

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

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 North Torrey Pines Road, Suite 125, La Jolla, CA

(Address of principal executive offices)

61-1547851

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

92037

(Zip Code)

Registrant's telephone number, including area code: (858) 500-8800

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

Title of each class
Common Stock, par value \$0.0001 per share

Name of each exchange on which registered
The Nasdaq Global Select Market

Securities registered pursuant to 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES NO

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a small reporting company)

Small reporting company

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

The aggregate market value of the voting and non-voting of common equity held by non-affiliates of the registrant was approximately \$45.8 million as of June 30, 2016 based on the closing price of \$2.71 as reported on the Nasdaq Global Select Market on such date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of March 10, 2017 was 21,384,817.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the registrant's 2017 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2016.

KURA ONCOLOGY, INC.
TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1. Business	2
Item 1A. Risk Factors	29
Item 1B. Unresolved Staff Comments	59
Item 2. Properties	59
Item 3. Legal Proceedings	59
Item 4. Mine Safety Disclosures	59
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	60
Item 6. Selected Financial Data	61
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	62
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	67
Item 8. Financial Statements and Supplementary Data	67
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	68
Item 9A. Controls and Procedures	68
Item 9B. Other Information	68
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	69
Item 11. Executive Compensation	69
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	69
Item 13. Certain Relationships and Related Transactions, and Director Independence	69
Item 14. Principal Accounting Fees and Services	69
PART IV	
Item 15. Exhibits, Financial Statement Schedules	70
Item 16. Form 10-K Summary	70
SIGNATURES	71

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “targets,” “likely,” “will,” “would,” “could,” “should,” “continue,” and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. The sections in this Annual Report entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this Annual Report, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our research and development activities, clinical trials and preclinical studies;
- the early stage of products under development;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our future product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- government regulation;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;
- our ability to obtain additional financing;
- our use of cash, cash equivalents, investments and other resources;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act, or JOBS Act;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; and
- our ability to attract and retain key management, scientific or clinical personnel.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this Annual Report, particularly in the “Risk Factors” section, that we believe could cause actual

results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we reference in this Annual Report, completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and we do not assume, and specifically disclaim, any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We intend to advance our product candidates through a combination of internal development and strategic partnerships and maintain significant development and commercial rights.

Precision medicine is an approach to the treatment of cancer in which treatment decisions are made based upon the presence or absence of specific molecular or genetic biomarkers that characterize an individual's tumor. As diagnostic testing of cancer patients has become more widespread, we are learning that tumors arising in diverse sites in the body may share the same types of molecular or genetic alterations, and it is those alterations that drive the cancer rather than the tissue of origin. In addition, research and clinical data suggest that some tumors have specific alterations that render them highly susceptible to product candidates that target those specific alterations.

Our lead product candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase. Tipifarnib has been studied in more than 5,000 cancer patients and has demonstrated compelling and durable anti-cancer activity in certain patients with a manageable side effect profile. We are evaluating tipifarnib in four Phase 2 clinical trials: the first in patients with locally advanced solid tumors that carry mutations in the Harvey rat sarcoma viral oncogene homolog, or HRAS, gene; the second in patients with peripheral T-cell lymphomas, or PTCL; the third in patients with lower risk myelodysplastic syndromes, or MDS; and the fourth in patients with chronic myelomonocytic leukemia, or CMML. Our goals with our ongoing Phase 2 clinical trials of tipifarnib are to confirm the clinical activity of tipifarnib in each disease indication, to validate biomarker hypotheses and to optimize dose and schedule for each disease to build a data package supporting advancement to pivotal study.

Our second product candidate is KO-947, a potent and selective small molecule inhibitor of extracellular signal related kinase, or ERK, which we are advancing as a potential treatment for patients with tumors that have mutations in, or other dysregulation of, the mitogen-activated protein kinase, or MAPK, signaling pathway. KO-947 demonstrates prolonged pathway inhibition, both in cells, or in vitro, and in animal models, or in vivo, enabling the potential for intermittent dosing on schedules up to once weekly. Additionally, the drug properties of KO-947 support an intravenous formulation, which may allow for higher drug concentration, and potentially improved tolerability in the clinic. We submitted an investigational new drug, or IND, application for KO-947 to the Food and Drug Administration, or FDA, which became effective in December 2016, and we anticipate initiation of our Phase 1 clinical trial of KO-947 in the first half of 2017.

Our third program is KO-539, a potent and selective small molecule inhibitor of the menin-mixed lineage leukemia, or menin-MLL, protein-protein interaction. Chromosomal translocations of the MLL gene play a causative role in the onset, development and progression of a subset of acute leukemias, and the activity of the MLL fusion proteins are critically dependent on binding the protein menin. Our preclinical data demonstrates that inhibitors of the menin-MLL interaction induced robust and durable regressions in multiple models of MLL-fusion leukemias. We nominated KO-539 as a development candidate for this program in December 2016.

Unless the context requires otherwise, references in this Annual Report to "Kura," "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 our reverse merger transaction which took place on March 6, 2015, or the Merger, 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.

Strategy

Our strategy is to discover, acquire, develop and commercialize innovative anti-cancer agents in oncology indications with significant unmet medical need and attractive commercial potential. The key components of our strategy include the following:

- Focus on developing novel, small molecule product candidates for the treatment for cancer;
- Identify molecular or genetic characteristics of patient tumors to identify patients more likely to benefit from our product candidates;
- Leverage clinical and pathology trends towards comprehensive tumor profiling and the use of companion diagnostics;
- Prioritize development of tipifarnib in clinical indications of high unmet need where improved outcomes are associated with specific biomarkers;
- Advance our pre-clinical programs into clinical proof-of-concept studies through a combination of internal development and strategic partnerships;
- Maintain significant development and commercial rights to our product candidates; and
- Build a sustainable product pipeline.

Precision Medicines in Cancer Treatment

Advancements in cancer genetics and new molecular diagnostic tools are helping define why some patients respond to a specific 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 specific cancers. We aim to improve patient outcomes and contribute to the reduction in healthcare costs by matching targeted therapeutics to the patients who will derive the most benefit. We are developing a pipeline of small molecule product candidates 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. This approach to treatment is known as precision medicine.

A pioneering example of a precision medicine in cancer was the development of small molecule inhibitors against epidermal growth factor receptor, or EGFR, in patients with advanced lung cancer. Researchers discovered that a subset of a lung cancer was associated with dysregulation of EGFR, and several small molecule product candidates, including erlotinib (Tarceva®) and gefitinib (Iressa®), were discovered and advanced into clinical testing. During the clinical trials, investigators realized that patients who had mutations in EGFR experienced a much higher response rate, defined as the proportion of patients with meaningful tumor shrinkage on their clinical imaging scans, relative to an unselected patient population when treated with Tarceva or Iressa. Specifically, patients with EGFR mutations have a response rate in the 65% range, as opposed to the 10% range noted in unselected lung patients. Tarceva was subsequently approved in the United States as a first-line treatment for patients with non-small cell lung cancer characterized by EGFR mutations. Other examples of approved agents developed using precision medicine approaches include inhibitors of anaplastic lymphoma kinase, or ALK, inhibitors of the Philadelphia chromosome, or BCR-ABL, and inhibitors of B-Raf proto-oncogene, serine/threonine kinase, or BRAF.

