our condensed statements of operations and comprehensive loss. As of June 30, 2018 and December 31, 2017, approximately $0.2 million related to management fees and reimbursements of research and development services are included in accounts receivable, related party on our condensed balance sheets.

- *Services Agreement*

  We have a services agreement with Wellspring pursuant to which we pay Wellspring for research and development services provided to us in an amount equal to the number of FTE's performing the services, at an annual FTE rate of $400,000, plus actual expenses as reasonably incurred. The initial term of this services agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the three months ended June 30, 2018 and 2017, we recognized approximately $0.4 million and $0.3 million, respectively, and for both the six months ended June 30, 2018 and 2017, we recognized $0.7 million from research and development services provided to us under this agreement as research and development expense, related party on our condensed statements of operations and comprehensive loss. As of June 30, 2018 and December 31, 2017, approximately $0.4 million and $0.2 million, respectively, related to research and development services under this agreement are included in accounts payable and accrued expenses, related party on our condensed balance sheets.

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, 2017 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, 2017 filed with the Securities and Exchange Commission, or SEC, on March 12, 2018.

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," "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 the "Company," "we," "us" and "our" refer to Kura Oncology, Inc., a Delaware corporation incorporated in the State of Delaware in August 2014.

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 that target cancer signaling pathways, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We intend to advance our product candidates through a combination of internal development and strategic partnerships and maintain significant development and commercial rights.

Our lead product candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase. Tipifarnib was previously studied in more than 5,000 cancer patients and demonstrated compelling and durable anti-cancer activity in certain patients with a manageable side effect profile. We are currently evaluating tipifarnib in multiple solid tumor and hematologic indications.

Our most advanced solid tumor indication is in patients with head and neck squamous cell carcinomas, or HNSCC, that carry mutations in the HRAS gene. In September 2017, we announced that our Phase 2 clinical trial of tipifarnib in patients with HRAS mutant HNSCC achieved its primary efficacy endpoint prior to the completion of enrollment. The clinical trial protocol required four confirmed, partial responses, per Response Evaluation Criteria in Solid Tumors version 1.1, or RECIST 1.1, criteria, out of 18 patients to meet its primary endpoint. Four confirmed, partial responses were observed among the first six evaluable HNSCC patients enrolled in the clinical trial. Updated data from the Phase 2 clinical trial were presented at the Multidisciplinary Head and Neck Cancers Symposium in February 2018, showing five confirmed partial responses among the first six evaluable HNSCC patients enrolled in the trial. In addition, objective responses greater than 18 months in duration were observed in two patients. All patients joined the study upon progression on prior therapy, including chemotherapy, cetuximab and immune therapy.

Based on the positive results observed to date in our ongoing Phase 2 study, or the RUN-HN trial, and following feedback from the United States Food and Drug Administration, or the FDA, and other regulatory authorities, we are

preparing to initiate our global, registration-directed Phase 2 clinical trial of tipifarnib in patients with HRAS mutant HNSCC by the end of 2018. The trial will include two cohorts: the first, which we have named AIM-HN, is designed to enroll at least 59 patients with recurrent or metastatic HRAS mutant HNSCC. The second cohort, which we have named SEQ-HN, is a non-interventional screening and outcomes study designed to characterize the natural history of patients with recurrent or metastatic HNSCC with HRAS mutations and to facilitate the identification of patients with HRAS mutations for potential enrollment into AIM-HN. We anticipate that the trial will be conducted at approximately 100 clinical sites worldwide and take approximately two years to enroll.

We are continuing to enroll HRAS mutant HNSCC patients in the RUN-HN trial and have expanded the trial to include a cohort of patients with other HRAS mutant squamous cell carcinomas, including patients with cutaneous squamous cell carcinoma. Meanwhile, an investigator-sponsored clinical trial of tipifarnib in patients with HRAS mutant urothelial carcinomas is ongoing, and another investigator-sponsored clinical trial of tipifarnib in patients with HRAS mutant lung squamous cell carcinoma has been initiated and is open for enrollment.

In December 2014, we entered into a license agreement with Janssen Pharmaceutica NV, or Janssen, which was amended in June 2016, which grants us exclusive global rights to develop and commercialize tipifarnib in all indications other than virology and includes the right to grant sublicenses. Under the license agreement, Janssen had a first right to negotiate for an exclusive license back from us to develop and commercialize tipifarnib on terms to be negotiated in good faith, which Janssen could exercise during the 60-day period following completion of a Phase 2 clinical trial of tipifarnib in HRAS mutant patients in oncology and delivery by us to Janssen of a data package from such clinical trial. In June 2018, Janssen declined to exercise this first right to negotiate.

In addition to our tipifarnib development program in solid tumors, we have identified potential biomarkers of activity for tipifarnib in hematologic malignancies, including: peripheral T-cell lymphomas, or PTCL; myelodysplastic syndromes, or MDS; acute myeloid leukemia, or AML; and chronic myelomonocytic leukemia, or CMML. These potential biomarkers include CXCL12 pathway biomarkers and markers of bone marrow homing. We continue to conduct our ongoing Phase 2 clinical trials with the goal of confirming the clinical activity of tipifarnib in these hematologic malignancies, validating our biomarker hypotheses and optimizing dose and schedule for each disease to build a data package supporting advancement to future pivotal studies. In May 2018, we were issued a U.S. patent directed to the use of tipifarnib in patients with CXCL12-expressing PTCL and AML. The patent has an expiration date of November 2037, excluding any possible patent term extension.

Our second product candidate is KO-947, a potent and selective small molecule inhibitor of extracellular signal related kinase which we are advancing as a potential treatment for patients with tumors that have mutations in, or other dysregulation of, the mitogen-activated protein kinase signaling pathway. Our preclinical data suggest that KO-947 has anti-tumor activity in KRAS- or BRAF-mutant adenocarcinomas as well as squamous cell carcinomas characterized by 11q13 amplifications. Our Phase 1 dose-escalation clinical trial of KO-947 in patients with locally advanced unresectable or metastatic, relapsed and/or refractory, non-hematological malignancies is ongoing, with the goal to assess the safety profile of KO-947 and identify a recommended dose and schedule that would permit KO-947 to be evaluated in a Phase 2 study in a patient population selected for potential clinical activity based on potential biomarkers we have identified in our preclinical studies. We anticipate having data from this trial available in 2019.

Our third program is focused on KO-539, a potent and selective small molecule inhibitor of the menin-mixed lineage leukemia, or menin-MLL, protein-protein interaction. Although KO-539 was originally designed as a potential therapy for MLL-rearranged leukemias, we have generated preclinical data that support the potential anti-tumor activity of KO-539 in additional, genetically-defined subsets of acute leukemia, including those with oncogenic driver mutations in NPM1 and DNMT3A. We estimate that, together with the mixed lineage leukemias, these mutations represent approximately half of diagnosed cases of AML.

ATM Facility

In January 2018, we sold an aggregate of 3,136,722 shares of our common stock under our at-the-market issuance sales agreement with Cowen and Company, LLC, or ATM facility, at a weighted average price per share of $18.85 for net proceeds of approximately $57.7 million. In March 2018, we amended the ATM facility to increase the maximum aggregate offering price under the ATM facility from up to $100.0 million to up to $160.0 million, which amount includes the shares of our common stock previously sold under the ATM facility for gross proceeds of approximately $59.3 million. In July 2018, we terminated the ATM facility.

