

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

**FORM 10-Q**

(Mark One)

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

**For the Quarterly Period Ended September 30, 2015**

**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**

**(State or Other Jurisdiction of  
Incorporation or Organization)**

**11119 N. Torrey Pines Road, Suite 125, La Jolla, CA  
(Address of Principal Executive Offices)**

**61-1547851  
(I.R.S. Employer  
Identification No.)**

**92037  
(Zip Code)**

**(858) 500-8800**

**(Registrant's Telephone Number, Including Area Code)**

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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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 November 13, 2015, the registrant had 21,370,560 shares of Common Stock (\$0.0001 par value) outstanding.

**KURA ONCOLOGY, INC.**  
**TABLE OF CONTENTS**

<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
<u>Item 1. Financial Statements</u>	3
<u>Condensed Balance Sheets – As of September 30, 2015 (unaudited) and December 31, 2014</u>	3
<u>Condensed Statements of Operations and Comprehensive Loss – Three and Nine Months Ended September 30, 2015 (unaudited) and August 22, 2014 (Inception) to September 30, 2014 (unaudited)</u>	4
<u>Condensed Statements of Cash Flows – Nine Months Ended September 30, 2015 (unaudited) and August 22, 2014 (Inception) to September 30, 2014 (unaudited)</u>	5
<u>Notes to Condensed Financial Statements (unaudited)</u>	6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	23
<u>Item 4. Controls and Procedures</u>	23
<b><u>PART II. OTHER INFORMATION</u></b>	<b>24</b>
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 6. Exhibits</u>	51
<u>Signatures</u>	52

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2015 (Unaudited)	December 31, 2014 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,215	\$ 1,124
Short-term investments	30,017	-
Accounts receivable, related party	379	30
Prepaid expenses and other current assets	695	42
Total current assets	42,306	1,196
Property and equipment, net	78	27
Other long-term assets	438	150
Other long-term assets, related party	5	5
Total assets	<u>\$ 42,827</u>	<u>\$ 1,378</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,654	\$ 846
Accounts payable, related party	1,057	134
Convertible notes payable, related party, current	-	2,036
Total current liabilities	4,711	3,016
Convertible notes payable, related party	-	493
Other long-term liabilities	332	1,295
Other long-term liabilities, related party	-	7
Total liabilities	5,043	4,811
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares issued and outstanding	-	-
Common stock, \$0.0001 par value; 200,000 and 100,000 shares authorized; 14,508 and 4,944 shares issued; and 10,936 and 411 shares outstanding, excluding 3,572 and 4,533 shares subject to repurchase as of September 30, 2015 and December 31, 2014, respectively	1	-
Additional paid-in capital	57,604	238
Accumulated comprehensive gain	1	-
Accumulated deficit	(19,822)	(3,671)
Total stockholders' equity (deficit)	37,784	(3,433)
Total liabilities and stockholders' equity (deficit)	<u>\$ 42,827</u>	<u>\$ 1,378</u>

(1) The balance sheet data at December 31, 2014 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 September 30, 2015	Nine Months Ended September 30, 2015	Period From August 22, 2014 (Inception) to September 30, 2014
<b>Operating Expenses:</b>			
Research and development	\$ 3,642	\$ 9,591	\$ 3
Research and development, related party	993	3,073	-
General and administrative	1,779	4,308	63
General and administrative, related party	14	51	-
Total operating expenses	<u>6,428</u>	<u>17,023</u>	<u>66</u>
<b>Other Income (Expense):</b>			
Management fee income, related party	300	900	-
Interest income	38	60	-
Interest expense	-	(42)	-
Interest expense, related party	-	(46)	-
Total other income	<u>338</u>	<u>872</u>	<u>-</u>
<b>Net loss</b>	<u>\$ (6,090)</u>	<u>\$ (16,151)</u>	<u>\$ (66)</u>
Net loss per share, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (1.98)</u>	<u>\$ (26.94)</u>
Weighted average number of shares used in computing net loss per share, basic and diluted	<u>10,723</u>	<u>8,136</u>	<u>2</u>
<b>Comprehensive Loss:</b>			
Net loss	\$ (6,090)	\$ (16,151)	\$ (66)
Unrealized gain on marketable securities	15	1	-
Comprehensive loss	<u>\$ (6,075)</u>	<u>\$ (16,150)</u>	<u>\$ (66)</u>

*See accompanying notes to condensed financial statements.*

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

	Nine Months Ended September 30, 2015	Period From August 22, 2014 (Inception) to September 30, 2014
<b>Operating Activities</b>		
Net loss	\$ (16,151)	\$ (66)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,663	-
Non-cash license fee expense	500	-
Change in value of derivative liability	268	-
Non-cash accrued interest expense	37	-
Non-cash accrued interest expense, related party	42	-
Depreciation expense	13	-
Amortization of discount on marketable securities	104	-
Changes in operating assets and liabilities:		
Accounts receivable, related party	(349)	-
Prepaid expenses and other current assets	(644)	-
Other long-term assets	(288)	(10)
Accounts payable and accrued expenses	2,561	60
Accounts payable, related party	923	-
Other long-term liabilities	(999)	-
Net cash used in operating activities	<u>(12,320)</u>	<u>(16)</u>
<b>Investing Activities</b>		
Purchases of marketable securities	(30,129)	-
Purchases of property and equipment	(49)	(11)
Net cash used in investing activities	<u>(30,178)</u>	<u>(11)</u>
<b>Financing Activities</b>		
Proceeds from issuance of common stock, net	47,586	-
Proceeds from issuance of convertible notes payable	5,000	-
Proceeds from issuance of notes payable, related party	-	100
Proceeds from issuance of restricted stock awards	3	9
Net cash provided by financing activities	<u>52,589</u>	<u>109</u>
Net increase in cash and cash equivalents	10,091	82
Cash and cash equivalents at beginning of period	1,124	-
Cash and cash equivalents at end of period	<u>\$ 11,215</u>	<u>\$ 82</u>
<b>Supplemental disclosure of non-cash financing activities:</b>		
Conversion of convertible notes and related accrued interest to common stock	\$ 4,327	\$ -
Conversion of convertible notes and related accrued interest to common stock, related party	\$ 3,288	\$ -

*See accompanying notes to condensed financial statements.*

**KURA ONCOLOGY, INC.**  
**Notes to Unaudited Condensed Financial Statements**

**1. Business and Organization**

Kura Oncology, Inc., is a clinical stage biopharmaceutical company discovering and developing personalized therapeutics for the treatment of solid tumors and blood cancers. We focus on the development of small molecule product candidates that target cell signaling pathways that are important to driving the progression of certain cancers. We aim to employ molecular diagnostics to identify patients with cancers who are likely to benefit from our targeted product candidates.

References in these Notes to Unaudited Condensed Financial Statements to the “Company” or “we”, “our” or “us”, refer to Kura Oncology, Inc., or Prior Kura, a private Delaware corporation incorporated in the State of Delaware in August 2014, for the periods prior to the Merger (as defined below) which took place on March 6, 2015, and Kura Oncology, Inc., a Delaware corporation incorporated in November 2007 and formerly known as Zeta Acquisition Corp. III, for the periods following the Merger.

Effective March 6, 2015, or Effective Time, we completed a reverse merger, or the Merger, with a wholly owned subsidiary of “Zeta Acquisition Corp. III,” or Zeta, a public shell company, leaving Prior Kura as the surviving entity. On March 31, 2015, the surviving entity merged with and into us. Zeta was formed in November 2007 with no specific business plan or purpose. As a result of the Merger and related transactions, Zeta changed its name to “Kura Oncology, Inc.” and began operating Prior Kura’s business.

Pursuant to the terms of an Agreement and Plan of Merger dated March 6, 2015, by and among Zeta, Kura Operations, Inc. and Prior Kura, at the Effective Time, each share of Prior Kura common stock outstanding immediately prior to the Effective Time was exchanged for one-half (0.5) of a share of our common stock. The share and price per share amounts presented in these Unaudited Condensed Financial Statements have been adjusted for such exchange. We issued an aggregate of 14,508,177 shares of our common stock upon such exchange of the Prior Kura common stock outstanding. In addition, at the Effective Time, we assumed Prior Kura’s 2014 Equity Incentive Plan that was in existence immediately prior to the Effective Time and concurrently approved the amendment and restatement of the Prior Kura 2014 Equity Incentive Plan, pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, which became effective in April 2015. Refer to Note 12, Equity Incentive Plan for detailed discussion of the 2014 Plan.