Precision medicine has several advantages over traditional drug development. We believe evidence-based selection of patients who are more likely to respond to a targeted therapy based on tumor biology provides the potential for: higher translatability from preclinical to clinical studies; increased overall response rates requiring fewer patients for clinical development; and expedited clinical development in areas of high unmet need. We believe the precision medicine approach has the potential for more efficient drug development with reduced risks, costs and timelines. However, achieving success through a precision medicine approach is predicated on a thorough understanding of tumor biology and the mechanism of action of the product candidate. To develop this understanding, we have conducted extensive translational research on each of our programs.

Our Approach to Development of Precision Medicines in Oncology

Translational research is the practice of synthesizing our knowledge of basic research, preclinical and clinical data to develop a “bench-to-bedside” understanding of the potential of our product candidates, and it is the principal methodology we utilize to guide our precision medicine approach. We evaluate our product candidates through both in vitro and in vivo experiments to evaluate their potential as therapeutics. One of the key tools we employ are patient-derived xenograft, or PDX, models. PDX models mostly retain the principal histologic and genetic characteristics of their donor tumor and have been shown in many instances to be predictive of clinical outcomes and are increasingly being used for preclinical drug evaluation, biomarker identification, biologic studies and personalized medicine strategies. We evaluate our product candidates in preclinical PDX studies seeking to corroborate clinical data and in our preclinical programs, to identify potential clinical indications.

In our experience, preclinical studies in PDX models are likely to be more informative late in preclinical development once we have generated a product candidate that we believe sufficiently inhibits the therapeutic target of interest. PDX models can be selected based on tumor types or on predefined molecular subtypes if that information is known and of interest, or both. We typically follow a two-step approach. In the first step, we use a limited number of models and test them with our product candidate at doses and schedules known to be effective and pharmacologically active in earlier preclinical studies. Data from the first step can be used to proceed to a second step and to refine model selection based on molecular understanding of responsive models. In the second step, a larger repertoire of models can be treated. The results of such a PDX campaign can inform our decision of whether to proceed to clinical development and which indications and biomarkers to prioritize in the clinical phase.

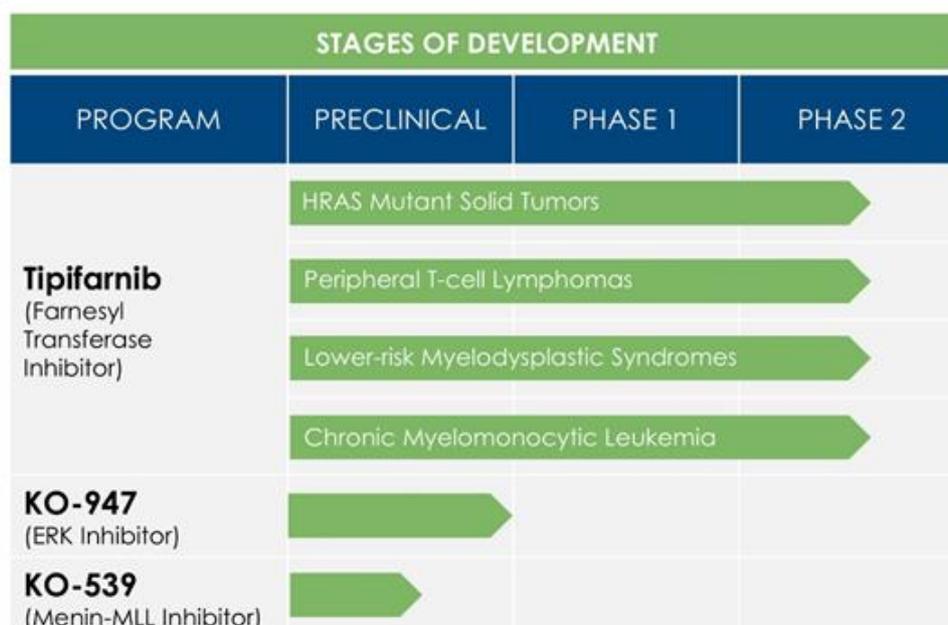
Because we often target molecular and/or genetic alterations that are detectable, companion diagnostic tests can be developed to identify these alterations. Once we have identified a target, we will initially use existing diagnostic tools to identify patient subsets that we believe will derive increased benefit from our product candidates. As we advance our product candidates clinically and determine the most important screening criteria, we intend to develop companion diagnostics as appropriate, with the help of technology partners, to seek to identify patients, and if our clinical development programs are successful, to support the potential registration and marketing of our product candidates.

Our clinical development strategy employs a disciplined approach designed to identify response signals early in development and reduce development risks. Based upon the data from our preclinical studies as well as any data from any third party preclinical and clinical data, we seek to evaluate our product candidates in well-defined patient populations and believe this gives us a higher likelihood of demonstrating a clinical benefit. This approach is intended to allow for early insight into the therapeutic potential of a product candidate and the possibility for rapid clinical development and expedited regulatory strategies.

We are employing some or all the steps above across our various programs as we advance our pipeline of targeted therapies. We believe the advantages of such an approach are the potential for higher translatability from preclinical to clinical studies, our ability to leverage clinical and pathology trends towards comprehensive tumor profiling and the potential for expedited clinical development.

Clinical Programs and Pipeline

The following table summarizes our current product pipeline:



Tipifarnib —An Oral Farnesyl Transferase Inhibitor

Overview

Tipifarnib is a new chemical entity, or NCE, and a member of a class of product candidates called farnesyl transferase inhibitors, or FTIs. Protein farnesylation is a key cell signaling process implicated in various cancer processes, including survival, growth and proliferation of tumor cells. Tipifarnib has been studied in more than 5,000 oncology patients and was observed to be generally well tolerated with a manageable side effect profile as a single agent. Although tipifarnib has a well-established safety profile and has demonstrated compelling and durable anti-cancer activity in certain patients, its activity has not been sufficient in any prior clinical trial to support marketing approval by the FDA. However, clinical and preclinical data suggest that, in certain selected patient populations, tipifarnib has the potential to provide significant benefit to cancer patients with limited treatment options. Objective responses with evidence of durable clinical benefit have previously been observed in each of the four cancer types currently under Phase 2 study at Kura. We in-licensed tipifarnib from Janssen Pharmaceutica NV, or Janssen, an affiliate of Johnson & Johnson, in December 2014, and have worldwide rights in all indications other than virology.

Development Strategy for Tipifarnib

Our development strategy employs a stepwise, disciplined approach, building upon prior observations of clinical benefit and designed to identify response signals early in development and reduce development risks. Based upon clinical data from us and others, including Janssen, as well as data from our preclinical studies, we seek to evaluate tipifarnib in well-defined patient populations that we believe give us a higher likelihood of demonstrating a compelling clinical benefit.

We currently have four company sponsored Phase 2 clinical studies ongoing with tipifarnib: the first in patients with squamous cell carcinomas of the head and neck, or SCCHN, that carry HRAS mutations, and patients with HRAS mutant thyroid cancer; the second in patients with PTCL; the third in patients with lower-risk MDS; and the fourth in patients with CMML. Tipifarnib is also being evaluated in an investigator sponsored clinical trial in patients with urothelial carcinoma tumors characterized by HRAS mutations.

Our goals with our ongoing Phase 2 clinical trials of tipifarnib are to confirm the clinical activity of tipifarnib in each disease indication and to optimize dose and schedule for each disease to build a data package supporting advancement to

pivotal study. In addition, we are seeking to address a set of criteria, which if satisfied, would support further clinical development. Those criteria include: biomarker validation; evidence of durable clinical benefit, potential for rapid clinical development; potential to move into earlier lines of therapy; attractive U.S. oncology commercial market; and potential for patent and regulatory exclusivity.