Public Offering

In July 2018, we completed a public offering in which we sold an aggregate of 4,600,000 shares of common stock at a price of $16.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately $74.5 million.

Liquidity Overview

As of June 30, 2018, we had cash, cash equivalents and short-term investments of $125.9 million. In July 2018, we completed a public offering for net proceeds of approximately $74.5 million. We expect our existing cash, cash equivalents and short-term investments will be sufficient to fund our current operations through 2021. However, we may need to raise additional funds sooner than expected to pursue other development activities related to our pipeline programs. We may seek to obtain additional financing in the future through equity or debt financings, or through collaborations, strategic partnerships or licensing arrangements with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan.

Our accumulated deficit was $118.6 million as of June 30, 2018. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

Financial Operations Overview

Research and Development Expenses

We focus on the research and development of our product 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, contract services and research supply, equipment and facility costs. 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 June 30, 2018, we have no in-licensed technologies that have 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 and investor and public relations, corporate activities and allocated facilities.

Other Income (Expense)

Other income (expense) consists primarily of management fee income, interest income and interest expense. Management fee income is earned in accordance with the management services agreement, as amended, with Araxes. Interest expense mainly consists of interest on long-term debt.

Income Taxes

We have incurred net losses and have not recorded any U.S. federal or state income tax benefits for the losses as they have been offset by valuation allowances.

Results of Operations

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Research and development expenses	$ 11,476	$ 5,652	$ 5,824	$ 23,042	$ 11,165	$ 11,877
General and administrative expenses	3,800	$ 2,278	1,522	7,225	4,418	2,807
Other income, net	537	110	427	924	230	694

Comparison of the Three Months Ended June 30, 2018 and 2017

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 June 30,		
	2018	2017	Change
External research and development expenses:			
Tipifarnib	$ 6,705	$ 2,095	$ 4,610
KO-947	713	1,042	(329)
Discovery and preclinical stage programs, collectively	1,040	605	435
Internal research and development expenses	3,018	1,910	1,108
Total research and development expenses	$ 11,476	$ 5,652	$ 5,824

The increase in external research and development expense for tipifarnib for the three months ended June 30, 2018 compared to the same period in 2017 was primarily due to increases of $3.5 million in clinical development expenses related to our ongoing Phase 2 clinical trials and companion diagnostics activities, and $1.0 million in manufacturing activities. Internal research and development expenses include personnel costs, non-cash share-based compensation expense, facilities and overhead expenses. The increase in internal research and development expenses was primarily due to increases of $0.7 million in non-cash share-based compensation and $0.6 million in personnel costs. We expect our research and development expenses to increase in future periods as we continue clinical development activities for our tipifarnib and KO-947 product candidates and further research and development of our other programs.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended June 30, 2018 compared to the same period in 2017 was primarily due to increases of $0.5 million in share-based compensation expense, $0.4 million in professional fees and $0.3 million in patent related costs. We expect our general and administrative expenses to increase in future periods to support our planned increase in research and development activities.

Other income, net. The increase in other income, net, for the three months ended June 30, 2018 compared to the same period in 2017 was primarily due to an increase of $0.5 million in interest income.

Comparison of the Six Months Ended June 30, 2018 and 2017

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

	Six Months Ended June 30,		
	2018	**2017**	**Change**
External research and development expenses:			
Tipifarnib	$ 13,757	$ 4,439	$ 9,318
KO-947	1,343	1,760	(417)
Discovery and preclinical stage programs, collectively	1,843	1,305	538
Internal research and development expenses	6,099	3,661	2,438
Total research and development expenses	$ 23,042	$ 11,165	$ 11,877

The increase in external research and development expense for tipifarnib for the six months ended June 30, 2018 compared to the same period in 2017 was primarily due to increases of $7.4 million in clinical development expenses related to our ongoing Phase 2 clinical trials and companion diagnostics activities, and $1.9 million in manufacturing activities. Internal research and development expenses include personnel costs, non-cash share-based compensation expense, facilities and overhead expenses. The increase in internal research and development expenses was primarily due to increases of $1.5 million in non-cash share-based compensation, $1.2 million in personnel costs.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2018 compared to the same period in 2017 was primarily due to increases of $0.9 million in share-based compensation expense, $0.6 million in patent related costs, $0.5 million in professional fees and compliance expenses and $0.4 million in personnel costs.

Other income, net. The increase in other income, net, for the six months ended June 30, 2018 compared to the same period in 2017 was primarily due to an increase of $0.8 million in interest income.

Liquidity and Capital Resources

As of June 30, 2018, we had cash, cash equivalents and short-term investments of $125.9 million. Since our inception, we have funded our operations primarily through equity and debt financings. We have devoted our resources to funding our research and development programs, including discovery research, preclinical and clinical development activities.

In July 2018, we completed a public offering in which we sold an aggregate of 4,600,000 shares of common stock at a price of $16.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately $74.5 million.

In January 2018, we sold an aggregate of 3,136,722 shares of our common stock under the ATM facility at a weighted average price per share of $18.85 for net proceeds of approximately $57.7 million. In March 2018, we amended the ATM

facility to increase the maximum aggregate offering price under the ATM facility from up to $100.0 million to up to $160.0 million, which amount includes the shares of our common stock previously sold under the ATM facility for gross proceeds of approximately $59.3 million. In July 2018, we terminated the ATM facility.

In April 2016, we entered into a loan and security agreement, as amended in May 2017, or the loan agreement, with Oxford Finance LLC and Silicon Valley Bank, or collectively referred to as the lenders. Under the loan agreement, we have borrowed $7.5 million, or Term Loan. The Term Loan matures on November 1, 2020, or Maturity Date. Repayment on the Term Loan was interest only through May 1, 2018, followed by 30 equal monthly payments of principal plus accrued interest commencing on June 1, 2018. The per annum interest rate for the Term Loan is the greater of (i) 7.75% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.25%. In addition, a final payment of 7.50% of the amounts of the term loan will be due on the earlier of the Maturity Date, acceleration or prepayment of the Term Loan. If we elect to prepay the Term Loan, a prepayment fee equal to 1% of the principal balance also will be due.

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. Our intellectual property is subject to 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 expect our existing cash, cash equivalents and short-term investments will be sufficient to fund our current operations through 2021. However, we may need to raise additional funds sooner than expected to pursue other development activities related to our pipeline programs. We may seek to obtain additional financing in the future through equity or debt financings or through collaborations, strategic partnerships or licensing arrangements with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan.

As of June 30, 2018, we had an accumulated deficit of $118.6 million. We have incurred operating losses since inception and negative cash flows from operating activities. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year. 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 revenue from product sales. We do not expect to generate significant revenue 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 anticipate that we will 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. We do not have any committed external source of funds. 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, we may have to relinquish valuable rights to our product candidates, including our 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:

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$ (25,443)	$ (14,732)
Net cash (used in) provided by investing activities	(25,857)	16,967
Net cash provided by financing activities	57,525	194

Operating Activities – The increase of $10.7 million in net cash used in operating activities for the six months ended June 30, 2018 as compared to the same period in 2017 was primarily due to a higher net loss of $14.0 million, offset by a $1.9 million decrease in payments of accounts payable and accrued expenses and a $2.5 million increase in non-cash share-based compensation.