Immediately following the Effective Time, pursuant to the terms of a Redemption Agreement dated March 6, 2015, by and among Zeta and its pre-Merger stockholders, we completed the closing of a redemption of 5,000,000 shares of our common stock, or the Redemption, from our pre-Merger stockholders for consideration of \$70,000, plus \$30,000 in professional fees related to the transaction. The 5,000,000 shares constituted all of the issued and outstanding shares of Zeta’s capital stock, on a fully-diluted basis, immediately prior to the Merger. Upon completion of the Merger and the Redemption, Prior Kura’s stockholders held 100% of the outstanding shares of our capital stock.

Immediately prior to the Merger, on March 6, 2015, Prior Kura sold 8,280,696 shares of our common stock to investors at a price of \$6.32 per share for gross proceeds of \$52.3 million, or the Financing. The Financing represented a qualified financing conversion event pursuant to the then outstanding convertible promissory notes. As such, upon the closing of the Financing, \$7.5 million in principal and \$115,000 in accrued interest on such convertible promissory notes through February 28, 2015 automatically converted into 1,204,870 shares of our common stock.

The Merger is accounted for as a reverse merger and a capital transaction. Prior Kura is the acquirer for accounting purposes and Zeta is the acquired company. Consequently, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the Merger are those of Prior Kura and are recorded at Prior Kura’s historical cost basis. Prior Kura was incorporated in August 2014; therefore, there were no operations in the periods prior to August 2014. The financial statements after completion of the Merger include our assets, liabilities and operations. The historical equity accounts and awards of Prior Kura, including par value per share, share and per share numbers, have been retrospectively adjusted to reflect the one for 0.5 shares common stock exchange, the par value of \$0.0001 and the number of shares received in the Merger.

**2. Basis of Presentation**

The accompanying unaudited condensed financial statements should be read in conjunction with Prior Kura’s audited financial statements and notes thereto for the year ended December 31, 2014 included in the final prospectus dated November 4, 2015 filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to our Registration Statement on Form S-1 (333-207534), originally filed on October 20, 2015, as amended, from which we derived our balance sheet as of December 31, 2014. 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 in 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.

### **3. Summary of Significant Accounting Policies**

#### ***Cash and Cash Equivalents***

Cash equivalents consist of highly liquid investments that are readily convertible to cash and that mature within three months or less from the date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments. Cash and cash equivalents consist primarily of cash in readily available checking and money market accounts.

#### ***Short-Term Investments***

Short-term investments are marketable securities with maturities greater than three months from date of purchase that are specifically identified to fund current operations. Short-term investments are classified as available-for-sale at fair value as determined by prices for identical or similar securities at the balance sheet date. These 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. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in interest income. The available-for-sale investments are carried at fair value with unrealized gains and losses recorded in other comprehensive loss and included as a separate component of stockholders' equity (deficit). Realized gains and losses from the sale of available-for-sale securities and declines in value judged to be other than temporary on short-term investments, if any, are determined on a specific identification basis and are reclassified out of other comprehensive loss and included in interest income in the condensed statements of operations and comprehensive loss.

#### ***Fair Value Measurements***

Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the 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.

#### ***Research and Development Expenses***

Research and development expenses consist of salaries, benefits, and other personnel costs, preclinical and clinical trial costs, manufacturing costs for non-commercial products, and research and development facilities costs. All such costs are charged to research and development expense as incurred when these expenditures have no alternative future uses. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are expensed as research and development costs at the time such costs are incurred. As of September 30, 2015, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

### ***Clinical Trial Costs and Accruals***

A significant portion of our clinical trial costs relate to contracts with contract research organizations, or CROs. The financial terms of our CRO contracts may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our condensed financial statements by matching those expenses with the period in which services and efforts are expended. As part of the process of preparing our condensed financial statements, we rely on cost information provided by our CROs (concerning monthly expenses as well as reimbursement for pass through costs). We are also required to estimate certain of our expenses resulting from our obligations under our CRO contracts. Accordingly, our clinical trial accrual is dependent upon the timely and accurate reporting of CROs and other third-party vendors. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Historically, we have had no material changes in clinical trial expense that had a material impact on our results of operations or financial position.

### ***Share-Based Payments***

Our share-based awards are measured at fair value on the date of grant based upon the estimated fair value of common stock. The fair value of awards expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award less estimated forfeitures. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model that requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock.

Awards granted to non-employees are subject to periodic revaluation over their vesting terms. The fair value of non-employee awards is remeasured at each reporting period as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant. We record the expense for stock option grants to non-employees based on the estimated fair value of the stock options using the Black-Scholes option pricing model. Estimated fair value of the restricted stock awards granted to non-employees is recorded on the earlier of the performance commitment date or the date the services required are completed and are remeasured at fair value during the service period. As non-employee restricted stock awards vest, they are remeasured at fair value and expensed based on the intrinsic value method which is measured as the difference between the exercise price paid for the restricted stock award and the fair value of the shares as the right of the repurchase lapses each vesting period.

### ***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 solely of unrealized gains and losses on marketable securities.

### ***Segment Reporting***

We operate in a single industry segment which is the discovery and development of personalized therapeutics for the treatment of solid tumors and blood cancers. Our chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

### ***Net Loss per Share***

We calculated basic net loss per common share 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 share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of unvested restricted stock awards and outstanding stock options under our equity plan. 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 stock awards representing an aggregate of 3,571,875 and 4,847,953 shares of common stock and options to purchase an aggregate of 410,000 and zero shares of common stock, are excluded from the calculation of diluted net loss per common share as of September 30, 2015 and 2014, respectively, due to the anti-dilutive effect of the securities.



## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2014-09, Revenue from Contracts with Customers (Topic 606), that supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance provides that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance.

In July 2015, the FASB voted to amend ASU 2014-09 by approving a one-year deferral of the effective date as well as providing the option to early adopt the standard on the original effective date. Accordingly, we will adopt the standard for the annual reporting period beginning after December 15, 2017, including interim periods within that reporting period. We are currently evaluating the alternative transition methods and the potential effects on our financial statements and future operating results.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods beginning after December 15, 2016, and for annual and interim periods thereafter. We are currently evaluating the potential changes from this ASU to our future financial reporting and disclosures.

## 4. Short-Term Investments

The following table summarizes, by major security type, our short-term investments that are measured at fair value on a recurring basis as of September 30, 2015, in thousands:

	Maturity (in years)	As of September 30, 2015			Fair Value
		Amortized Cost	Unrealized Gains	Unrealized Losses	
Government sponsored entities	2 years or less	\$ 13,288	\$ 6	\$ -	\$ 13,294
Corporate debt securities	2 years or less	11,534	5	(10)	11,529
Commercial paper	1 year or less	5,194	-	-	5,194
Total		<u>\$ 30,016</u>	<u>\$ 11</u>	<u>\$ (10)</u>	<u>\$ 30,017</u>

As of September 30, 2015, \$9.3 million of our investments had maturities greater than one year. These 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. We review our investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. As of September 30, 2015, we had not recognized any such impairment in our condensed financial statements.

## 5. Fair Value Measurements

### Investment Securities

As of September 30, 2015, we had cash equivalents and short-term investments measured at fair value on a recurring basis. As of December 31, 2014, we did not have any cash equivalents or short-term investments measured at fair value on a recurring basis. The carrying amounts of our financial instruments, which include cash equivalents, prepaid expenses, accounts payable, accrued expenses and all related party amounts approximate their fair values as of September 30, 2015, primarily due to their short-term nature. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision.

Available-for-sale marketable securities consist of corporate debt securities, commercial paper and government sponsored entities and 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 table summarizes, 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 as of September 30, 2015, in thousands:

	Fair Value Measurements at September 30, 2015			
	Balance	Level 1	Level 2	Level 3
<b>Cash equivalents:</b>				
Money market funds	\$ 10,953	\$ 10,953	\$ -	\$ -
<b>Short-term investments:</b>				
Government sponsored entities	13,294	-	13,294	-
Corporate debt securities	11,529	-	11,529	-
Commercial paper	5,194	-	5,194	-
Total short-term investments	30,017	-	30,017	-
Total	\$ 40,970	\$ 10,953	\$ 30,017	\$ -

### Derivative Liability

Our license agreement with The Regents of the University of California San Francisco, or UCSF, which was amended in April 2015, provides for an indexed milestone payment upon the occurrence of a qualified financing and a subsequent initial public offering or a change of control event (Indexed Milestone Event), as defined in the agreement. The indexed milestone was determined to qualify as an embedded derivative liability requiring an estimate of fair value. We estimated the fair value of our derivative liabilities at the time of issuance and subsequent remeasurement at each reporting date using a probability model that considers the probability of achieving the events that would trigger such liabilities and the estimated time period the liabilities would be outstanding. The estimates are based, in part, on subjective assumptions and could differ materially in the future. Changes to these assumptions can have a significant impact on the fair value of the derivative liabilities.