We anticipate we will have additional data from our Phase 2 clinical trial in HRAS mutant solid tumors and from our Phase 2 clinical trial in PTCL in 2017 and data from our Phase 2 clinical trial in lower-risk MDS and our Phase 2 clinical trial in CMML in the first half of 2018. If the data from one or more of these Phase 2 clinical trials supports further clinical development, we would plan to initiate a registrational clinical trial of tipifarnib in at least one disease indication.

Protein Farnesylation and Tipifarnib

Tipifarnib is a potent and selective inhibitor of protein farnesylation. Certain cellular proteins must associate with the intracellular membrane to function. One of the mechanisms by which proteins are associated with the membrane is protein farnesylation, which modifies the protein by attaching a farnesyl group. Another, related mechanism is protein geranylgeranylation, which is attachment of a geranylgeranyl group to the protein. Protein farnesylation and protein geranylgeranylation, collectively called protein prenylation, cause intracellular proteins to become anchored to the inside of the cell membrane due to the hydrophobic nature of the farnesyl and geranylgeranyl groups.

The enzyme that catalyzes the attachment of the farnesyl groups to proteins is called farnesyl transferase. Small molecule inhibitors of the FTIs have been discovered, and several including tipifarnib have been evaluated in human clinical trials. Many proteins involved in cellular signaling undergo prenylation because they must be associated with other proteins at the inner cellular membrane of the tumor cell to function. Treatment of tumors with FTIs results in the reversal of several hallmarks of cancer, including mitotic arrest, induction of apoptosis, growth inhibition, invasion, angiogenesis and tumor growth, as well as induction of tumor regression in animal models.

Among the hundreds of proteins that are estimated to be prenylated, most are either exclusively farnesylated or geranylgeranylated; some are both farnesylated and geranylgeranylated, and others are naturally farnesylated but become geranylgeranylated, when farnesyl transferase is inhibited. HRAS is an example of a protein that is exclusively farnesylated while Kirsten rat sarcoma viral oncogene homolog, or KRAS, and neuroblastoma RAS viral oncogene homolog, or NRAS, are two proteins that are naturally farnesylated but may become geranylgeranylated upon treatment with FTIs.

One of our strategies is to identify the farnesylated proteins and signaling pathways, the inhibition of which is responsible for the antitumor effects of tipifarnib. In our ongoing Phase 2 clinical trial of patients with HRAS mutant SCCHN, our initial clinical activity demonstrates that HRAS is one such protein. Similarly, our preclinical data in PDX models of SCCHN also demonstrate consistent and significant anti-tumor activity. In our ongoing Phase 2 clinical trial of patients with CMML, we are evaluating our hypothesis that tipifarnib may be less efficacious in patients with mutations in either NRAS or KRAS, which we believe is due to their ability to utilize the geranylgeranyl transferase for localization to the intracellular membrane and leads to resistance to tipifarnib.

With an improved understanding of the molecular mechanism of action of farnesylation as well as new approaches and technologies, including next-generation sequencing, or NGS, we believe we can identify proteins critically important to tumor cells and that are uniquely farnesylated. This may both enhance our understanding of the mechanism of action of tipifarnib, and enable us to select patients whose tumors are sensitive to inhibition of farnesyl transferase and who are more likely to respond to these treatments.

HRAS Mutant Tumors

Market Opportunity

Retrovirus-associated DNA sequences, or RAS, is a family of membrane-associated proteins that are involved in regulating cell division in response to growth factor stimulation. HRAS is a member of the RAS family, which includes two other proto-oncogenes: KRAS and NRAS. Collectively, the three RAS genes constitute one of the most frequently mutated families of oncogenes in human cancers. Although HRAS mutations are less common overall relative to KRAS and NRAS mutations, they have a relatively high prevalence in cancers of the upper digestive tract, skin, thyroid and urinary bladder.

Collectively, cancers that have an HRAS mutation are estimated to have an annual incidence of approximately 8,000 patients in the United States. SCCHN and squamous non-small cell lung cancer, or Sq-NSCLC, are together estimated to

represent more than half the total, with an estimated annual U.S. incidence of approximately 2,800 to 3,400 patients for SCCHN and 1,000 to 1,700 patients for Sq-NSCLC.

SCCHN is a cancer that arises from a squamous cell. Squamous cells are found in the outer layer of skin and in the mucous membranes, which are the moist tissues that line body cavities such as the airways and intestines. SCCHN develops in the mucous membranes of the mouth, nose, and throat and is classified by its location. SCCHN is caused by a variety of factors that can alter the DNA in cells. The strongest risk factors for developing this form of cancer are tobacco use, including smoking or using chewing tobacco, and heavy alcohol consumption. In addition, infection with certain strains of human papillomavirus, or HPV, is linked to the development of SCCHN. HPV infection is one of the factors that accounts for the increasing incidence of SCCHN among younger people.

Researchers have identified mutations in many genes in people with SCCHN; however, it is not yet clear what role most of these mutations play in the development or progression of cancer. One gene implicated in the development and progression of SCCHN is HRAS, and HRAS mutant SCCHN represents a significant unmet medical need. The relapsed and/or refractory SCCHN patient population has an overall survival of approximately six to eight months and few therapeutic options, and new therapies, including immunotherapy, typically show a response rate in the range of 10-20%.

In addition to HRAS mutations present at the time of initial diagnosis, both published preclinical and clinical data suggest that the proportion of patients with HRAS mutations increases as HRAS is a mechanism of resistance to anti-EGFR therapy in SCCHN. HRAS mutations have been shown to be a mechanism of resistance to both erlotinib and cetuximab in SCCHN cell lines, and RAS-mediated acquired resistance to cetuximab has been observed in SCCHN patients. As cetuximab in combination with chemotherapy represents a current standard of care for the front-line treatment of patients with SCCHN, the potential presence of HRAS mutations as a mechanism of acquired resistance could enlarge the potential market opportunity for tipifarnib as a treatment for HRAS mutant SCCHN.

HRAS as a Human Oncogene

The HRAS protein is involved in regulating cell division in response to growth factor stimulation. Growth factors act by binding cell surface receptors that span the cell's plasma membrane. Once activated, receptors stimulate signal transduction events in the cytoplasm, a process by which proteins and second messengers relay signals from outside the cell to the cell nucleus and instruct the cell to grow or divide. HRAS is localized in the plasma membrane, and is an early player in many signal transduction pathways. HRAS acts as a molecular on/off switch – once HRAS is turned “on” it recruits and activates proteins necessary for the propagation of the receptor's signal. In certain tumors, mutations in HRAS or its upstream regulators cause HRAS to be permanently “on,” resulting in persistent activation of downstream growth and proliferation signals that drive tumor cell growth. FTIs work to prevent the aberrant growth and proliferation of cells that are dependent on these signaling pathways by inhibiting protein farnesylation and subsequent membrane localization of HRAS, thereby switching HRAS “off.” HRAS membrane localization is solely dependent on protein farnesylation, and therefore we believe that tipifarnib has the potential for the treatment of HRAS mutant solid tumors.