Investing Activities – The decrease of $42.8 million in net cash provided by investing activities for the six months ended June 30, 2018 as compared to the same period in 2017 was due to an $87.5 million increase in purchases of marketable securities, offset by a $44.7 million increase in proceeds from maturities of marketable securities.

Financing Activities – Net cash provided by financing activities for the six months ended June 30, 2018 consisted primarily of an aggregate of approximately $57.7 million in net proceeds from the sale of common stock under the ATM facility.

Off-Balance Sheet Arrangements

As of June 30, 2018, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates of the Company

Our discussion and analysis of our financial condition and results of operations are based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ from these estimates. 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, 2017.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Pursuant to Item 305(c) of Regulation S-K, we are not required to provide disclosures under this item until after December 31, 2018.

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 Chief Executive Officer and Chief Financial Officer (who will be joining us on August 21, 2018), 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 Chief Executive Officer (who is currently both our principal executive officer and principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive 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 report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during our most recent quarter ended June 30, 2018 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

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, 2017, filed with the SEC on March 12, 2018.

Risks Related to Our Financial Position and Need For Additional Capital

We expect to incur losses over the next several years and may never achieve or maintain profitability.

We expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through equity and debt financings. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. 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 companion diagnostics for our product candidates;
- establish 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 from comparable foreign authorities for these product candidates and manufacturing, marketing and selling those 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 the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause 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.*

We are a clinical-stage company that has incurred losses since our inception and expect to continue to incur substantial losses in the foreseeable future. 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 timing of clinical trials;
- our ability to secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;
- our and our 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 product candidates that may compete with our 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 contract research organizations, or CROs, to adhere to clinical study and other regulatory requirements;
- the ability of third-party manufacturers to manufacture our product candidates and key ingredients needed to conduct clinical trials and, if approved, successfully commercialize our 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
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

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.

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 development 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 studies for our product candidates and undertaking clinical studies of tipifarnib and KO-947. We have not yet demonstrated our ability to successfully complete any clinical trials, including those clinical trials in support of FDA approval, develop companion diagnostics, obtain marketing approvals, manufacture a commercial scale product, 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 are available for treating patients. 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. We may in the future need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need to obtain substantial additional capital in connection with our continuing operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we will need to raise additional capital in connection with our continuing operations. We expect to finance our cash needs through a combination of equity offerings and debt financings.

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.

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 and transactions with affiliates, 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 declare a default under our term loan facility upon the occurrence of an event of default, which includes 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.

Risks Related to the Discovery and Development of Our Product Candidates

We are highly dependent on the success of our lead product candidate, tipifarnib, which is still in clinical development, and we cannot give any assurance that tipifarnib or any other product candidates, will receive regulatory approval, which is necessary before they can be commercialized.*

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize our lead product candidate, tipifarnib. Our other product candidates are in earlier stages of development. 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 may never be able to develop a marketable product.

Tipifarnib 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. The FDA has also informed us that an approved companion diagnostic is required in order to obtain approval of tipifarnib in HRAS mutant HNSCC. Companion diagnostics are subject to regulation as medical devices and must be separately approved for marketing by the FDA. We are not permitted to market or promote tipifarnib, or any other 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 risks and we cannot predict success in these jurisdictions.

We plan to initiate our AIM-HN trial in patients with HRAS mutant HNSCC by the end of 2018. There is no guarantee that this trial will commence or be completed on time or at all. Prior to receiving approval to commercialize tipifarnib or future product candidates, if any, in the United States or internationally, we must demonstrate to the satisfaction of the FDA and other regulatory authorities, that such product candidates are safe and effective for their intended uses. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of a drug candidate may not be replicated in subsequent clinical trials. There is no guarantee that the high level of clinical activity observed in our ongoing Phase 2 RUN-HN clinical trial will be replicated in our planned AIM-HN clinical trial. 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 dialog with the FDA and other regulatory bodies regarding our clinical trial design, including the patient selection criteria, dosing plan and statistical analysis plan. There is a risk that the FDA or other regulatory agencies could at any time raise objections. Any such objections could delay the initiation or completion of our planned AIM-HN clinical trial. Although we believe from our discussions with the FDA and the minutes from our recent End of Phase 2 meeting with the FDA, that if our AIM-HN clinical trial is positive, there is the potential for accelerated approval of tipifarnib for the treatment of patients with relapsed or refractory HNSCC who harbor the HRAS mutation, the FDA has substantial discretion in the approval process and may not grant approval based on data from the AIM-HN and RUN-HN trials. Even if the trial results are positive, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do. If the results of the trial 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 tipifarnib.

We have not previously submitted a New Drug Application, or NDA, to the FDA, or similar product approval filings to comparable foreign authorities, or received marketing approval for any product candidate, and we cannot be certain that tipifarnib will be successful in clinical trials or receive regulatory approval for any indication. We cannot anticipate whether or when we will seek regulatory review of tipifarnib for any other indications. If we do not receive regulatory approvals for and successfully commercialize tipifarnib 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 tipifarnib, our revenues will be dependent, in part, on our collaborator's ability to commercialize the companion diagnostic as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for the treatment of HNSCC are not as significant as we estimate, our business and prospects will be harmed.

Our discovery, preclinical and clinical development is 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 is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. 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 enough patients to identify if 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 tipifarnib, we have designed our Phase 2 clinical trials of tipifarnib, and expect to design future clinical trials of tipifarnib and our other product candidates, to include patients whose tumors harbor the applicable molecular and/or genetic alterations 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 to show early and statistically significant evidence of clinical efficacy. 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 whose tumors harbor the applicable genetic alterations 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, 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.

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

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies 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 of tipifarnib, the eligibility criteria of our clinical trials will further limit the pool of available study 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 study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study including the number and frequency of study required procedures and tests, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

Enrollment in our ongoing Phase 2 clinical trial of tipifarnib in patients with HRAS mutant HNSCC has proceeded more slowly than anticipated. We believe this may be primarily due to two factors. First, with the approvals in the United States of the immune therapy agents nivolumab and pembrolizumab, many HNSCC patients are now being treated with one of these agents after failure of first line treatments such as chemotherapy and/or cetuximab. Nivolumab has also received marketing approval in certain countries in the European Union. Second, many physicians who treat HNSCC patients do not routinely screen their patients for genetic mutations, such as HRAS, which we believe is because, to date, targeted therapies have not been available to treat HNSCC patients. To seek to address these issues, we expanded the number of clinical sites in Europe and in the United States and have contracted with third-party laboratories to facilitate the genetic screening of patients for our clinical sites. We are planning to adopt similar measures for our AIM-HN clinical trial of tipifarnib in HRAS mutant HNSCC. While the enrollment rate in our RUN-HN trial has increased, there is no guarantee that these efforts will be effective in further accelerating enrollment in our ongoing Phase 2 clinical trial of tipifarnib in patients with HRAS mutant HNSCC or in our planned AIM-HN clinical trial.