As of September 30, 2015, the fair value of the derivative liability was determined to be \$464,000 based on the completion of the qualified financing event in March 2015 and the public offering completed in November 2015. See Note 14, Subsequent Event, for detailed information on the public offering. The UCSF derivative liability is measured at fair value (Level 3) on a recurring basis. No transfers between levels have occurred during the periods presented.

According to the payment terms as defined in the agreement, 50% of the liability is due in December 2015, 30 days after the Indexed Milestone Event, and the remaining 50% will be due in November 2016. As such, \$232,000 of the derivative liability balance was reclassified to current liabilities and is included in accounts payable and accrued expenses on the condensed balance sheets, and the remaining balance is included in other long-term liabilities on the condensed balance sheets.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs, in thousands:

	Derivative Liabilities
Balance at December 31, 2014	\$ 196
Change in fair value (1)	268
Balance at September 30, 2015	\$ 464

- (1) The amount is included within research and development expenses on our condensed statements of operations and comprehensive loss. The change in fair value of the derivative liability for the three and nine months ended September 30, 2015 was (\$39,000) and \$268,000, respectively.

## 6. Property and Equipment, Net

Property and equipment consisted of the following, in thousands:

	September 30, 2015	December 31, 2014
Computer equipment	\$ 85	\$ 26
Software	7	2
Property and equipment, gross	92	28
Less: accumulated depreciation	(14)	(1)
Property and equipment, net	\$ 78	\$ 27

## 7. Accounts Payable and Accrued Liabilities

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

	September 30, 2015	December 31, 2014
Accounts payable	\$ 407	\$ 226
Accrued expenses	2,287	581
Accrued compensation and benefits	960	39
Total accounts payable and accrued expenses	\$ 3,654	\$ 846

## 8. Notes Payable

### *Araxes Convertible Note*

In October 2014, we entered into a Note Purchase Agreement and Convertible Promissory Note with an affiliated company Araxes Pharma LLC, or Araxes, under which Araxes provided a \$2.0 million loan in the form of a convertible promissory note. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 326,443 shares of our common stock.

### *Araxes Asset Purchase Agreement – Convertible Note*

As consideration for the patents acquired under the Araxes Asset Purchase Agreement entered into in December 2014, Araxes issued a convertible promissory note equal to the purchase price of the patent rights of \$500,000. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 80,293 shares of our common stock.

### *January 2015 Convertible Notes*

In January 2015, we entered into a Note Purchase Agreement and Convertible Promissory Note for a \$3.0 million loan with various persons and entities named within the agreement, or the January 2015 Note Holders, of which \$710,000 were with certain officers and certain officers' related parties. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 479,667 shares of our common stock.

### *JJDC Convertible Note*

In accordance with the license agreement with Janssen Pharmaceutica NV, or Janssen, a foreign entity headquartered in Belgium and an affiliate of Johnson & Johnson, Inc., in January 2015 we entered into a Convertible Promissory Note with Janssen's affiliated company, Johnson & Johnson Innovation – JJDC, Inc., or JJDC, for \$1.0 million. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 159,615 shares of our common stock.

### *February 2015 Convertible Notes*

In February 2015, we entered into a Note Purchase Agreement and Convertible Promissory Note with entities named within the agreement, or the February 2015 Note Holders, under which the February 2015 Note Holders provided a \$1.0 million loan in the form of convertible promissory notes. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 158,852 shares of our common stock.

## 9. License Agreements

### *License Agreement with The University of Michigan*

In December 2014, we entered into a license agreement with The Regents of The University of Michigan, or Michigan, under which we received certain license rights for a non-refundable upfront license, annual maintenance fees and payments upon achievement of certain development and sales-based milestones. The licensed asset consists of a number of compounds, which are in the lead discovery/lead optimization phase. All future development, regulatory and commercial work on the asset will be completed fully and at our sole expense. Michigan retains the right to use the asset for non-commercial research, internal and/or educational purposes, with the right to grant the same limited rights to other non-profit research institutions. Furthermore, the agreement stipulates contingent consideration for the issuance of shares equivalent to a set dollar value upon the occurrence of a qualified financing or a change of control event, as defined in the amendment to the agreement, consistent with the terms issued to any future investors or the per share consideration to be received by other shareholders. As a result of the Financing, we issued 79,113 shares of our common stock at a fair value of \$500,000, which was recognized as research and development expense during the nine months ended September 30, 2015.

The agreement will terminate upon the last-to-expire patent rights, or may be terminated by us at any time with 90 days written notice of termination or terminated by Michigan upon a bankruptcy by us, payment failure by us that is not cured within 30 days or a material breach of the agreement by us that is not cured within 60 days.

### *Sponsored Research Agreement with The University of Michigan*

In February 2015, we entered into a Sponsored Research Agreement with Michigan under which we will sponsor up to \$2.7 million of research at Michigan over a three-year period. We will receive a non-exclusive right to any technology developed under this agreement and have an option right for an exclusive right to any such licenses developed under the agreement. The Sponsored Research Agreement allows for termination with notice at any time by us. In the event of termination by us prior to the second anniversary of the agreement, other than due to breach by Michigan, we will be required to pay costs budgeted through the second anniversary up to \$2.0 million of the sponsored research amount. Any costs incurred for the Sponsored Research Agreement will be expensed as incurred. For the three and nine months ended September 30, 2015, we recorded approximately \$251,000 and \$627,000, respectively, in research and development expense under this research agreement.

Collectively, our outstanding license agreements provide for specified development, regulatory and sales-based milestone payments up to a total of \$81.7 million payable upon occurrence of each stated event, of which \$1.2 million relates to the initiation of certain development activities, \$30.5 million relates to the achievement of specified regulatory approvals for the first indication and up to \$50.0 million for the achievement of specified levels of product sales. Additional payments will be due for each subsequent indication if specified regulatory approvals are achieved. All milestone payments under the agreements will be recognized as research and development expense upon completion of the required events because the triggering events are not considered to be probable until they are achieved. As of September 30, 2015, we have not achieved any milestones under the agreements. Furthermore, if all the programs are successfully commercialized, we will be required to pay tiered royalties on annual net product sales ranging from the low single digits to the low teens, depending on the volume of sales and the respective agreement.

## 10. Commitments and Contingencies

From time to time, we may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of our business. Any of these claims could subject us to costly legal expenses and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. 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.

## 11. Stockholders' Equity

Immediately prior to the Merger, on March 6, 2015, Prior Kura sold 8,280,696 shares of our common stock at a price of \$6.32 per share, for net proceeds of approximately \$48.2 million, net of \$4.1 million in fees. The Financing represented a qualified financing conversion event pursuant to our convertible promissory notes. As such, upon the closing of the Financing, an aggregate of \$7.5 million in principal under our convertible promissory notes and \$115,000 in accrued interest through February 28, 2015 automatically converted into 1,204,870 shares of our common stock. In addition, we incurred approximately \$568,000 in costs related to the Merger which were accounted for as financing costs in additional paid-in capital.

Effective April 13, 2015, pursuant to our amended and restated certificate of incorporation, we have authorized capital stock consisting of 200,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share.

## 12. Equity Incentive Plan

In August 2014, Prior Kura adopted the Prior Kura 2014 Equity Incentive Plan. In connection with the Merger as discussed in Note 1, at the Effective Time of the Merger, we adopted the Prior Kura 2014 Equity Incentive Plan and approved the amendment and restatement of the Prior Kura 2014 Equity Incentive Plan pursuant to the 2014 Plan, which became effective April 13, 2015. Under the 2014 Plan, a total of 5,975,000 shares are reserved for issuance. As of September 30, 2015, there were 621,500 shares of common stock reserved for future stock awards under the 2014 Plan. The 2014 Plan provides equity-based incentives in the form of stock awards to employees and other providers of services to us. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation to eligible recipients. Recipients of incentive stock options shall be eligible to purchase shares of our common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options to be granted under the Plan is ten years.

### Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2015, in thousands (except per share data):

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
Balance at December 31, 2014	-	
Granted	410	\$ 6.32
Balance at September 30, 2015	<u>410</u>	<u>\$ 6.32</u>
Exercisable at September 30, 2015	<u>3</u>	<u>\$ 6.32</u>

The weighted average assumptions used to estimate the fair value of stock options granted to employees in the nine months ended September 30, 2015 using the Black-Scholes option pricing model were as follows:

Weighted average grant date fair value per share	\$ 4.02
Expected volatility	70.8%
Expected term (in years)	6.00 — 6.08
Risk free interest rate	1.8%
Expected dividend yield	-

There were no stock options granted from August 22, 2014 (Inception) to September 30, 2014, or during the three months ended September 30, 2015. In estimating fair value for stock options issued under the 2014 Plan, expected volatility was based on historical volatility of comparable publicly-traded companies because our common stock has only been publicly traded since September 16, 2015. Due to the lack of historical option exercise data, we estimated the expected term using the simplified method. The risk-free interest rates are based on the U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future. We apply an estimate of forfeitures at the time of grant based on historical experience and revise our estimate in subsequent periods if actual forfeitures differ from those estimates.

### Restricted Stock Awards

Restricted stock awards were granted at a price equal to the estimated fair market value on the date of grant. The restricted stock awards generally vest over four years from the original vesting date, with certain grants subject to one-year cliff vesting. The vesting provisions of individual awards may vary as approved by our Board of Directors. In connection with the issuance of restricted common stock, we maintain a repurchase right where shares of restricted common stock are released from such repurchase right over a period of time of continued service by the recipient. The repurchase price for unvested stock awards will be the lower of (i) the fair market value of the shares of common stock on the date of repurchase or (ii) their original purchase price. As of September 30, 2015, there were 3,571,875 shares subject to repurchase, of which 3,007,759 shares were related to employee stock awards, and 564,116 shares were related to non-employee stock awards, respectively.

The following is a summary of restricted share activity for the nine months ended September 30, 2015, in thousands (except per share data):

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Balance at December 31, 2014	4,533	\$ 0.002
Granted	-	
Vested	(961)	
Unvested at September 30, 2015	<u>3,572</u>	\$ 0.003
Vested at September 30, 2015	<u>1,372</u>	\$ 0.003

For the nine months ended September 30, 2015, 766,157 and 194,842 shares underlying restricted stock awards granted to employees and non-employees, respectively, vested. As of September 30, 2015, 1,088,241 and 283,384 shares of underlying restricted stock awards granted to employees and non-employees, respectively, were vested. For the three and nine months ended September 30, 2015, we recognized share-based compensation expense related to restricted stock awards totaling \$412,000 and \$1.5 million, respectively, of which \$378,000 and \$1.3 million related to non-employee restricted stock awards, respectively.

The following table summarizes share-based compensation expense for all equity awards granted, in thousands:

	<u>Three Months Ended September 30, 2015</u>	<u>Nine Months Ended September 30, 2015</u>
Research and development	\$ 433	\$ 1,440
General and administrative	101	223
Total share-based compensation expense	<u>\$ 534</u>	<u>\$ 1,663</u>

There was no share-based compensation expense related to equity awards during the period August 22, 2014 (Inception) to September 30, 2014.

### 13. Related Party Transactions

As discussed in Note 8, in January 2015, we entered into a Note Purchase Agreement and Convertible Promissory Note for a \$3.0 million loan with the January 2015 Note Holders, of which \$710,000 were with certain officers and certain officers' related parties. As a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 was automatically converted into 479,667 shares of our common stock.

Our president and chief executive officer is also the sole managing member of our affiliated company Araxes. Four individuals are significant stockholders of each of us and Araxes. The following is a summary of all transactions with Araxes for the nine months ended September 30, 2015:

#### *Convertible Promissory Notes*

As described in Note 8, as a result of the Financing, the total of unpaid principal and accrued interest as of February 28, 2015 for the convertible note payable to Araxes was automatically converted into 326,443 shares of our common stock. In addition, the total of unpaid principal and accrued interest as of February 28, 2015 for the convertible note payable related to the Araxes asset purchase was automatically converted into 80,293 shares of our common stock.

#### *Facility Sublease*

We sublease office space from Araxes for a base rent of approximately \$5,000 per month plus operating expenses, taxes, insurance, and utilities applicable to the subleased property. Rent expense related to this sublease for the three and nine months ended September 30, 2015 was \$24,000 and \$73,000, respectively. There was no rent expense related to this sublease for the period August 22, 2014 (Inception) to September 30, 2014. The sublease will expire on August 30, 2016.

### *Management Fees*

We have a management services agreement with Araxes under which Araxes pays us a fixed \$100,000 a month for management services. In addition, the agreement allows for Araxes to pay us an amount equal to the number of full time equivalents, or FTE, performing collaboration services for Araxes, at an annual FTE rate of \$350,000, plus actual expenses as reasonably incurred. The agreement has an initial term expiring on December 31, 2015 and 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 December 31, 2015 or the expiration of the then-renewal term.

### *Services Agreement*

We have a services agreement with Wellspring Biosciences LLC (a wholly owned subsidiary of Araxes) which allows for payment of research and development services provided to us of 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. This services agreement has an initial term expiring on December 31, 2015 and 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 December 31, 2015 or the expiration of the then-renewal term.

## **14. Subsequent Event**

In November 2015, we completed a public offering whereby we issued an aggregate of 6,883,467 shares of common stock at \$8.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and estimated offering expenses, were approximately \$50.5 million.

## 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 and the audited financial statements and notes thereto as of and for the year ended December 31, 2014 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus dated November 4, 2015 filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, relating to our Registration Statement on Form S-1 (333-207534), originally filed on October 20, 2015, as amended, or the Final Prospectus.

This Quarterly Report includes forward-looking statements and information within the meaning of Section 27A of 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.

Unless otherwise provided in this Quarterly Report, references to the “Company,” “we,” “us” and “our” refer to Kura Oncology, Inc., or Prior Kura, a private Delaware corporation incorporated in the State of Delaware in August 2014, for the periods prior to the Merger (as defined below) which took place on March 6, 2015, and Kura Oncology, Inc., a Delaware corporation incorporated in November 2007 and formerly known as Zeta Acquisition Corp. III, for the periods following the Merger.

### Overview

We are a clinical stage biopharmaceutical company discovering and developing personalized therapeutics for the treatment of solid tumors and blood cancers. We focus on the development of small molecule product candidates that target cell signaling pathways that are important to driving the progression of certain cancers. We aim to employ molecular diagnostics to identify patients with cancers who are likely to benefit from our targeted product candidates.

Advancements in cancer genetics and new molecular diagnostic tools are helping define why some patients respond to a particular therapy while other patients receive little to no clinical benefit. This new era in cancer drug discovery and development offers the potential for innovative treatments that are safer and more effective for patients with particular cancers. We aim to improve patient outcomes and contribute to the reduction in healthcare costs by matching targeted therapeutics to the patients who will benefit the most. We are developing drugs designed to inhibit the mutated or abnormally functioning cellular pathways that drive cancer growth and intend to pair them with molecular diagnostics to identify those patients with tumors most likely to respond to treatment.

We are developing our lead product candidate, tipifarnib, a farnesyl transferase inhibitor, in both solid tumors and blood cancers based on previously generated clinical data, preclinical data and our identification of potential molecular biomarkers. We in-licensed tipifarnib from Janssen Pharmaceutica NV, an affiliate of Johnson & Johnson, in December 2014. We initiated a Phase 2 clinical trial of tipifarnib in patients who have solid tumors with HRAS mutations in May 2015, and a Phase 2 clinical trial in patients with peripheral T cell lymphoma, or PTCL, in September 2015. We plan to initiate a Phase 2 clinical trial in patients with lower risk myelodysplastic syndromes, or MDS, in the first half of 2016.