Clinical Development in HRAS Mutant Tumors

We initiated a Phase 2 clinical trial in May 2015 to test the hypothesis that tipifarnib can be used as a treatment for advanced tumors with a known HRAS mutation. We designed this clinical trial based on preclinical data which demonstrated that tipifarnib inhibits HRAS mutant cell proliferation and HRAS tumor growth in mouse models. Sponsorship of the investigational new drug application, or IND, for tipifarnib previously filed by Janssen has been transferred to us. The clinical trial is designed to enroll 2 cohorts of 18 patients each. Cohort 1 is enrolling subjects with malignant thyroid tumors with HRAS mutations, independently of thyroid histology. Cohort 2 was initially designed to enroll any subject with a non-hematological HRAS mutant tumor other than thyroid cancer who meets the eligibility criteria. This clinical trial has a two-stage study design to minimize the number of study subjects treated if tipifarnib is not sufficiently efficacious. If more than one response is observed in the cohort, seven additional subjects will be enrolled (stage 2). If one or no objective response is observed in a cohort after the first 11 evaluable patients, the cohort will be closed to further enrollment. The clinical trial will be considered positive if at least four responses are observed in a cohort (out of 18 subjects). The primary endpoint is objective response rate, and tumor response assessments will be conducted according to Response Evaluation Criteria in Solid Tumors version 1.1 criteria (confirmation of response is required).

In March 2017, we presented data from stage 1 of our ongoing Phase 2 HRAS clinical trial at the 15th International Congress on Targeted Anticancer Therapies, including data from a small cohort of three patients with HRAS mutant SCCHN as well as data from preclinical studies. We reported that, among the three patients with HRAS mutant SCCHN treated with

tipifarnib, we had observed two patients with confirmed partial responses, who had been on study for more than 16 months and 10 months, respectively, as well as a third patient who experienced disease stabilization for seven months. We also reported data on a small cohort of patients with HRAS mutant salivary gland cancer, who experienced prolonged disease stabilization.

Our clinical and preclinical data suggests that, among cancers with HRAS mutations, squamous cell tumors, such as SCCHN and Sq-NSCLC, are among the more sensitive tumors to treatment with tipifarnib. Based upon the clinical activity we observed in patients with HRAS mutant SCCHN treated with tipifarnib, we have amended the protocol of our Phase 2 clinical trial to focus enrollment in the second stage of the second cohort entirely on patients with HRAS mutant SCCHN. To facilitate enrollment, we are adding additional clinical sites outside the United States and are engaging with third party laboratories to provide screening of patient samples for HRAS mutant status. Additionally, we are exploring opportunities to evaluate the activity of tipifarnib in HRAS mutant Sq-NSCLC.

Investigator Sponsored Trial in HRAS Mutant Urothelial Carcinoma

In addition to the company sponsored Phase 2 clinical trials, a Phase 2 investigator sponsored clinical trial of tipifarnib for the treatment of advanced, previously treated urothelial carcinomas that carry HRAS mutations, was initiated in November 2015. This clinical trial is sponsored by the Samsung Medical Center and designed to enroll at least 18 patients. The primary endpoint of this clinical trial is objective response rate, and secondary endpoints include progression-free survival, duration of response, and safety.

Companion Diagnostics

Patients are currently being enrolled in the Phase 2 HRAS mutant tumor clinical trials based either upon information from the clinical sites on the patients' tumor HRAS mutation status or upon this information obtained from third party laboratories who conduct genetic screening on patient samples for the clinical sites. If the results of our Phase 2 clinical trial in HRAS mutant SCCHN cancer are positive, we plan to partner development and validation of a companion diagnostic test to aid in the selection of patients with HRAS mutant tumors in subsequent clinical trials of tipifarnib and to prepare and submit an investigational device exemption, or IDE, for use of the assay in such clinical trials. We expect that the companion diagnostic test will either be a qualitative polymerase chain reaction, or qPCR, -based assay or an NGS-based assay. A qPCR-based assay would be technically similar to the qPCR-based assay already developed and approved by the FDA for KRAS. We expect that regulatory approval of tipifarnib as a treatment for patients with HRAS mutant tumors will require FDA approval of an HRAS assay in the form of a companion diagnostic test that has been validated for accuracy, precision and reproducibility.

Peripheral T-Cell Leukemia

Market Opportunity

Lymphoma is the most common blood cancer. The two main forms of lymphoma are Hodgkin's lymphoma, or HL, and Non-Hodgkin's lymphoma, or NHL. Lymphoma occurs when cells of the immune system called lymphocytes grow and multiply uncontrollably. Cancerous lymphocytes can travel to many parts of the body, including the lymph nodes, spleen, bone marrow, blood, or other organs, and form tumors. The body has two main types of lymphocytes that can develop into lymphomas: B-cells and T-cells.

PTCL consists of a group of rare and usually aggressive (fast-growing) NHLs that develop from mature T-cells. PTCLs collectively account for about five to ten percent of all NHL cases, corresponding to an annual incidence of approximately 5,000 patients per year in the United States. By some estimates, the incidence of PTCL is growing significantly, and the increasing incidence may be attributable to an aging population.

PTCLs are sub-classified into various subtypes, each of which are typically considered to be separate diseases based on their distinct clinical differences. Most of these subtypes are rare; the three most common subtypes are PTCL not otherwise specified, angioimmunoblastic T-cell lymphoma, or AITL, and anaplastic large-cell lymphoma, or ALCL, that collectively account for approximately 70 percent of all PTCLs in the United States.

Treatment Options for PTCL

For most PTCL subtypes, the frontline treatment regimen is typically combination chemotherapy, such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), EPOCH (etoposide, vincristine, doxorubicin, cyclophosphamide, prednisone), or other multi-drug regimens.

Patients who relapse or are refractory to frontline treatments are typically treated with gemcitabine in combination with other chemotherapies, including gemcitabine, vinorelbine (Navelbine®) and doxorubicin (Doxil®) in a regimen called GND, or other chemotherapy regimens such as DHAP (dexamethasone, cytarabine, cisplatin) or ESHAP (etoposide, methylprednisolone, cytarabine, and cisplatin).

Because most patients with PTCL will relapse, some oncologists recommend giving high-dose chemotherapy followed by an autologous stem cell transplant to some patients who had a good response to their initial chemotherapy. Non-cytotoxic therapies that have been approved for relapsed or refractory PTCL, such as pralatrexate (Foloty®), romidepsin (Istodax®) and belinostat (Beleodaq®), are associated with relatively low objective response rates (25-27% overall response rate, or ORR) and relatively short durations of response (8.2-9.4 months). Accordingly, we believe the treatment of relapsed/refractory PTCL remains a significant unmet medical need.

The five-year survival for patients with PTCL is low—roughly 35% by most published records—and few treatment options provide a durable treatment effect. Treatments in the relapsed or refractory setting are not very effective. Therefore, National Comprehensive Cancer Network guidelines currently recommend that patients seek participation in a clinical trial for the initial treatment.

Previous Phase 2 Experience with Tipifarnib in the Treatment of PTCL

A prior Phase 2 clinical trial of tipifarnib was sponsored by the National Cancer Institute and conducted at the Mayo Clinic and University of Iowa from 2004 to 2009 in adult patients with relapsed or refractory lymphoma. As part of that study, 93 patients with various B-cell and T-cell lymphomas were enrolled, including 17 patients with T-cell lymphoma, and patients received tipifarnib 300 mg twice daily on days 1-21 of each 28-day cycle. Tipifarnib was generally well tolerated on this dose and schedule. Across all 93 patients, the grade 3 or 4 toxicities were primarily reversible myelosuppression, with 11% anemia, 37% neutropenia, and 32% thrombocytopenia.