Additionally, in estimating the frequency of biomarkers, such as the frequency of HRAS mutations in patients with HNSCC, we rely on data published in the scientific literature as well as our experience and that of our collaborators. Initial studies on the frequency of HRAS mutation in HNSCC were conducted in a mostly human papillomavirus, or HPV, negative population that does not reflect the increase in HPV-related HNSCC in the United States. 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. Moreover, sample quality in academic studies of molecular biomarkers may not reflect standard clinical practice that is focused on pathological diagnosis. If the frequency of HRAS mutations detected in our ongoing clinical trials for tipifarnib is significantly different, it may take us longer to screen patients to identify those patients with HRAS mutations who may be candidates for our clinical trials. Even if patients carrying HRAS mutations are identified, interest to participate in clinical trials is low in HNSCC and potential study subjects may be located far away from potential clinical trial sites. Any delay or failure by us or third-party collaborators to screen patients or identify patients with HRAS mutations for enrollment in our ongoing trials could delay or prevent us from completing our clinical trials which could prevent us from obtaining regulatory approval or commercializing tipifarnib 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 in identifying 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.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. 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 complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical 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. For example, the preliminary data we have presented from our positive Phase 2 clinical trial of tipifarnib in HRAS mutant HNSCC, may not predict the results of our planned AIM-HN clinical trial or any other later-stage clinical trials we may conduct. The primary endpoint of our planned AIM-HN clinical trial will be objective response rate as determined using RECIST 1.1 criteria and as determined by independent radiological review. Independent radiological review refers to a formal process whereby third-party radiologists who are not affiliated with the drug development program are engaged to provide an independent assessment of the primary radiological images. All of our patient responses disclosed to date in our ongoing Phase 2 clinical trial in HRAS mutant HNSCC have been assessed by the trial investigators. In contrast to independent radiology review, investigator assessed response is performed by investigators or their affiliated radiology colleagues who may be aware of the study treatment, patient history or other information that could impact their choices in applying the rules and conventions of RECIST 1.1. Conversely, independent radiology reviewers have limited access to non-radiographic clinical information or other ancillary information, which could have informed their application of RECIST 1.1 response rules. The published literature demonstrates a consistent decrease in response rate when investigator assessed response rates are verified by independent radiology review. Furthermore, HNSCC lesions are difficult to assess due to the complexity of the anatomic locations. For our AIM-HN clinical trial we will be identifying trial subjects with measurable disease that meets criteria for RECIST 1.1 target lesions by independent radiology review. This may further reduce the number of subjects eligible to join the AIM-HN trial within the small pool of HRAS mutant HNSCC patients.

Potential molecular biomarkers we have identified in retrospective analyses of data from clinical trials of tipifarnib in certain hematological cancer indications may not be validated as biomarkers of tipifarnib activity in our ongoing Phase 2 clinical trials or future clinical trials we may conduct in these indications. 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. For instance, the FDA previously issued a non-approval letter to Janssen Pharmaceutica NV, or Janssen, for tipifarnib as a treatment for elderly, untreated AML in June 2005. It is impossible to predict when or if 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 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 or comparable foreign regulatory authorities, or IRBs have comments on our study plans for our clinical trials of tipifarnib or any of our other product candidates, that we are required to address, such studies 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. 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 studies 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.

Preclinical and clinical testing of tipifarnib that has been conducted to date may not have been performed in compliance with applicable regulatory standards, which could lead to increased costs or material delays for their further development.

We licensed the rights to develop our lead product candidate, tipifarnib, from Janssen in December 2014, and the development of tipifarnib prior to our license was conducted wholly by Janssen or any third parties with which it had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. Because we had no input on Janssen's development activities relating to tipifarnib, we may discover that all or certain elements of the clinical trials and studies or tipifarnib manufacturing activities it performed have not been in compliance with applicable regulatory standards or have otherwise been deficient, particularly relative to current requirements as development of tipifarnib began in the 1990s. Any such deficiency in the prior development of tipifarnib may adversely affect our ability to obtain regulatory approval for tipifarnib.

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.

Tipifarnib has been studied in more than 5,000 oncology patients and was generally well tolerated and exhibited a manageable side effect profile. The most common hematologic adverse events of any grade were neutropenia (low white blood cell count), anemia and thrombocytopenia (low platelet count). The most common non-hematologic adverse events of any grade were gastrointestinal system disorders (nausea, anorexia, diarrhea and vomiting), fatigue and rash. Treatment discontinuation across the prior tipifarnib clinical studies has been in the range of approximately 20-25%. We are exploring a range of doses and dosing schedules in our ongoing Phase 2 clinical trials. The side effects observed so far in our ongoing Phase 2 clinical trials of tipifarnib have been generally consistent with the prior observations; however, there is no guarantee that additional or more severe side effects will not be identified through further clinical studies, including our planned AIM-HN clinical trial. Rights to develop tipifarnib in virology indications have been granted by Janssen to EB Pharma LLC, or EB Pharma, a subsidiary of Eiger BioPharmaceuticals. Undesirable side effects may be identified in clinical trials that EB Pharma may conduct in virology indications, which may negatively impact the development, commercialization or potential value of tipifarnib.

We are currently evaluating KO-947 in a Phase 1 clinical trial in patients with non-hematological malignancies. 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 clinical trials for tipifarnib, KO-947 or other product

candidates 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 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.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results.

As one of the central elements of our business strategy and clinical development approach, we seek to screen and identify subsets of patients with molecular or genetic alterations who may derive meaningful benefit from our product candidates. To achieve this, certain of our programs will require the development and commercialization of a companion diagnostic. We rely on third-party collaborators for development of companion diagnostics for use in clinical trials and, if successful, will rely on third-party collaborators for development of companion diagnostics for commercialization of our product candidates. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. For example, for tipifarnib for the treatment of HRAS mutant HNSCC, we and our third-party collaborators are working to develop and validate a qualitative polymerase chain reaction-based assay, to identify patients with HRAS mutant tumors, and to prepare and submit an investigational device exemption, or IDE, for use of the companion diagnostic in our planned AIM-HN clinical trial in this indication. In our ongoing Phase 2 clinical trial of tipifarnib in HRAS mutation HNSCC, patients are currently being enrolled based on information from the clinical sites on the patients' tumor HRAS mutation status. Typically, this information is being obtained by the clinical sites from next-generation sequencing, or NGS, panels used by the site to characterize patients' tumors. The results of NGS panels being currently used at our clinical sites may not be accurate or consistent across sites, and our development of tipifarnib or a companion diagnostic may be delayed or complicated by a change in assay methodology.

If the results of our other Phase 2 clinical trials of tipifarnib or our Phase 1 clinical trial of KO-947 are positive and we validate our biomarker hypotheses in those clinical trials, we plan to partner development and validation of companion diagnostic tests to aid in the selection of patients in any subsequent clinical trials we decide to pursue for those product candidates and to prepare and submit an IDE for use of the companion diagnostic in the clinical trials, when necessary. Any delay or failure by us or our third-party collaborators to develop or obtain IDE approval for use of companion diagnostics in our clinical trials could delay or prevent us from commencing or completing our clinical trials. 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. To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. The FDA has informed us that an approved companion diagnostic is required in order to obtain approval of tipifarnib in HRAS mutant HNSCC. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. The approval of a companion diagnostic as part of the product label will limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect. 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.

Failure by us or our third-party collaborators to successfully commercialize companion diagnostics developed for use with our product candidates could harm our ability to commercialize these product candidates.

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 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;
- may not commit sufficient resources to the marketing and distribution of such product or products; 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.

Risks Related to Our Dependence on Third Parties

We rely on third-party contractors and organizations to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials.