Our pipeline also includes two preclinical programs. We are advancing KO-947, a small molecule inhibitor of extracellular-signal-regulated kinases 1 and 2 as a potential treatment for patients with tumors that have mutations in or other dysregulation of the mitogen-activated protein kinase signaling pathway, including pancreatic cancer, colorectal cancer, non-small cell lung cancer and melanoma. We are also developing orally available, small molecule inhibitors of the menin-mixed lineage leukemia, or menin-MLL, interaction, which are currently in lead optimization as a potential treatment for patients with acute leukemias involving translocations or partial tandem duplications of the MLL gene.

We were originally incorporated in the State of Delaware in November 2007 under the name Zeta Acquisition Corp. III. Zeta Acquisition Corp. III was a “shell” company registered under the Exchange Act with no specific business plan or purpose until it began operating our business through the Merger and changed its name to “Kura Oncology, Inc.” Prior Kura was incorporated in August 2014; therefore, there were no operations prior to August 2014. Refer to “Recent Developments” below for detailed discussions on the transaction.

Our accumulated deficit was \$19.8 million as of September 30, 2015. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years as we continue the clinical development of, and seek regulatory approval for, our product candidates. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to raise capital, in addition to capital from our public offering completed in November 2015, for the further development of our existing product candidates and we may also need to raise additional funds sooner than expected to pursue other development activities related to our other pipeline programs. As of September 30, 2015, we had cash, cash equivalents, and short-term investments of \$41.2 million. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships 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.

## **Recent Developments**

### ***Private Placement***

Immediately prior to the Merger, we sold to accredited investors approximately \$60.0 million of our shares of common stock, or 18,971,136 shares, at a price of \$3.16 per share (as adjusted to 9,485,566 shares at a price of \$6.32 per share, after giving effect to the Merger), which included approximately \$7.5 million in principal and \$0.1 million in accrued interest from the conversion of our then outstanding convertible promissory notes.

### ***Reverse Merger***

On March 6, 2015, or the Effective Time, pursuant to an Agreement and Plan of Merger dated March 6, 2015, we completed a reverse merger, or the Merger, with a wholly owned subsidiary of a public “shell” company named “Zeta Acquisition Corp. III,” or Zeta, leaving Prior Kura as the surviving entity. On March 31, 2015, the surviving entity merged with and into us. Zeta was formed in November 2007 with no specific business plan or purpose until it began operating our business through the Merger. As a result of the Merger and related transactions, Zeta changed its name to “Kura Oncology, Inc.”

At the Effective Time, each share of Prior Kura common stock that was issued and outstanding immediately prior to the Effective Time was automatically exchanged for 0.5 shares of our common stock. We issued an aggregate of 14,508,177 shares of our common stock upon such exchange of the outstanding shares of Prior Kura. In addition, at the Effective Time, we assumed Prior Kura’s 2014 Equity Incentive Plan that was in existence immediately prior to the Effective Time and concurrently approved the amendment and restatement of the Prior Kura 2014 Equity Incentive Plan pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, which became effective in April 2015. As of the Effective Time, there were no outstanding options to purchase shares of Prior Kura common stock under the Prior Kura 2014 Equity Incentive Plan.

Immediately following the Effective Time, pursuant to the terms of a Redemption Agreement dated March 6, 2015, by and among Zeta and its pre-Merger stockholders, we completed the closing of a redemption of 5,000,000 shares of Zeta’s common stock from its then-current stockholders in consideration of \$70,000, plus \$30,000 in professional costs related to the transaction. The 5,000,000 shares constituted all of the issued and outstanding shares of its capital stock, on a fully-diluted basis, immediately prior to the Merger.

The Merger is accounted for as a reverse merger and a capital transaction. Prior Kura is the acquirer for accounting purposes and Zeta is the acquired company. Consequently, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the Merger are those of Prior Kura and are recorded at Prior Kura’s historical cost basis.

## **Public Offering**

In November 2015, we completed a public offering whereby we issued an aggregate of 6,883,467 shares of common stock at \$8.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and estimated offering expenses, were approximately \$50.5 million.

## **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 salaries, benefits and other personnel costs, preclinical and clinical trial costs, manufacturing costs for non-commercial products and research and development facilities costs. All such costs are charged to research and development expense as incurred when these expenditures have no alternative future uses. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses (in other research and development projects or otherwise) and, therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of September 30, 2015, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

As of September 30, 2015, we had incurred an aggregate of approximately \$15.3 million in research and development expenses related to the in-licensing and development of our product candidates and pipeline programs. 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 trial costs;
- the number of trials required for approval;
- the number of sites included in the 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 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 trial;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

We expect to incur substantial research and development expenses during the remainder of 2015 based on increased clinical development activities for our tipifarnib program and research and development activities for our other programs.

### General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits 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 fees for accounting, auditing, consulting and legal services, corporate expenses, travel and allocated facilities.

We expect that our general and administrative expenses will increase in the future as we expand our operating activities and maintain and expand our patent portfolio.

### Other Income (Expense)

Other income (expense) consists primarily of management fee income, interest income, and non-cash interest expense. Management fee income is earned in accordance with the management services agreement with an affiliated company Araxes Pharma LLC, or Araxes. Interest expense consists of interest accrued on convertible notes.

### 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

Prior Kura (the accounting acquirer) was incorporated in August 2014; therefore, there were minimal operations for the period from August 22, 2014 (Inception) to September 30, 2014.

### Three Months Ended September 30, 2015

The following table sets forth our results of operations for the three months ended September 30, 2015 and for the period from August 22, 2014 (Inception) to September 30, 2014, in thousands:

	Three Months Ended September 30, 2015	Period From August 22, 2014 (Inception) to September 30, 2014	Period-to-Period Change
Research and development	\$ 4,635	\$ 3	\$ 4,632
General and administrative	1,793	63	1,730
Other income, net	338	-	338

*Research and Development Expenses.* Research and development expenses were \$4.6 million and \$3,000 for the three months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. Research and development expenses for the three months ended September 30, 2015 were primarily comprised of \$2.7 million in outsourced research contracts, \$0.8 million in compensation and related personnel costs, \$0.4 million in share-based compensation mainly related to stock awards to consultants, and \$0.5 million in outsourced clinical development costs. We expect to incur substantial research and development expenses in the future based on increased clinical development activities for our tipifarnib product candidate and research and development for KO-947 and our other programs.

*General and Administrative Expenses.* General and administrative expenses were \$1.8 million and \$63,000 for the three months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. General and administrative expenses for the three months ended September 30, 2015 were primarily comprised of \$0.7 million in compensation costs, \$0.6 million in professional and consulting fees, \$0.2 million in corporate expenses, and \$0.1 million in share-based compensation. We expect that our general and administrative expenses will increase in the future as we expand our operating activities and maintain and expand our patent portfolio.

*Management Fee Income, Related Party.* Management fee income, related party was \$0.3 million and zero for the three months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. In accordance with the management services agreement with Araxes, we receive a fixed monthly fee of \$100,000 for management services. The agreement has an initial term expiring on December 31, 2015 and 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 December 31, 2015 or the expiration of the then-current renewal term.

### Nine Months Ended September 30, 2015

The following table sets forth our results of operations for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, in thousands:

	Nine Months Ended September 30, 2015	Period From August 22, 2014 (Inception) to September 30, 2014	Period-to-Period Change
Research and development	\$ 12,664	\$ 3	\$ 12,661
General and administrative	4,359	63	4,296
Other income, net	872	-	872

*Research and Development Expenses.* Research and development expenses were \$12.7 million and \$3,000 for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. Research and development expenses for the nine months ended September 30, 2015 were primarily comprised of \$6.8 million in outsourced research contracts, \$2.1 million in compensation and related personnel costs, \$1.1 million in outsourced clinical development costs, \$1.4 million in share-based compensation mainly related to stock awards to consultants, and \$0.8 million in license fees related to in-process research and development. We expect to incur substantial research and development expenses in the future based on increased clinical development activities for our tipifarnib product candidate and research and development for KO-947 and our other programs.

*General and Administrative Expenses.* General and administrative expenses were \$4.4 million and \$63,000 for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. General and administrative expenses for the nine months ended September 30, 2015 were primarily comprised of \$2.0 million in compensation costs, \$1.3 million in professional and consulting fees, \$0.4 million in corporate expenses, and \$0.2 million in share-based compensation. We expect that our general and administrative expenses will increase in the future as we expand our operating activities and maintain and expand our patent portfolio.

*Management Fee Income, Related Party.* Management fee income, related party was \$0.9 million and zero for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. In accordance with the management services agreement with Araxes, we receive a fixed monthly fee of \$100,000 for management services.

### Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through sales of our common stock and convertible notes. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. We have incurred operating losses since inception and negative cash flows from operating activities. As of September 30, 2015, we had an accumulated deficit of \$19.8 million. We expect to continue to incur operating losses for the foreseeable future as we continue the development and potential commercialization of our product candidates.

As of September 30, 2015, we had cash, cash equivalents, and short-term investments of \$41.2 million. Prior to the Merger, on March 6, 2015, we received net proceeds of \$48.2 million, net of financing costs of \$4.1 million, from the sale of common stock in an offering to accredited investors. Since inception through September 30, 2015, we received cash proceeds of \$7.0 million from the sale of convertible notes. In November 2015, we completed a public offering in which we raised approximately \$50.5 million, net of underwriting discounts, commissions and estimated offering expenses.

While we believe that our existing cash resources, including the net proceeds from our recent public offering, will be sufficient to fund our cash requirements for the next twelve months, we will require significant additional financing in the future to continue to fund our operations. We may seek to obtain additional financing in the future through equity or debt financings or through collaborations or partnerships with other companies. If we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations will be materially adversely affected.

The following table provides a summary of our net cash flow activity for each of the periods set forth below, in thousands:

	<b>Nine Months Ended September 30, 2015</b>	<b>Period From August 22, 2014 (Inception) to September 30, 2014</b>
Net cash used in operating activities	\$ (12,320)	\$ (16)
Net cash used in investing activities	(30,178)	(11)
Net cash provided by financing activities	52,589	109

Net cash used in operating activities was \$12.3 million and \$16,000 for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. Net cash used in operating activities during the nine months ended September 30, 2015 primarily consisted of \$16.2 million of net losses incurred and was adjusted for non-cash items such as share-based compensation expenses of \$1.7 million and license fees of \$0.5 million. Net cash used in operating activities during the nine months ended September 30, 2015 also included an increase in prepaid expenses and other current assets of \$0.6 million, a decrease in other long-term liabilities of \$1.0 million, and an increase in accounts payable and accrued expenses of \$3.5 million due to timing of payments.

Net cash used in investing activities was \$30.2 million and \$11,000 for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. Net cash used in investing activities for the nine months ended September 30, 2015 consisted mainly of purchases of marketable securities.

Net cash provided by financing activities was \$52.6 million and \$109,000 for the nine months ended September 30, 2015 and the period from August 22, 2014 (Inception) to September 30, 2014, respectively. Net cash provided by financing activities for the nine months ended September 30, 2015 resulted from receipt of \$47.6 million in net proceeds from the sale of common stock in March 2015 and \$5.0 million in proceeds from the issuance of convertible notes. Net cash provided by financing activities for the period from August 22, 2014 (Inception) to September 30, 2014 primarily resulted from net proceeds from the issuance of a convertible promissory note to Araxes.

### **Current and Future Financing Needs**

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. 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 and licensing arrangements. We do not have any committed external source of funds. Additional capital may not be available on reasonable terms, if at all. 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.

### **Off-Balance Sheet Arrangements**

As of September 30, 2015, we did not have any off-balance sheet arrangements.

## Critical Accounting Policies and Significant Judgments and Estimates of the Company

Management's 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 required estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the condensed financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our condensed financial statements appearing elsewhere in this report, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our condensed financial statements.

### *Research and Development Expenses*

We make estimates of our accrued expenses as of each balance sheet date in our condensed financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed. 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.

### *Derivative Liability*

Our license agreement with The Regents of the University of California San Francisco, or UCSF, provides for an indexed milestone payment upon the occurrence of a qualified financing and a subsequent initial public offering or a change of control event, as defined in the agreement. The indexed milestone was determined to qualify as an embedded derivative liability requiring an estimate of fair value. The UCSF derivative liability is measured at fair value on a recurring basis. The fair value of the derivative liability as of September 30, 2015 was based on the qualified financing event completed on March 6, 2015 and the public offering completed in November 2015.

### *Share-Based Payments*

Our share-based awards are measured at fair value on the date of grant based upon the estimated fair value of common stock. The fair value of awards expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award less estimated forfeitures. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model that requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock.

Awards granted to non-employees are subject to periodic revaluation over their vesting terms. The fair value of non-employee awards is remeasured at each reporting period as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant. We record the expense for stock option grants to non-employees based on the estimated fair value of the stock options using the Black-Scholes option pricing model. Estimated fair value of the restricted stock awards granted to non-employees is recorded on the earlier of the performance commitment date or the date the services required are completed and are remeasured at fair value during the service period. As non-employee restricted stock awards vest, they are remeasured at fair value and expensed based on the intrinsic value method which is measured as the difference between the exercise price paid for the restricted stock award and the fair value of the shares as the right of the repurchase lapses each vesting period.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### ***Interest Rate and Market Rate Risk***

We are exposed to interest rate risk on our cash equivalents and short-term investments which are invested primarily in money market funds, government sponsored entities, corporate debt securities, and commercial paper. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. Some of the financial instruments that we invest in could be subject to market risk. This means a change in prevailing interest rates may cause the value of the instruments to fluctuate. As of September 30, 2015, based on our current investment portfolio, we do not believe that our financial position or results of operations would be materially impacted by an immediate change of 10% in interest rates.

### **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, 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 and Chief 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 and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

#### ***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 September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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**

*In addition to the information included or incorporated by reference in this Quarterly Report, 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 included in the Final Prospectus.*

**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. We anticipate that our expenses will increase substantially if and as we:

- continue development of our product candidates;
- initiate new clinical trials for our product candidates;
- seek marketing approvals 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, obtaining marketing approval from the Food and Drug Administration, or FDA, 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 large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical 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 its 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 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 coverage or sufficient reimbursement for our products;
- our ability, and the ability of third parties such as clinical 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 an early-stage clinical development company. 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 and preparing for and undertaking clinical studies of our most advanced product candidate, tipifarnib. We have not yet demonstrated our ability to commence or successfully complete any clinical trials, including those clinical trials in support of FDA approval, 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, as a new business, 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 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. We do not have any committed external source of funds. 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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (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 may be limited. As a result of our recently completed private placement and public offering, and other transactions that have occurred over the past three years, we may have triggered an “ownership change” limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal and state taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

**Risks Related to the Discovery and Development of Our Product Candidates**

***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 is novel and may never lead to marketable products.***

The discovery and development of targeted drug 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 we will need to screen and identify these patients. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic alterations. 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 our products 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.

***Our research and development programs and product candidates are at an early stage of development. As a result we are unable to predict if or when we will successfully develop or commercialize our product candidates.***

Our clinical-stage product candidate, tipifarnib, as well as our other pipeline assets are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. We currently have no product candidates beyond Phase 2 clinical trials. We commenced a Phase 2 clinical trial of tipifarnib in advanced solid tumors with the HRAS mutation in May 2015, commenced a Phase 2 clinical trial in PTCL in September 2015 and anticipate commencing a Phase 2 clinical trial in patients with lower risk MDS in the first half of 2016. Our development candidate in our extracellular-signal-regulated kinases, or ERK, program, KO-947, is in IND-enabling pre-clinical development, and our other programs, including our menin-MLL program, are in earlier stages of discovery and development. Each of our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics. Companion diagnostics are subject to regulation as medical devices and we may be required to obtain marketing approval for accompanying companion diagnostics before we may commercialize our product candidates.

We cannot be certain that clinical development of tipifarnib or any of our other product candidates will be successful or that we will obtain regulatory approval or be able to successfully commercialize any of our product candidates and generate revenue. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. Any such failure could cause us to

abandon further development of any one or more of our product candidates and may delay development of other product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Tipifarnib has been studied in more than 5,000 oncology patients and was generally well tolerated and exhibited a manageable side effect profile. However, there is no guarantee that unacceptable side effects will not be identified in our clinical trials of tipifarnib. In prior studies tipifarnib demonstrated anti-cancer activity in certain patient subsets. However the anti-cancer activity observed was not sufficient to support marketing approval by the FDA in the indication in which it was sought. Although we are designing our clinical trials to target the patient subsets who we believe are most likely to benefit from treatment with tipifarnib, there is no guarantee that our clinical trials will be successful. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any new drug applications, or NDAs, with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenue.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our or our future collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, if required, 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 patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

***Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. We may find it difficult to enroll patients in our ongoing Phase 2 clinical trial for tipifarnib in HRAS mutant solid tumors or our ongoing Phase 2 clinical trial for tipifarnib in PTCL.***

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. The patient population for our product candidates is not completely defined, but it is substantially smaller than other cancer indications, because we are looking for the same type of genetic alterations across different tumor types and the number of patients with these alterations may be small. For example, with respect to tipifarnib, we do not know how many patients will have the target HRAS mutations that tipifarnib is expected to inhibit. With regard to our Phase 2 clinical trial in PTCL, there are a limited number of patients with PTCL, as well as a limited number of clinical centers that treat these patients, and there is substantial competition to recruit these patients to clinical trials.