Although the clinical trial enrolled a relatively small number of patients with T-cell lymphomas, a 41% response rate (seven responses out of 17 patients) was observed in patients with T-cell NHL, including four objective responses out of eight patients with PTCL (three complete response, or CR, and one partial response). We believe the results observed from this Phase 2 clinical trial suggest that tipifarnib can be administered for prolonged periods and may produce durable responses as a single agent in relapsed lymphoma in a group of patients who were heavily pretreated, including those with PTCL.

Clinical Development in PTCL

Based on the promising results observed in the Phase 2 lymphoma study at the Mayo Clinic and University of Iowa, we initiated a Phase 2 clinical trial in September 2015 to test the hypothesis that tipifarnib can be used as a treatment for relapsed or refractory PTCL. This clinical trial is being conducted under the IND that was transferred to us from Janssen. Our goals with the Kura-sponsored Phase 2 clinical trial are to confirm the clinical activity of tipifarnib, to validate biomarker hypotheses and to optimize dose and schedule for the treatment of patients with relapsed or refractory PTCL.

The current study protocol has a two-stage design for a total number of 18 eligible patients. If one or no objective response is observed after the first 11 evaluable patients (stage 1), the study will be closed to further enrollment. If more than one response is observed, seven additional patients will be enrolled (stage 2). The clinical trial will be considered positive if at least four responses are observed (out of 18 patients). The primary endpoint is objective response rate, and tumor response assessments are conducted according to the International Workshop Criteria for the assessment of responses in lymphoma. Potential biomarkers that may contribute to the identification of patients who may benefit from tipifarnib therapy will be investigated in the study. These include genes that are expressed and/or mutated in tumor samples, and blood circulating cytokines.

In March 2017, we reported that both stage 1 and stage 2 of the Phase 2 clinical trial have been fully enrolled. We have observed initial signals of clinical activity, including three objective responses, and one additional patient is pending best response assessment. In addition, potential biomarkers have been identified that may allow us to identify patients who are more likely to benefit from treatment with tipifarnib. Based on this preliminary data we have amended the trial protocol to enroll approximately 12 additional patients to seek to verify the initial observations.

Myelodysplastic Syndromes

Market Opportunity

MDS are a group of hematopoietic stem cell malignancies with significant morbidity and mortality. MDS is characterized by ineffective blood cell production, or hematopoiesis, leading to low blood cell counts, or cytopenias, and high risk of progression to acute myeloid leukemia, or AML. MDS is a highly heterogeneous disease, and the severity of symptoms and disease progression can vary widely among patients. The current standard clinical tool to evaluate risk stratification, including survival and risk for AML transformation, and treatment options is the revised International Prognostic Scoring System, or IPSS-R. The IPSS-R differentiates patients into five risk groups (Very Low, Low, Intermediate, High, Very High) based on evaluation of cytogenetics, percentage of blasts (undifferentiated blood cells) in the bone marrow, hemoglobin levels, and platelet and neutrophil counts.

According to the American Cancer Society, or ACS, the annual incidence of MDS is approximately 13,000 patients in the United States, the majority of which are 60 years of age or older. The estimated prevalence is over 60,000 patients in the United States. Approximately 75% of patients fall into the IPSS-R risk categories of Very Low, Low, and Intermediate, collectively known as lower risk MDS, which is our target patient population for our planned Phase 2 MDS clinical trial.

Treatment Options for MDS

Therapeutic options fall into three categories including supportive care, low intensity therapy and high intensity therapy. Supportive care includes the use of red blood cell and platelet transfusions as well as administration of hematopoietic cytokines such as erythropoiesis stimulating agents or colony stimulating factors to improve blood counts. Low intensity therapies include hypomethylating agents such as azacytidine (Vidaza®) and decitabine (Dacogen®), biological response modifiers such as lenalidomide (Revlimid®), and immunosuppressive treatments such as cyclosporine A or antithymocyte globulin. High intensity therapies include chemotherapeutic agents such as idarubicin, cytarabine, fludarabine and topotecan, and hematopoietic stem cell transplantation.

National Comprehensive Cancer Network, or NCCN, guidelines recommend that lower risk patients (IPSS-R groups Very Low, Low, Intermediate) receive supportive care or low intensity therapies with the major therapeutic goal of hematologic improvement, or HI. A substantial portion of lower risk MDS patients lack effective therapies, and NCCN guidelines recommend clinical trials as additional therapeutic options. We believe that treatment of MDS remains a significant unmet need requiring the development of novel therapies.

Previous Phase 2 Experience with Tipifarnib in the Treatment of MDS

A prior Phase 2 clinical trial of tipifarnib was sponsored by Johnson & Johnson and conducted at 19 sites in seven countries from 2002 to 2006 in adult patients with intermediate to high risk MDS. This study also included patients with chronic myelomonocytic leukemia. Eighty-two patients with IPSS-R scores of Intermediate-1, Intermediate-2, and High risk MDS were enrolled in the study, and patients received tipifarnib 300 mg twice daily on days 1-21 of each 28-day cycle. The median age of patients was 67 (range 39-86 years). The median time since diagnosis was 8.8 months (range 0-128 months) and 37% (30 of 82) had been received prior therapy. The ORR for all patients was 31.7% (26 of 82), with 14.6% (12 of 82) CR and 17.1% (14 of 82) HI. In the 12 complete responders, the median response duration was 11.5 months (range 2.0-21.9 months), and the median TTP was 12.4 months (3.9-23.8 months). Median duration of HI was 18 weeks (range six to 76 weeks). Median OS was 11.7 months for all patients.

Tipifarnib was generally well tolerated. Ten patients died during the treatment period with five deaths due to progressive disease and five due to an adverse event of which only one was considered drug-related. This death was due to coronary insufficiency triggered by anemia and severe internal bleeding in the context of nonresponsive MDS with persistent Grade 4 thrombocytopenia. Grade 3-4 adverse events were primarily neutropenia, thrombocytopenia and anemia, and were reported as possibly drug-related in 15 patients (18%), 26 patients (32%), and 15 patients (18%), respectively. We believe the results of this study suggest that tipifarnib may produce durable responses as a single agent in patients with intermediate to high risk MDS.

Clinical Development in MDS

We initiated a Phase 2 clinical trial to investigate the anti-tumor activity of tipifarnib in patients with lower risk MDS in the second quarter of 2016. We have prioritized lower risk MDS because of the prevalence of this disease and our belief that treatment of lower risk MDS remains a significant unmet medical need. We expect that the activity of tipifarnib in lower risk MDS will be no less than the activity observed in the previously investigated intermediate/high risk setting, which is a more aggressive form of the disease. Our Phase 2 study in lower risk MDS is designed to investigate the activity of tipifarnib in approximately 58 eligible subjects, and has a primary endpoint of transfusion independence according to the adult Myelodysplastic/Myeloproliferative Neoplasms International Working Group criteria or related response assessment system. Based on anecdotal evidence of hematological improvement observed in several patients enrolled in the study, we have amended the protocol to explore dose regimens to seek to optimize those initial observations.

Exploratory Biomarkers

We have identified potential biomarkers that could be predictive of response to tipifarnib in MDS patients. One of these potential biomarkers is the killer cell immunoglobulin-like receptor 2DS2, or KIR2DS2, which is commonly expressed on natural killer cells and some T-cells and serves to regulate their activity. Autoimmunity is known to play a key role in the onset of lower risk MDS, and KIR2DS2 has been shown to predispose patients to onset of both MDS and autoimmune diseases. KIR2DS2 is present in approximately 60% of MDS patients.