We rely, and expect to continue to rely, on third-party contractors, clinical data management organizations, independent contractors, medical institutions and clinical investigators to support our preclinical development activities and conduct our clinical trials, including our ongoing Phase 2 clinical trials of tipifarnib, our Phase 1 clinical trial of KO-947, our planned AIM-HN clinical trial of tipifarnib in HRAS mutant HNSCC and any other subsequent clinical trials of tipifarnib. These agreements may terminate for a variety of reasons, including a failure to perform by the third parties. If we are required to enter into alternative arrangements, our product development activities could be delayed.

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. The third parties on whom we rely may terminate their engagements with us at any time, which 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 research on our product candidates by such third parties.

Our reliance on these 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 practices 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 a government-sponsored database, 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.

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

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 do not have any manufacturing personnel. 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 tipifarnib and our other product candidates for preclinical and clinical testing. We will 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 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 ingredient, 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. We have recently developed a modified drug product manufacturing process and a modified tablet formulation of tipifarnib which we plan to use in our AIM-HN clinical trial. Even though our Phase 1 relative bioavailability study indicated pharmacokinetic comparability between the original and the modified tablets, we cannot be certain that in our AIM-HN or other clinical trials we will not observe differences between the tablets which could impact clinical outcomes.

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 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.

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 will 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 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.

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, we will not be able to commercialize 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 and by the European Medicines Agency, or EMA, and 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. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. 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, clinical 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.

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.

We may not be able to benefit from available regulatory exclusivity periods if another company obtains regulatory approval for tipifarnib before we do.

As the composition of matter patents covering tipifarnib expired in the United States and in countries in Europe in 2016 and we have only one issued U.S. patent directed to one of our potential tipifarnib indications, our commercial strategy for tipifarnib relies on obtaining other patents related to tipifarnib and on non-patent regulatory exclusivity. In the United States, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon FDA approval of an NDA for a new chemical entity, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that the FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. EB Pharma has licensed rights from Janssen to develop tipifarnib in virology indications. If EB Pharma obtains regulatory approval for tipifarnib in a virology indication before we obtain regulatory approval in one of our oncology or other non-virology indications, the five-year exclusivity period would commence on the date upon which EB Pharma obtains regulatory approval, and as a result, the period of regulatory exclusivity to which we may be entitled may be reduced or eliminated and the commercial prospects for tipifarnib could be harmed as a result.

Additionally, if EB Pharma obtains approval of tipifarnib for a virology indication, EB Pharma may sell tipifarnib at a lower price, which could adversely affect the price at which we could sell tipifarnib for oncology or other non-virology indications.

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.

We intend to pursue an orphan designation for at least some of our product candidates, including tipifarnib. However, obtaining an orphan designation can be difficult, and we may not be successful in doing so for tipifarnib or any of our product candidates. The EMA does not generally recognize for orphan designation, molecular defined subsets of non-orphan disease indications, and as an example, EMA recently rejected orphan designation for a drug product for ALK-positive NSCLC. As such, we do not expect to be able to obtain orphan drug designation in Europe for tipifarnib in the subset of HRAS mutant HNSCC at the current time. Even if we were to obtain orphan exclusivity for a product candidate, that exclusivity may not effectively protect the product 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 the later drug is shown to be safer, 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 tipifarnib 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 tipifarnib 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 tipifarnib for the orphan indication.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, 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 do not currently have Fast Track Designation for any of our product candidates but intend to seek Fast Track Designation if our clinical data supports such a designation. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for Fast Track Designation. The FDA has broad discretion whether to grant this designation. Even if we believe a specific product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain drug approval.

A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, 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 do not currently have Breakthrough Therapy Designation for any of our product candidates, but we intend to seek such designation if our clinical data supports such a designation. 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. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for 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. However, the reduced timelines may introduce significant chemistry, manufacturing and controls challenges for product development. 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.

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;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; 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 information can also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors and our general business operations will be subject to applicable anti-kickback, fraud and abuse, privacy and other healthcare laws and regulations, which could expose us to criminal sanctions, 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 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 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 and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, 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 federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, 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, and their implementing regulations, also imposes 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;
- the federal Physician Payments Sunshine Act 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 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;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, thus complicating compliance efforts, including the European Union General Data Protection Regulation, or GDPR, which went into effect on May 25, 2018, and imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

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 or marketing expenditures.

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, individual 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, disgorgement, 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 criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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, 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.

Among the provisions of the ACA of importance to our potential product candidates and our business are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. On December 22, 2017, President Trump signed into law new federal tax legislation which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump

signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for 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. For example, 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, 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Moreover, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Future legislation could potentially change drug pricing dynamics.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The Right to Try Act, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

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. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

Foreign legislative changes may also affect our ability to commercialize our product candidates. Effective as of May 25, 2018, the GDPR imposes privacy and security obligations on any entity that collects and/or processes personal information from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance.

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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our 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 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 chemotherapy 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. In addition, physicians, patients and third-party payors may prefer other novel products to ours, such as the recently approved immune-oncology therapies, in which there is increasing awareness and interest. 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 prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

We currently have no marketing and sales force. If we are unable to establish effective sales or marketing capabilities or 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 currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Capable managers with commercial experience may need to be identified and successfully recruited to our company. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. 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. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. 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 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 tipifarnib, KO-947, KO-539 and any other future product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA 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. 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. Generic products are currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic 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 other 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 is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for new or current products 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 our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about 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 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 the 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.

If insurance 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 an 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.

Our current product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we 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 Our Intellectual Property

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

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, confidentiality agreements, and license agreements to protect the intellectual property related to our current product candidates and development programs. If the 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 is threatened, it could threaten our ability to commercialize any of our current or future product candidates or products. Further, if we encounter delays in our development efforts, the period 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.

Our patent rights may not protect our patent protected products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights. For example, 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 the United States and countries in Europe 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. In July 2017, the U.S. Patent and Trademark Office, or U.S. PTO, issued us a patent directed to the use of tipifarnib in certain patients with HRAS mutant HNSCC and in May 2018 the U.S. PTO issued us a patent directed to the use of tipifarnib in patients with CXCL12-expressing PTCL or AML. Although these patents are currently in force, there is no guarantee that a court would agree that either of the patents are valid or enforceable. Further, if a competitor were to develop tipifarnib for use in an indication other than that claimed by the patents, we would not be able to prevent them from marketing tipifarnib in the United States or other jurisdictions based on the patent. We are pursuing additional U.S. and foreign method of use patents for tipifarnib, however there is no guarantee that any such patents will be granted. In April 2017, the U.S. PTO issued us a patent covering the composition of matter of KO-947 and certain structurally related compounds, and methods of using the compounds for the treatment of cancers. We are pursuing additional U.S. and foreign patents for KO-947, however there is no guarantee that any such patents will be granted. Patent term extension may be available in the United States to account for regulatory delays in obtaining human marketing approval for a product candidate; however, only one patent may be extended per marketed compound. Under our license agreement with Janssen, we and Janssen agree to cooperate in obtaining available patent term extensions. We and Janssen may not reach agreement and no patent term extension may be obtained. Additionally, the applicable authorities, including the U.S. PTO and the FDA, and any equivalent regulatory authority in other countries, may not agree 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, our competitors who obtain the requisite regulatory approval can offer products with the same API as tipifarnib so long as the competitors do not infringe any method of use 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 tipifarnib from Janssen and compounds in our menin-MLL program from the University of Michigan. 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.