In addition to the potentially small populations, 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.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product 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 FDA or institutional review board, or IRB, decisions; and
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results.

***We may not be successful in our efforts to build a pipeline of product candidates.***

A key element of our strategy is to build a pipeline of small molecule product candidates that inhibit cancer signaling targets where we believe outcomes can be improved by using molecular diagnostics to identify those patients whose tumors have the genetic mutations most likely to respond to treatment, and to progress those product candidates through clinical development for the treatment of a variety of different types of cancer. We may not be able to develop product candidates that are safe and effective inhibitors of all or any of these targets. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

***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 all of 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 later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. 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 issued a non-approval letter for tipifarnib in acute myelogenous leukemia, 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 IRBs have comments on our study plans for our ongoing or planned Phase 2 clinical trials of tipifarnib that we are required to address, such studies may be delayed. There can be no assurance that the FDA 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:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a 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 trial sites;
- inability, delay, or failure in identifying and maintaining a sufficient number of 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 trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a 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 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 would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

***We may not be successful in advancing the clinical development of our product candidates, including tipifarnib.***

In order to execute on our strategy of advancing the clinical development of our product candidates, we have designed our Phase 2 clinical trials of tipifarnib, and expect to design future trials, to include patients whose tumors harbor the applicable genetic alterations that we believe contribute to particular cancer subsets. Our goal in doing this is to enroll patients who have the highest probability of responding to the drug, in order to show early and statistically significant evidence of clinical efficacy. If we are unable to include patients whose tumors harbor the applicable genetic alterations, or if our product fails 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 trials and a greater likelihood of not obtaining regulatory approval. In addition, because the natural history of different tumor types is variable, we will need to study our product candidates, including tipifarnib, in clinical trials specific for a given tumor type and this may result in increased time and cost. Even if our product candidate demonstrates efficacy in a particular tumor type, we cannot guarantee that any product candidate, including tipifarnib, will behave similarly in all tumor types, and we will be required to obtain separate regulatory approvals for each tumor type we intend a product candidate to treat. If any of our clinical trials are unsuccessful, our business will suffer.

***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 have only recently licensed the rights to develop our lead product candidate, tipifarnib, from Janssen Pharmaceutica NV, or Janssen, 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 trials and studies 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 1990's. Any such deficiency in the prior development of tipifarnib may adversely affect our ability to obtain regulatory approval for tipifarnib. We and Janssen are in the process of transitioning the safety database from studies previously conducted by Janssen to us. We cannot assure you that our efforts to transition the database from Janssen will be completed on a timely basis, or at all. If we are unable to successfully complete the transition of Janssen's tipifarnib safety database to us on a timely basis, our development plans may be delayed, which could harm our business, prospects, financial condition and results of operations.

***If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.***

If our product candidates are associated with undesirable 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%. There is no guarantee that additional or more severe side effects will not be identified through further clinical studies. Rights to develop tipifarnib in certain non-oncology indications have been granted by Janssen to EB Pharma, a subsidiary of Eiger BioPharmaceuticals. Janssen may grant rights to other non-oncology indications to other third parties. Undesirable side effects may be identified in clinical trials that EB Pharma or any other third party may conduct in non-oncology indications, which may negatively impact the development, commercialization or potential value of tipifarnib. These or other drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. 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 the compound. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Because we have limited financial and managerial resources, we 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 a genetic alteration who may derive meaningful benefit from our drug product candidates. To achieve this, certain of our programs may be dependent on the development and commercialization of a companion diagnostic. We intend to partner development of companion diagnostics for use in clinical trials and, if successful, 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. Each agency that approves a product will independently need to approve the companion diagnostic before or concurrently with its approval of the product candidate, and before a product can be commercialized. 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.

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. 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 related product candidates.

***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 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 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. Our product candidates may not be effective, may be only moderately effective 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 expire in 2016 in the United States and in countries in Europe, our commercial strategy for tipifarnib relies on obtaining patents covering methods of use of 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, or NCE, 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 certain indications outside of our exclusive field of oncology and Janssen may license rights to other non-oncology indications to other third parties. If EB Pharma or another third party obtains regulatory approval for tipifarnib in a non-oncology indication before we obtain regulatory approval in one of our oncology indications, the five year exclusivity period would commence on the date upon which EB Pharma or another third party 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 would be harmed as a result.

Additionally, if EB Pharma or another third party obtains approval of tipifarnib for another indication outside of oncology, EB Pharma or the other third party may sell tipifarnib at a lower price, which could adversely affect the price at which we could sell tipifarnib for oncology 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 drug 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 Drug 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, 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 expect that we may in the future pursue an orphan drug designation for at least some of our product candidates, including tipifarnib. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so for any of our product candidates. Even if we were to obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from the competition of different drugs for the same 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 drug 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 drug designation and FDA approval of tipifarnib for an oncology indication, we would be entitled to seven years of marketing exclusivity for that orphan drug 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 such 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 for the FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular 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 may seek such 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, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

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

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. 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. 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-marketing regulatory requirements and could be subject to post-marketing 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 FDA and other regulatory authorities. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or 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, requirements regarding the distribution of samples to physicians, tracking and reporting of payments to physicians and other healthcare providers, and recordkeeping.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of 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-marketing 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 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, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- 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, or the HITECH Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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 ownership and investment interests held by physicians or their immediate family; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, imprisonment, exclusion of products 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 Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, 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 False Claims Act and the 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% 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.

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, will stay in effect through 2024 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.

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

***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 Our Dependence on Third Parties

***We expect to 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 trials.***

We will rely on third party contractors, clinical data management organizations, independent contractors, medical institutions and clinical investigators to support our pre-clinical development activities and conduct our clinical trials, including our Phase 2 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 would be delayed.

We compete with many other companies, some of which may be our 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 would 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 will reduce our control over these activities but will 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 trial. Moreover, the FDA and other regulatory authorities require us to comply with standards, commonly referred to as good clinical practices, or GCPs, 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 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 expect to 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 will 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. Janssen has provided us with its existing inventory of clinical supply of tipifarnib. Janssen also provided us with its existing inventory of crude drug substance and bulk key intermediate for manufacture of drug substance for tipifarnib. A portion of the clinical supply of tablets of tipifarnib provided by Janssen have a non-uniform surface where the film coating on the tablets has worn away to a varying degree. We believe this surface erosion is a cosmetic defect only and has no impact on patient safety or the effectiveness of the tablets, and an insignificant impact on taste masking, and that this clinical supply will support our ongoing and planned Phase 2 clinical trials for tipifarnib. However there is no guarantee that clinical trial participants will accept all the tablets and that our existing clinical supply will be sufficient for our ongoing and planned Phase 2 clinical trials or for any unanticipated extension of our Phase 2 clinical trials. If we are required to manufacture additional clinical supplies our Phase 2 clinical trials may be delayed. We rely, and expect to continue to rely, on third parties, for the manufacture of 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.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval.

Any performance failure on the part of our existing or future manufacturers 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;
- 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.

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.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

### **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. 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. 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 and any other future product candidates. See “Description of Our Business—Competition.”

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 and 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 the CMS, an agency within the U.S. Department of Health and Human Services, 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. Further, 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. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective.

Reimbursement agencies in Europe 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. 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.

***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 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 active pharmaceutical ingredient, or API, of tipifarnib expire in 2016 in the United States, countries in Europe and other jurisdictions. 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. Patent term extension may be available in the U.S. to account for regulatory delays in obtaining human marketing approval for tipifarnib; 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. Patent and Trademark Office, or 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 or formulations patents that we may hold. Competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We expect that following expiration of composition of matter 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 oncology indications 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 were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we 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.