Our interest in KIR2DS2 and other killer cell immunoglobulin-like receptors, or KIRs, was triggered by the results of our retrospective analysis of gene expression from bone marrow samples in 34 previously untreated poor-risk and elderly AML patients who were treated with tipifarnib in a prior Cancer Therapy Evaluation Program, or CTEP 20, Phase 2 clinical trial sponsored by the National Cancer Institute. Twenty-five of the patients in CTEP 20 had prior MDS. We observed that expression of several markers, including KIR2DS2, strongly correlated with clinical benefit, including complete response rate, progression free survival, and OS.

We hypothesize that tipifarnib may influence the signaling of KIR2DS2 through its inhibition of protein farnesylation, either of RAS proteins or other farnesylated proteins in the cell. Through this mechanism, we believe that tipifarnib could improve patient outcomes. Because KIR2DS2 and the related receptor KIR2DS5 are known to predispose to autoimmunity and the onset of MDS, we believe that tipifarnib could attenuate the autoimmune process that causes severe cytopenias in lower risk MDS. This hypothesis is being evaluated in our ongoing Phase 2 clinical trial in lower risk MDS.

Companion Diagnostics

If the results of our Phase 2 clinical trial in MDS are positive, and KIR2DS2 or other immune cell markers are shown to be predictive of response to tipifarnib, we would expect to partner development and validation of a companion diagnostic test to aid in the selection of patients in subsequent clinical trials of tipifarnib in this patient population. Genetic assays and semi-quantitative gene expression assay detecting the presence or absence of certain of these markers are already available and used in some instances in bone marrow transplantation.

Chronic Myelomonocytic Leukemia

Market Opportunity

CMML is a disorder of bone marrow stem cells in which an increase in white blood cells, or monocytosis, is a defining feature. The clinical presentation of CMML varies from predominantly myelodysplastic, an ineffective production of blood cells, to predominantly myeloproliferative, an overproduction of blood cells. CMML is primarily a disease of the elderly with a median age at diagnosis of 65 to 75 years, and an estimated annual incidence of approximately 1,100 patients in the United States.

Treatment Options for CMML

The prognosis for patients with CMML is poor, with median survival of two to three years and a 15% to 20% risk of transformation to AML. The three-year survival for patients with CMML is low — roughly 29% by most published records — and few treatment options provide a durable treatment effect. Management of CMML typically focuses on supportive care as therapeutic options are limited. Accordingly, we believe treatment of adult CMML remains an unmet medical need.

Previous Phase 2 Experience with Tipifarnib in the Treatment of CMML

In a prior Phase 2 clinical trial of tipifarnib sponsored by Johnson & Johnson and in adult patients with intermediate to high risk MDS, of the 82 patients treated, 19 were classified as having CMML according to the French American British classification. Based on an intent to treat analysis of these CMML patients using the International Working Group (2000) response criteria for MDS, responses were observed in four of the 19 patients (21%), with one CR and three complete responses with incomplete platelet recovery, or CRp. Median duration of response was 225 days and median time to transformation to AML was not estimable. Median overall survival in these patients was 440 days. Tipifarnib was generally well tolerated. Grade 3 or 4 adverse events reported across all patients were primarily myelosuppression: thrombocytopenia, anemia, and neutropenia. We believe the results observed from this Phase 2 clinical trial suggest that tipifarnib may produce durable responses as a single agent in patients with CMML.

Clinical Development in CMML

We initiated a Phase 2 clinical trial of tipifarnib in CMML in October 2016. Our Phase 2 clinical trial is designed to evaluate the anti-tumor activity of tipifarnib in CMML. As part of the study, we also plan to test a biomarker hypothesis, which may allow us to identify those patients most likely to experience durable responses. We anticipate that the clinical trial would recruit approximately 20 patients.

Exploratory Biomarkers

We have identified potential biomarkers that could be predictive of response to tipifarnib in CMML patients. Two of these potential biomarkers are the proto-oncogenes NRAS and KRAS. Like the HRAS homolog, NRAS and KRAS proteins are involved in regulating cell division in response to growth factor stimulation. In certain tumors, mutations in KRAS or NRAS cause those proteins to be permanently “on,” resulting in persistent activation of downstream growth and proliferation signals that drive tumor cell growth. Mutations in NRAS or KRAS are present in approximately 30% of CMML patients.

KRAS and NRAS are similar to HRAS in that they can utilize the protein farnesylation pathway for membrane localization; however, KRAS and NRAS are distinct from HRAS in that they can also utilize an alternate enzyme, the geranylgeranyl transferase, for membrane localization and become resistant to FTI treatment. We hypothesize that patients with NRAS mutant CMML will be less sensitive to treatment with tipifarnib relative to patients with the wild-type NRAS because NRAS will remain a driver of the disease even upon treatment with tipifarnib. If we validate our hypothesis in the ongoing Phase 2 clinical trial, the likely development path for tipifarnib in CMML would be in the NRAS wild-type CMML population.

Companion Diagnostics

If the results of our Phase 2 clinical trial in CMML are positive, and wild-type NRAS or KRAS are shown to be predictive of response to tipifarnib, we would expect to partner development and validation of a companion diagnostic test to aid in the selection of patients in subsequent clinical trials of tipifarnib in this patient population. Genetic assays detecting the presence or absence of certain of these genes and markers are already commercially available.

Registration Strategy for Tipifarnib

Our goals with our ongoing Phase 2 clinical trials of tipifarnib are to confirm the clinical activity of tipifarnib in each disease indication, to validate biomarker hypotheses and to optimize dose and schedule for each disease to build a data package supporting advancement to pivotal study. For each disease indication, we plan to evaluate a number of criteria in determining whether to advance tipifarnib. These criteria include: biomarker validation, evidence of durable, clinical benefit, potential for rapid clinical development, potential to move into earlier lines of therapy, the potential for patent and regulatory exclusivity and the commercial potential.

We anticipate we will have additional data from our Phase 2 clinical trial in HRAS mutant solid tumors and from our Phase 2 clinical trial in PTCL in 2017 and data from our Phase 2 clinical trial in lower-risk MDS and our Phase 2 clinical trial in CMML in the first half of 2018. If the data from one or more of these Phase 2 clinical trials supports further clinical development, we would plan to initiate a registrational clinical trial of tipifarnib in at least one disease indication. The use of regulatory pathways such as orphan drug or breakthrough therapy designation will be driven by the specific patient population and data from the Phase 2 clinical trials.

ERK Inhibitor Program

Overview

We are advancing KO-947, a small molecule inhibitor of ERK, as a potential treatment for patients with tumors that have dysregulated activity due to mutations or other mechanisms in the MAPK pathway, including lung cancers, colorectal cancers and pancreatic cancers. We anticipate initiation of our Phase 1 clinical trial of KO-947 in the first half of 2017. We acquired KO-947 from Araxes Pharma LLC, or Araxes, a private biopharmaceutical company.