With respect to the patent portfolio for tipifarnib, which is in-licensed from Janssen, Janssen maintains rights to prosecute and maintain patents and patent applications within the portfolio as well as to assert such patents against infringers within and outside the scope of our license, and to defend such patents against claims of invalidity and unenforceability. Although we have rights to consult with Janssen on actions taken as well as back-up rights of prosecution and enforcement, rights to tipifarnib granted to another licensee, such as EB Pharma, could potentially influence Janssen's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us.

If we breach any of the agreements under which we license from third parties the 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 from Janssen the use, development and commercialization rights in all indications other than virology, for our lead product candidate, tipifarnib. We have also in-licensed rights to potential product candidates in other programs in our pipeline. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of the Janssen agreement and the rights we license under it and our other in-license agreements. The Janssen license agreement provides that we are subject to diligence obligations relating to the commercialization and development of tipifarnib, 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 Janssen, or any of our other license agreements or license agreements we may enter into on which our business or product candidates are dependent, 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, including, with respect to our license agreement with Janssen, tipifarnib. The loss of the rights licensed to us under our license agreement with 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.

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. For example, India and China do not allow 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.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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 the 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.

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 will be 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 firm and rely on our outside counsel to pay these fees due to non-U.S. 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. 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 interference or derivation 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.

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

Presently we have rights to intellectual property under 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 tipifarnib, as well as an exclusive worldwide license for all therapeutic indications for certain compounds in our other programs, including in our menin-MLL program. 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 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 protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we 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, 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 them, or those to whom they communicate it, 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.

Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

We currently have a limited number of employees, are highly dependent on our Chief Executive Officer and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.*

We are a clinical development company with a limited operating history, and, as of June 30, 2018, we had only 34 full-time employees and two part-time employees. We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our

President and Chief Executive Officer, Antonio Gualberto, M.D., Ph.D., our Head of Development and Chief Medical Officer, and Pingda Ren, Ph.D., our Senior Vice President, Chemistry and Pharmaceutical Sciences, 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. Additionally, Dr. Wilson currently also serves as President and Chief Executive Officer of Avidity Biosciences, LLC. As a result, Dr. Wilson is not able to devote all of his business time and attention to our business. Conflicts may arise in the future if there are competing demands on Dr. Wilson's time and attention and our business may be harmed as a result.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing 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 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 and preclinical 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 expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and commercial, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or 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 manage growth could delay the execution of our business plans or disrupt our operations.

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. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, 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. This is particularly true in Europe, which is undergoing a continued severe economic crisis. 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.

The United Kingdom's referendum to leave the European Union or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our financial condition.

Our business could be negatively impacted by cyber security threats.*

In the ordinary course of our business, we use our data centers and our networks to store and access our proprietary business information. We face various cyber security threats, including cyber security attacks to our information technology infrastructure and attempts by others to gain access to our proprietary or sensitive information. The procedures and controls we use to monitor these threats and mitigate our exposure may not be sufficient to prevent cyber security incidents. The result of these incidents could include disrupted operations, lost opportunities, misstated financial data, liability for stolen assets or information, increased costs arising from the implementation of additional security protective measures, litigation and reputational damage. Any remedial costs or other liabilities related to cyber security incidents may not be fully insured or indemnified by other means.

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. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it 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.

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, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. 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.

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 until June 30, 2018, were $24.03 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 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;
- 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 potential 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. 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 statement could adversely affect the market price of our common stock in the public market, should one develop, 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 filed a shelf registration statement with the SEC, which has been declared effective, to register the resale of 13,947,599 shares of our common stock, which represents a substantial portion of the shares of our common stock issued in connection with our reverse merger transaction. The shelf registration statement permits the resale of these shares at any time, subject to restrictions under applicable law. The resale of a substantial 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 statement, the selling stockholders named in such registration statement will continue to offer shares covered by the shelf registration statement 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 statement 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, 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 will require 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.

We are an emerging growth company, which will allow us to take advantage of certain reduced disclosure obligations as a public reporting company that may make our common stock less attractive to investors.

We are an "emerging growth company" under the Jumpstart Our Business Startups Act. As an emerging growth company we are eligible to take advantage of certain extended accounting standards and exemptions from various reporting requirements that are not available to other public reporting companies that are not emerging growth companies. For instance, we are exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and financial statements, commonly known as an "auditor discussion and analysis"; we are not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders; we are not required to comply with the requirement of auditor attestation of management's assessment of internal control over financial reporting, which is required for some other public reporting companies by Section 404 of the Sarbanes-Oxley Act; we are eligible for reduced disclosure obligations regarding executive compensation in our periodic and annual reports; and we are eligible for reduced financial statement disclosure in any registration statements under the Securities Act or reports under the Exchange Act that we may file. For as long as we continue to be an emerging growth company, which we anticipate will be for the foreseeable future, we expect that we will take advantage of the reduced disclosure obligations available to us as an emerging growth company. As a result, our publicly available disclosure may not be as robust or comprehensive as that of other public reporting companies that are not emerging growth companies.

Further, as an emerging growth company, we can elect to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to take advantage of this extended transition period and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, outstanding stock options, 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 January 2018, we sold an aggregate of 3,136,722 shares of our common stock under the ATM facility at a weighted average price per share of $18.85 for net proceeds of approximately $57.7 million. In March 2018, we amended the ATM facility to increase the maximum aggregate offering price under the ATM facility from up to $100.0 million to up to $160.0 million, which amount includes the shares of our common stock previously sold under the ATM facility for gross proceeds of approximately $59.3 million. In July 2018, we terminated the ATM facility. Also in July 2018, we completed a public offering in which we sold an aggregate of 4,600,000 shares of common stock at a price of $16.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately $74.5 million.

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 June 30, 2018, we had 841,776 shares of common stock reserved for future issuance under our 2014 Plan and options to purchase up to an aggregate of 3,097,372 shares of common stock outstanding. The number of shares available for future grant under our 2014 Plan will

automatically increase on January 1 of each year through January 1, 2025 by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2018, an automatic increase pursuant to the 2014 Plan occurred, resulting in 1,208,683 additional shares available for future grant under the 2014 Plan. 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 June 30, 2018, we had 238,705 shares of common stock reserved for future issuance under our ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year through January 1, 2025 by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2017, the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in January 2018.

In addition, warrants to purchase up to 33,988 shares of our common stock at an exercise price of $3.31 per share are outstanding as of June 30, 2018.

Any future grants of options, 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 a majority 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 66⅔% 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; and
- 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.

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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain, and our business and financial condition could be adversely affected. In addition, it is unknown if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is likewise uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. 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 (by value) in its equity ownership 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.

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.