Recent 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 recently 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, only 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. 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 to develop tipifarnib in the field of oncology, including patents and patent applications we exclusively licensed from Janssen, as well as exclusive worldwide licenses 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 use or proprietary rights held by third parties. 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 an early-stage clinical development company with a limited operating history, and, as of September 30, 2015, we had only 25 employees. We are highly dependent on the expertise of Troy E. Wilson, our President and Chief Executive Officer, Antonio Gualberto, our Chief Medical Officer, Yi Liu, our Chief Scientific Officer, and Pingda Ren, 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 NanoMedicines, 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.

***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.\****

Since November 5, 2015, shares of our common stock have been listed on the NASDAQ Global Select Market, and from September 16, 2015 to November 4, 2015, shares of our common stock were quoted for trading on the OTC Markets—OTCQB tier in very limited volume. From September 16, 2015 to November 10, 2015, the price per share of our common stock has ranged from a high of \$25.00 to a low of \$7.50. Prior to September 16, 2015, our common stock was not publicly-traded. We cannot predict the extent to which investor interest in our company will sustain an active trading market on the NASDAQ Global Select Market 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.

***The designation of our common stock as a “penny stock” would limit the liquidity of our common stock.***

Our common stock may be deemed a “penny stock” (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a “penny stock” is a common stock that is not listed on a securities exchange and trades for less than \$5.00 per share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stocks in start-up companies are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser’s written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there may be less trading activity in penny stocks in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

***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.

***Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to continue to attract the attention of research analysts at major brokerage firms.***

Because we did not become a reporting company by conducting an underwritten initial public offering of our common stock, security analysts of brokerage firms may not continue to provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for 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 registration statement with the SEC, which was declared effective on July 21, 2015, to register the resale of 14,279,820 shares of our common stock, which represents substantially all of the shares of our common stock issued in connection with the Merger. The shelf registration statement permits the resale of these shares at any time, subject to applicable lock-up restrictions described in the "Certain Relationships and Related Person Transactions—Lock-Up Provisions in Registration Rights Agreement" section of the Final Prospectus. 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.

***A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.\****

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Our directors, executive officers and certain stockholders who own an aggregate of approximately 5,205,061 shares of our common stock are subject to a lock-up agreement with us contained in the Registration Rights Agreement dated as of March 6, 2015 and/or a separate lock-up agreement with the underwriters of our recently completed public offering pursuant to which these persons have agreed, subject to specified exceptions, not to sell, transfer, dispose of, contract to sell, sell any option or contract to purchase, or otherwise transfer or dispose of, directly or indirectly, without the written consent of such underwriters, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock for a period of 180 days after the date of the Final Prospectus. Once these lock-up provisions expire, these shares, which are registered on our shelf registration statement that was declared effective on July 21, 2015, can be freely sold in the public market subject to limitations under applicable securities laws, which could cause the market price of our common stock to drop significantly.



***At any time when our shelf registration statement may not be available, the liquidity and price of our common stock could significantly decline and it may be difficult for you to sell your shares, if at all.\****

Although we filed a registration statement with the SEC, which was declared effective on July 21, 2015, to register the resale of 14,279,820 shares of our common stock, which represents substantially all of the shares of our common stock issued in connection with the Merger, and the shelf registration statement permits the resale of these shares at any time, subject to applicable lock-up restrictions described in the “Certain Relationships and Related Person Transactions—Lock-Up Provisions in Registration Rights Agreement” section of the Final Prospectus, such registration may not be available at all times. We are not currently eligible to register the resale of our common stock included in our shelf registration statement on Form S-3, and, therefore, have registered the resale of these securities on Form S-1. As a result, under certain circumstances, we must update the registration statement for the resale of such shares of our common stock by filing post-effective amendments to the registration statement that will not be effective until each is declared effective by the SEC. Between the time it is determined that the registration statement must be updated by a post-effective amendment and the time the SEC declares the applicable post-effective amendment effective, the registration statement will not be available for use and the price of our common stock could decline during that time. The SEC has broad discretion to determine whether any registration statement (including any post-effective amendment) will be declared effective and may delay or deny the effectiveness of any registration statement or post-effective amendment filed by us for a variety of reasons. Therefore, at any time when our shelf registration statement may not be available, the liquidity and price of our common stock could significantly decline and it may be difficult for you to sell your shares, if at all.

***We will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.***

As a public company, and particularly if and after we cease to be an “emerging growth company” or a “smaller reporting company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the rules and regulations of the SEC and NASDAQ impose numerous requirements on public companies, including requirements relating to our corporate governance practices, with which we will need to comply. Further, we are required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive.

Prior Kura was not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the Merger. Our management team and board of directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff and engaging consultants to assist in designing and implementing such procedures. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

***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 the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. 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 need to be evaluated frequently. 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 due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

***We are an emerging growth company and a smaller reporting 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 JOBS Act and a “smaller reporting company” as defined in applicable rules under the Exchange Act. As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain extended accounting standards and exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications. For instance, we are exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, 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 of 2002; 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 and/or a smaller reporting 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 a result of those respective classifications. As a result, our publicly available disclosure may not be as robust or comprehensive as that of other public reporting companies that do not qualify for those classifications.

***Management and our board of directors beneficially own a substantial amount of our outstanding equity securities and will be able to exert substantial control over us.***

Our executive officers and directors beneficially own a substantial percentage of our outstanding equity securities. Accordingly, if they act as a group, our executive officers and directors will be able to significantly influence all business decisions, including with respect to such matters as amendments to our charter, other fundamental corporate transactions such as mergers, asset sales and the sale of us, and otherwise will be able to significantly influence our business and affairs.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, outstanding stock options 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 could cause the market price of our common stock to decline.

Pursuant to our 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of September 30, 2015, we had 621,500 shares of common stock reserved for future issuance under our 2014 Plan and options to purchase up to an aggregate of 410,000 shares of common stock outstanding, each at an exercise price of \$6.32 per share. In addition, as of September 30, 2015, we had 25,000 shares of common stock reserved for future issuance under our 2015 ESPP. 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 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;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 $\frac{2}{3}$ % of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than 66 $\frac{2}{3}$ % of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; 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 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.

***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 future payment of cash dividends in the future would depend on our financial condition, contractual restrictions, 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**

See the Exhibit Index immediately following the signature page of this report.

## 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: November 13, 2015

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

Date: November 13, 2015

By: /s/ Heidi Henson  
Heidi Henson  
Chief Financial Officer and Secretary  
(Principal Financial and Accounting Officer)

**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.		S-1 (Exhibit 3.1)	4/17/2015	333-203503
3.2	Certificate of Merger relating to the Merger of Kura Operations, Inc. with and into Kura Oncology, Inc., filed with the Secretary of State of the State of Delaware on March 6, 2015.		8-K (Exhibit 3.3)	3/12/2015	000-53058
3.3	Certificate of Ownership and Merger relating to the merger of Kura Oncology, Inc. with and into the Registrant, filed with the Secretary of State of the State of Delaware on March 6, 2015, relating to the name change of the Registrant.		8-K (Exhibit 3.4)	3/12/2015	000-53058
3.4	Amended and Restated Bylaws of the Registrant.		8-K (Exhibit 3.5)	3/12/2015	000-53058
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
10.1+	Kura Oncology, Inc. Non-Employee Director Compensation Policy, as amended.		S-1 (Exhibit 10.13)	10/20/2015	333-207534
10.2	Office Lease, dated August 1, 2015, by and between Kura Oncology, Inc. and 55 Cambridge Parkway, LLC.		S-1 (Exhibit 10.16)	10/20/2015	333-207534
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350	X			
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definition.				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	XBRL Taxonomy Presentation Linkbase Document				

+ Indicates management contract or compensatory plan.

## CERTIFICATION

I, Troy E. Wilson, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2015

/s/ Troy E. Wilson

Troy E. Wilson, Ph.D., J.D.

President and Chief Executive Officer

## CERTIFICATION

I, Heidi Henson, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2015

/s/ Heidi Henson

---

Heidi Henson

Chief Financial Officer and Secretary

**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 September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, as President and Chief Executive Officer of the Company, and Heidi Henson, as Chief Financial Officer and Secretary of the Company, each 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.

/s/ Troy E. Wilson

\_\_\_\_\_  
Troy E. Wilson, Ph.D., J.D.  
President and Chief Executive Officer

/s/ Heidi Henson

\_\_\_\_\_  
Heidi Henson  
Chief Financial Officer and Secretary

Date: November 13, 2015

Date: November 13, 2015