Aberrant signaling caused by mutations or dysregulation of the MAPK pathway are frequent contributors to the development of cancer in humans and are associated with numerous tumor types. Many cancers harbor genetic mutations in components of the MAPK pathway, especially in protein kinases, that lock transformed cells in a pro-growth state, even in the absence of external growth signals. Studies have shown that such aberrations in the MAPK pathway, including mutations in KRAS or BRAF, and other components of the pathway, are frequent contributors to the development of cancer in humans. Targeted cancer drugs, including vemurafinib (ZELBORAF®) and dabrafenib (TAFINLAR®), trametinib (MEKINIST®) and cobimetinib (COTELLIC®), which are small molecule inhibitors of the proteins BRAF and MEK, respectively, and have been approved by the FDA for treatment of BRAF V600E mutant metastatic melanoma, are currently being investigated in other tumor types. We believe that these drugs have validated the use of small molecule inhibitors of the MAPK pathway in cancer. Although inhibitors of BRAF and MEK have demonstrated clinical activity in selected patients, durable responses in patients are limited, as median time to disease progression is approximately six to seven months and resistance is often associated with pathway reactivation of the ERK signaling pathway. Accordingly, we believe that a therapeutic product candidate that can block signaling of the MAPK pathway through potent, selective and prolonged inhibition of ERK should reduce or prevent cancer growth and may have a beneficial effect for patients.

KO-947 is a potent and selective inhibitor of ERK, exhibits potent anti-proliferative activity across a broad panel of tumor cell lines with mutations in BRAF, NRAS or KRAS and induces tumor regressions at tolerable doses in *in vivo* models. KO-947 demonstrates prolonged pathway inhibition, both *in vitro* and *in vivo*, enabling the potential for intermittent dosing on schedules up to once weekly. Additionally, the drug properties of KO-947 support an intravenous formulation, which may allow for increased drug concentration and potentially improved tolerability in the clinic. We believe these properties of KO-947 differentiate it from other ERK inhibitors currently in development.

Market Overview

Activating mutations in the KRAS gene are commonly found in a wide variety of tumor types. Among cancer indications with large patient populations, KRAS mutations are found in approximately 93 percent of pancreatic cancers, approximately 40 percent of colorectal cancers and approximately 12 percent of NSCLC. According to the ACS in 2017, there are estimated to be over 54,000 cases of pancreatic cancer, 135,000 cases of colorectal cancer and over 190,000 cases of NSCLC diagnosed each year in the United States. We believe this corresponds to approximately 49,000 cases of KRAS mutant pancreatic cancer, 54,000 cases of KRAS mutant colorectal cancer, and 23,000 cases of KRAS mutant NSCLC each year in the United States. These cancers typically present relatively late in their clinical course, when locally directed therapy (surgery and radiation) is not curative. The treatment of locally advanced and metastatic cancers represents a significant unmet medical need.

Preclinical Data for KO-947

KO-947, demonstrates potent inhibition of the ERK kinase and high selectivity relative to a panel of approximately 400 kinases. KO-947 also demonstrates prolonged inhibition of the MAPK pathway *in vivo*. Following a single dose *in vivo*, KO-947 demonstrated a near complete inhibition of MAPK pathway signaling for more than 72 hours. The prolonged inhibition of the pathway supports the potential for intermittent dosing schedules.

KO-947 has been evaluated in a panel of more than 100 different PDX models comprising 20 different clinical indications, utilizing intermittent dosing, to identify and prioritize potential lead clinical indications. Results obtained from these studies demonstrate that KO-947 induces tumor regressions in BRAF or RAS mutated tumor models as well as in tumor models lacking BRAF/RAS mutations but characterized by other dysregulations of the MAPK pathway. In each of these subsets of tumors characterized by mutation or dysregulation of the MAPK pathway, KO-947 demonstrated response rates of greater than 50%. Preclinical data for KO-947 was published in a poster presented at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, or EORTC, in Munich, Germany in November 2016.

Through our preclinical studies we have identified potential development opportunities including KRAS and BRAF mutant cancers and squamous cell carcinomas. In addition, we have identified potential biomarkers to enable patient selection strategies for clinical development. Our goal is to identify those indications with the potential for single agent activity, enabling accelerated development. We believe the advantages of a precision medicine-based approach to the development of KO-947 include the potential for translatability from preclinical PDX studies to human clinical studies, the ability to leverage clinical and pathology trends towards comprehensive tumor profiling and the potential for meaningful single agent activity to permit more rapid clinical development and commercialization.

Phase 1 Clinical Trial

We submitted an IND application for KO-947 to the FDA, which became effective in December 2016, and we anticipate initiation of our Phase 1 clinical trial of KO-947 in the first half of 2017. Our planned Phase 1 clinical trial is designed to determine the maximum tolerated dose, or MTD, of KO-947 in subjects with locally advanced unresectable or metastatic, relapsed and/or refractory, non-hematological malignancies. If an MTD cannot be identified, a recommended phase 2 dose will be determined. In addition, extension cohorts may be conducted to further characterize the safety and tolerability of KO-947 and seek to provide preliminary evidence of anti-tumor activity. The clinical trial is planned to be conducted at multiple centers in the United States and the European Union.

Menin-MLL Program

Overview

We are developing orally bioavailable small molecule inhibitors of the menin-MLL interaction, including the development candidate, KO-539, for the treatment of MLL-r and MLL-Partial Tandem Duplication, or MLL-PTD, acute leukemias, a genetically defined subtype of the two most common forms of acute leukemia, AML and acute lymphoblastic leukemia, or ALL. We licensed the menin-MLL program from the Regents of The University of Michigan, or the University of Michigan.

The MLL gene is a common target of chromosomal translocations found in patients with AML and ALL, which affects both children and adults. Fusion of MLL with one of over 50 different partner genes forms oncogenes encoding MLL fusion proteins, which play a causative role in the onset, development and progression of MLL-r leukemias. MLL fusion proteins up-regulate expression of target genes involved in the malignant transformation of blood cells, however, the fusion protein is critically dependent on binding the oncogenic co-factor menin to function. This implies that the menin-MLL interaction represents a valuable target for molecular therapy.

MLL-r leukemias are an aggressive subtype of two of the most common forms of acute leukemia, ALL and AML. The estimated five-year OS rate for adult patients with the MLL-r subtype of AML ranges from approximately 5% to 24%. Patients with MLL-r leukemias are routinely diagnosed using existing technologies that are commonly used in clinical settings. As a result, there is high awareness of MLL-r leukemias among oncologists. The disease predominantly occurs in two different demographics—an adult population and an infant/pediatric population. While they share a common genetic alteration, the adult disease is frequently a secondary leukemia resulting from prior chemotherapy for a different, unrelated cancer, and the childhood disease arises de novo. MLL-r leukemias are caused by a chromosomal translocation involving the MLL gene.

Another subset of AML carries the MLL-PTD mutation that shares many of the hallmarks of MLL-r leukemias. MLL-PTD typically confers a worse prognosis with shortened overall and event free survival in childhood and adult AML. The annual incidence of MLL-r and MLL-PTD patients is estimated to be 3,500 patients in the United States, and those patients currently have limited options other than chemotherapy or allogeneic stem cell transplant. There are no approved therapies specifically indicated for either the MLL-r or MLL-PTD leukemias. We believe there remains a significant unmet medical need.

In preclinical studies, inhibitors of the menin-MLL interaction have demonstrated potent and selective inhibition of the proliferation of MLL-r leukemia cell lines. We have further demonstrated that the inhibition of the menin-MLL interaction results in the down-regulation of MLL-r target genes, and an up-regulation of markers of differentiation. In vivo studies show robust and durable efficacy in multiple models of MLL-r leukemia, and demonstrate a strong correlation with the gene expression endpoints. Data was published in a poster presented at the EORTC in Munich, Germany in November 2016.