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
2.1	Agreement and Plan of Merger, dated March 6, 2015, by and among the Registrant, Kura Operations, Inc. and Kura Oncology, Inc.		8-K (Exhibit 2.1)	3/12/2015	000-53058
2.2	Agreement and Plan of Merger, dated March 6, 2015, by and between the Registrant and Kura Oncology, Inc., relating to the name change of the Registrant.		8-K (Exhibit 2.2)	3/12/2015	000-53058
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	Registration Rights Agreement, dated as of March 6, 2015, by and among Kura Oncology, Inc. and the Investors listed on Schedule A thereto.		8-K (Exhibit 4.2)	3/12/2015	000-53058
4.3	Warrant to Purchase Stock by Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
10.1	Second Amendment to Management Services Agreement, effective as of April 1, 2018, by and between the Registrant and Araxes Pharma LLC.		10-Q (Exhibit 10.1)	5/8/2018	001-37620
10.2	Amended and Restated Sales Agreement, dated March 12, 2018, by and between the Registrant and Cowen and Company, LLC.		8-K (Exhibit 10.1)	3/12/2018	001-37620
10.3+	Kura Oncology, Inc. Amended and Restated Non-Employee Director Compensation Policy.		10-K (Exhibit 10.10)	3/12/2018	001-37620
10.4	Underwriting Agreement, dated June 27, 2018, by and between the Registrant and Leerink Partners LLC		8-K (Exhibit 1.1)	6/28/2018	001-37620
10.5	Executive Employment Agreement, effective as of July 1, 2018, by and between the Registrant and John Farnam.	X			
31.1	Certification of Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification 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	XBRL Instance Document.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			

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.
A Delaware corporation

Date: August 6, 2018

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

Exhibit 10.5

KURA ONCOLOGY, INC.

EXECUTIVE EMPLOYMENT AGREEMENT
FOR
JOHN FARNAM

This Executive Employment Agreement (the "***Agreement***"), entered into between Kura Oncology, Inc. (the "***Company***") and **JOHN FARNAM**(the "***Executive***") (collectively, the "***Parties***"), is effective as of July 1, 2018 (the "***Effective Date***").

WHEREAS, the Company desires Executive to provide employment services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services; and

WHEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position. Executive will serve as the **CHIEF OPERATING OFFICER** of the Company. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies.

1.2 Duties and Location. Executive will perform such duties as are required by the Company's **CHIEF EXECUTIVE OFFICER** to whom Executive will report. Executive's primary office location will be the Company's San Diego, California office. The Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, and to require reasonable business travel. The Company may modify Executive's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time.

1.3 Policies and Procedures. The employment relationship between the Parties will be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement will control.

2. COMPENSATION.

2.1 Salary. For services to be rendered hereunder, Executive will receive a base salary at the rate of $**355,000.00** per year (the "***Base Salary***") payable in installments in accordance with the Company's regular payroll schedule.

2.2 **Bonus.** Executive will be eligible for an annual discretionary bonus of up to **40**% of Executive's Base Salary (the "***Annual Bonus***"). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors ("***Board***") in its sole discretion based upon the Company's and Executive's achievement of objectives and milestones to be determined on an annual basis by the Board. Executive must remain an active employee through the end of any given calendar year in order to earn an Annual Bonus for that year and any such bonus will be paid prior to March 15 of the year following the year in which such bonus was earned. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before the end of the calendar year.

2.3 **Equity.** Subject to the approval by the Company's Board of Directors, and as further consideration for Executive's employment, the Company shall grant Executive an option to purchase **115,000** shares of the Company's common stock ("Common Stock") at a per share exercise price equal to the closing sales price for the Common Stock on the principal trading market for the Common Stock on the grant date of the option (the "***Option***"). The Option will be subject to the terms and conditions of the Company's Amended and Restated 2014 Equity Incentive Plan (the "Plan"), and an option agreement between Company and Executive. The Option will be subject to vesting over a four (4) year period according to the following schedule: 25% of the shares will vest as of the one-year anniversary of the vesting commencement date and 1/48th of the shares will vest monthly thereafter, so long as Executive remains in continuous service with the Company through the applicable vesting dates.

3. **Standard Company Benefits.** Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

4. **Vacation.** Executive will be entitled to accrue and use paid vacation in accordance with the terms of the Company's vacation policy and practices, provided, however, that in no event will Executive's vacation accrual rate be lower than 3 weeks per year.

5. **Expenses.** The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. **Termination of Employment; Severance.**

6.1 **At-Will Employment.** Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause or advance notice.

6.2 **Termination Without Cause; Resignation for Good Reason.**

(a) Not in Connection with a Corporate Transaction. In the event Executive's employment with the Company is terminated by the Company without Cause (other than by reason of death or disability), or Executive resigns for Good Reason, then provided such termination or resignation constitutes a "separation from service" (as defined under Treasury

Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), the Separation from Service occurs more than 59 days prior to or 12 months after the closing of a Corporate Transaction, the Company shall pay Executive's base salary and accrued and unused vacation benefits earned through the date of termination, at the rate in effect at the time of termination, less standard deductions and withholdings. In addition, if Executive provides a signed release of claims in a form reasonably satisfactory to the Company (the "***Release***") and allows such Release to become irrevocable and effective no later than 60 days following Executive's Separation from Service, and provided that Executive remains in compliance with the terms of this Agreement, the Company will provide Executive with the following severance benefits:

(i) a cash lump-sum payment in an amount equal to **12** months of Executive's annual base salary at the rate in effect on the effective date of Executive's Separation from Service, ignoring any decrease in base salary that forms the basis for Good Reason, payable on the 60th day following Executive's Separation from Service.

(ii) Provided Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***"), the Company will pay the COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable), subject to withholding if deemed necessary to comply with applicable laws, through the period (the "***COBRA Premium Period***") starting on the Executive's Separation from Service and ending on the earliest to occur of: (i) **12** months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(b) In Connection with a Corporate Transaction. In the event Executive's employment with the Company is terminated by the Company without Cause (other than by reason of death or disability), or Executive resigns for Good Reason, and provided such termination or resignation constitutes a Separation from Service and such the Separation from Service occurs within 59 days prior to, on or within 12 months following the closing of a Corporate Transaction, the Company shall pay Executive's base salary and accrued and unused vacation benefits earned through the date of termination, at the rate in effect at the time of termination, less standard deductions and withholdings. In addition, if Executive provides a signed Release and allows such Release to become irrevocable and effective no later than 60 days following Executive's Separation from Service, and provided that Executive remains in compliance with the terms of this Agreement, the Company will provide Executive with the following severance benefits:

(i) A cash lump-sum payment in an amount equal to **12** months of Executive's annual base salary at the rate in effect on the effective date of Executive's Separation from Service, ignoring any decrease in base salary that forms the basis for Good Reason, less standard deductions and withholdings, payable on the 60th day following Executive's Separation from Service.

(ii) A cash lump-sum payment in an amount equal to the Executive's full target bonus amount for services to be performed during the year in which the Corporate Transaction occurs, less standard deductions and withholdings, payable on the 60th day following Executive's Separation from Service.

(iii) Provided Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***"), the Company will pay the COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable), subject to withholding if deemed necessary to comply with applicable laws, through the period (the "***COBRA Premium Period***") starting on the Executive's Separation from Service and ending on the earliest to occur of: (i) **12** months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(iv) One hundred percent of any equity held by Executive will be deemed vested and exercisable (if applicable) as of Executive's last day of employment, provided, however, that with respect to any performance based vesting equity awards held by Executive that have multiple vesting levels depending upon the level of performance, such equity awards will vest at the target level.

(c) COBRA. Notwithstanding Sections 6.2(a)(ii) and 6.2(b)(iii), if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether the Executive or the Executive's qualifying family members elect COBRA continuation coverage (the "***Health Care Benefit Payment***"). The Health Care Benefit Payment shall be paid in monthly or bi-weekly installments on the same schedule that the COBRA premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA insurance premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the COBRA Premium Period, but determined without regard to whether or not the Executive continues to be eligible for COBRA coverage.

6.3 Resignation Without Good Reason; Termination for Cause; Death or Disability. If Executive resigns without Good Reason, or the Company terminates Executive's service for Cause, or upon a termination due to Executive's death or disability, then all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and Executive will not be entitled to any severance benefits under Section 6.2(a) or Section 6.2(b).

7. Section 280G.

7.1 If any payment or benefit Executive would receive from the Company or otherwise (***"Payment"***) would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"***), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable

marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

7.2 In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

7.3 Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Corporate Transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Corporate Transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

7.4 The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

8. SECTION 409A.

8.1 It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Code Section 409A.

8.2 A termination of employment will not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a Separation from Service and, for purposes of any such provision of this Agreement, references to a "termination," "termination of service" or like terms will mean Separation from Service. If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered deferred compensation under Code Section 409A payable on account of a Separation from Service, such payment or benefit will be made or provided at the date which is the earlier of (A) the expiration of the six-month period measured from the date of such Separation from Service of Executive, and (B) the date of Executive's death, to the extent required under Code Section 409A. Upon the expiration of the foregoing delay period, all payments and benefits delayed pursuant to this Section 8.2 (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) will be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due under this Agreement will be paid or provided in accordance with the normal payment dates specified for them herein.

8.3 To the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" for purposes of Code Section 409A, (A) all expenses or other reimbursements hereunder will be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by Executive, (B) any right to reimbursement or in-kind benefits will not be subject to liquidation or exchange for another benefit, and (C) no such reimbursement, expenses eligible for reimbursement, or in-kind benefits provided in any taxable year will in any way affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

8.4 For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days, the actual date of payment within the specified period will be within the sole discretion of the Company. Notwithstanding any other provision of this Agreement to the contrary, in no event will any payment under this Agreement that constitutes "nonqualified deferred compensation" for purposes of Code Section 409A be subject to offset by any other amount unless otherwise permitted by Code Section 409A.

9. DEFINITIONS.

9.1 ***"Cause"*** with respect to Executive means Executive has: (a) been convicted of or pled guilty or *nolo contendere* to a felony or any crime involving moral turpitude or dishonesty; (b) participated in a fraud or act of dishonesty against the Company; (c) materially breached any agreement between such Executive and the Company or any written policy of the Company, and not cured such breach within five days of the Company's written notice of such breach; (d) engaged in conduct that demonstrates gross unfitness to serve; or (e) engaged in willful misconduct or refused to comply with any lawful directive of the Company, and not cured such noncompliance within five days of the Company's written notice of such noncompliance.

9.2 ***"Code"*** means the Internal Revenue Code of 1986, as amended.

9.3 "***Good Reason***" will exist for Executive's resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent:

(a) a material reduction in Executive's base salary, unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees;

(b) a material reduction in Executive's duties (including responsibilities and/or authorities);

(c) a material reduction in the authority, duties, or responsibilities of the supervisor to whom Executive is required to report, including a requirement that Executive report to an employee of the Company instead of the Chief Executive Officer;

(d) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than 50 miles as compared to Executive's then-current principal place of employment immediately prior to such relocation; or

(e) any other action or inaction that constitutes a material breach by the Company of this Agreement or any agreement under which Executive provides services.

Provided, however that, such termination by the Executive shall only be deemed for Good Reason pursuant to the foregoing definition if (i) the Company is given written notice from the Executive within 30 days following the first occurrence of the condition that Executive considers to constitute Good Reason describing the condition and the Company fails to satisfactorily remedy such condition within 30 days following such written notice, and (ii) the Executive terminates employment within 90 days following the end of the period within which the Company was entitled to remedy the condition constituting Good Reason but failed to do so.

9.4 ***"Corporate Transaction"*** means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(a) a sale, lease or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its subsidiaries;

(b) a merger, consolidation, or similar transaction of the Company following which such entity is not the surviving entity;

(c) a merger, consolidation or similar transaction of the Company following which such entity is the surviving entity but the shares outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

Notwithstanding the foregoing, the term Corporate Transaction will not include (i) a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, or (ii) the acquisition of securities of the Company by an investor or any affiliate thereof that acquires the Company's securities in a transaction or series of related transactions the primary

purpose of which is to obtain financing for the Company through the issuance of equity securities. In addition, to the extent required for compliance with Code Section 409A, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

10. PROPRIETARY INFORMATION OBLIGATIONS.

10.1 Confidential Information Agreement. As a condition of employment, Executive will execute and abide by the Company's standard form of Proprietary Information and Invention Assignment Agreement (the "***Confidentiality Agreement***") and Arbitration Agreement.

10.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment with the Company, except as expressly authorized by that third party. During Executive's employment with the Company, Executive will use in the performance of Executive's duties only information which is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

11. OUTSIDE ACTIVITIES DURING EMPLOYMENT.

11.1 Non-Company Business. Except with the prior written consent of the Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any employment, occupation or business enterprise, other than ones in which Executive is a passive investor or as permitted under Section 11.2. Executive shall be entitled to serve on the board of directors of such other companies as may be approved in advance by the Chief Executive Officer, in each case, so long as Executive remain in compliance with Section 11 and such service does not interfere with Executive's duties under this Agreement. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

11.2 No Adverse Interests. Except with the prior written consent of the Chief Executive Officer, Executive will not during the term of Executive's employment with the Company acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise, provided that this does not prohibit Executive's continued involvement in any existing investments or ownership, for investment purposes only, of not more than 3% of the outstanding stock of any company listed on a national securities exchange, or actively traded in a national over-the-counter market.

12. NON-SOLICITATION. Executive agrees that during the period of employment with the Company and for 12 months after the date Executive's employment is terminated for any reason, Executive will not, either directly or through others, solicit or encourage or attempt to solicit or encourage any employee, independent contractor, or consultant of the Company to terminate his or

her relationship with the Company in order to become an employee, consultant or independent contractor to or for any other person or entity.

13. **Dispute Resolution.** To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, Executive's employment, or the termination of Executive's employment, including but not limited to statutory claims, will be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in San Diego, California, conducted by JAMS, Inc. ("***JAMS***") under the then applicable JAMS rules (which can be found at the following web address: http://www.jamsadr.com/rulesclauses). By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator will: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator will be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company will pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of the Executive if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

14. **General Provisions.**

14.1 **Notices.** Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

14.2 **Severability.** Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

14.3 **Waiver.** Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it will not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

14.4 **Complete Agreement.** This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise

or representation other than those expressly contained herein, and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

14.5 **Counterparts.** This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

14.6 **Headings.** The headings of the paragraphs hereof are inserted for convenience only and will not be deemed to constitute a part hereof nor to affect the meaning thereof.

14.7 **Successors and Assigns.** This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which will not be withheld unreasonably.

14.8 **Choice of Law.** All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

Kura Oncology, Inc.

By: /s/ Heidi Henson
Name: Heidi Henson
Title: CFO

Executive

/s/ John Farnam
John Farnam

Exhibit 31.1

CERTIFICATION

I, Troy E. Wilson, Ph.D., J.D., certify that:

1. I have reviewed this Form 10-Q of Kura Oncology, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2018

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Kura Oncology, Inc. (the "Company") for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, Ph.D., J.D., as President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Kura Oncology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Date: August 6, 2018

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