Opportunity for Kura Oncology

Our menin-MLL development program is aimed at identifying product candidates with the potential to effectively treat patients with MLL-r leukemias—a subset of adult and pediatric patients who today have no effective therapy—as well as MLL-PTD leukemias, a subset of AMLs that have no effective therapy. Additionally, we are evaluating oncology indications where menin dysregulation may play a role in the onset, development and progression of these cancers. We nominated KO-539 as a development candidate in December 2016.

License and Asset Purchase Agreements

Janssen Pharmaceutica NV

In December 2014, we entered into a license agreement with Janssen, which was amended in June 2016, which grants us exclusive global rights to develop and commercialize tipifarnib in all indications other than virology and includes the right to grant sublicenses. We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize tipifarnib and, with the exception of the transfer to us without cost of Janssen's existing inventory of tipifarnib material, we are responsible for all future development and commercialization costs for tipifarnib. Under the license agreement, Janssen has a first right to negotiate for an exclusive license back from us to develop and commercialize tipifarnib on terms to be negotiated in good faith. Janssen may exercise this right of first negotiation during the 60-day period following completion of a Phase 2 clinical trial of tipifarnib in HRAS mutant patients in oncology and delivery by us to Janssen of a complete data package from such clinical trial.

Under the terms of the license agreement, in January 2015 we issued a convertible promissory note in the principal amount of \$1.0 million to Johnson & Johnson Innovation—JJDC, Inc., which automatically converted into shares of common stock in our March 2015 private placement. When and if commercial sales of tipifarnib begin, we are obligated to pay Janssen tiered royalties of low double digit percentages of our net sales, depending on the amount of our net sales, with standard provisions for royalty offsets in the event of generic competition or compulsory licenses, on a product-by-product and country-by-country basis until the later of the expiration of the last to expire valid claim of the licensed patents covering the licensed product in the field in such country, the expiration of any regulatory exclusivity with respect to such product in such country, and ten years from our first commercial sale. We are also required to make regulatory milestone payments to Janssen of up to \$25 million in the aggregate, if specified regulatory approvals are achieved for the first indication and additional payments for each subsequent indication if specified regulatory approvals are achieved. In addition, we are required to make sales milestone payments of up to \$50 million in the aggregate if specified sales thresholds are surpassed. If we grant sublicenses under the license from Janssen, we are required to pay to Janssen a percentage of any upfront, lump-sum or milestone payments received from our sublicensee, subject to certain exclusions for regulatory milestone payments due under the license agreement.

The license agreement with Janssen will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Janssen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. If we fail to meet our obligations under the license agreement and are unable to cure such failure within specified time periods, Janssen can terminate the license agreement, resulting in a loss of our rights to tipifarnib.

Araxes Pharma LLC

In December 2014, we entered into an asset purchase agreement with Araxes, which was amended and restated in February 2015, under which we purchased all of Araxes' patent rights in the ERK program, including KO-947 and additional backup compounds, and related intellectual property. When and if commercial sales of a product candidate covered by the purchased patent rights begin, we are obligated to pay Araxes tiered royalties of low single digit percentages of our net sales, depending on the amount of our net sales with standard provisions for royalty offsets. We are also required to make development and regulatory milestone payments to Araxes of up to \$9.7 million in the aggregate if specified development events and regulatory approvals are achieved. Under the terms of the asset purchase agreement, in December 2014 we issued

a convertible promissory note in the principal amount of \$0.5 million to Araxes, which automatically converted into shares of common stock in our March 2015 private placement.

In December 2014, we entered into a license agreement with the University of Michigan, which was amended in March 2015, July 2015, September 2016 and February 2017, 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 several 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. The University of 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 our March 2015 private placement, we issued to the University of Michigan 79,113 shares of our common stock at a fair value of \$0.5 million. 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 the University of 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.

Research and Development

Our research and development expenses were \$20.4 million and \$17.8 million, during the years ended December 31, 2016 and 2015, respectively. See Part II – Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report for additional detail regarding our research and development activities.

Competition

The development and commercialization of new products to treat cancer is intensely competitive and subject to rapid and significant technological change. Although we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical, and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition with respect to our current product candidates, and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue approaches to targeting molecular alterations and signaling pathways associated with cancer. Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, less costly, or possessing better safety profiles than our products, and these competitors may be more successful than us in manufacturing and marketing their products.

In addition, we will need to develop our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Tipifarnib Competition

Although there are currently no approved drugs targeting farnesyl transferase, we are aware of several compounds that are now or have previously been in clinical development, including Merck's lonafarnib, Bristol-Myers Squibb's BMS-214662, Astellas Pharma's (formerly OSI) CP-609,754, and AstraZeneca's AZD3409. To our knowledge, there are no ongoing clinical trials evaluating any of these agents for the treatment of cancer. However, the initiation of clinical development of another of these agents in an oncology setting could become competitively significant, and if tipifarnib or our other product candidates do not offer sustainable advantages over competing products, we may not be able to successfully compete against current and future competitors.

Even if we are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the targeted therapeutic indications of PTCL and MDS. Competitive drugs currently approved for PTCL include belinostat (Beleodaq[®]) and pralatrexate (Folotyn[®]), marketed by Spectrum Pharmaceuticals, romidepsin (Istodax[®]), marketed by Celgene, and brentuximab vedotin (Adcetris[®]) (for ALCL), marketed by Seattle Genetics. Competitive drugs currently approved for MDS include azacytidine (Vidaza[®]) and lenalidomide (Revlimid[®]), marketed by Celgene, and decitabine (Dacogen[®]) marketed by Otsuka and Johnson & Johnson. Although there are currently no drugs approved specifically for the treatment of HRAS-mutant solid tumors, there are several targeted therapies approved for the treatment of SCCHN including Eli Lilly's/Merck KGaA's cetuximab (Erbix[®]), Bristol Myers Squibb's nivolumab (Opdivo[®]) and Merck's pembrolizumab (Keytruda[®]), and thyroid cancer, including AstraZeneca's vandetanib (Caprelsa[®]), Bayer's sorafenib (Nexavar[®]), Exelixis' cabozantinib (Cometriq[®]) and Eisai's lenvatinib (Lenvima[®]). There are no targeted therapies approved for the treatment of urothelial cancer or CMML.

ERK Inhibitor Competition

While there are currently no approved drugs targeting ERK, we are aware of several compounds that are in clinical development, including Roche/Genentech's raxoxertinib (RG-7842/GDC-0994) BioMed Valley Discoveries' ulixertinib (BVD-523), Eli Lilly's LY-3214996, Merck's MK-8353 and Novartis' LTT-462. Furthermore, it is possible that other companies are also engaged in discovery or preclinical development of compounds targeting ERK. These competitors, if successful in clinical development, may achieve clinical activity, regulatory approval and market adoption in advance of our compounds, constraining the ability of our compounds to gain significant market share. Although we believe that KO-947 presents several potential advantages relative to these aforementioned candidates, including potency, prolonged pathway inhibition and the ability to be administered as an intravenous infusion, these results may not translate to superior therapeutic benefit in clinical trials.

Menin-MLL Inhibitor Competition

There are no drugs, to our knowledge, approved or in clinical trials targeting the menin-MLL protein-protein interaction. Although there are no targeted therapies approved specifically for the treatment of MLL-r leukemias, there are several products in clinical development, including Epizyme's EPZ-5676 and Novartis's midostaurin, as well as Pfizer's palbociclib (IBRANCE[®]), which has received accelerated approval in combination with letrozole, for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer as initial endocrine-based therapy for their metastatic disease.

Commercialization

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in discovery, preclinical or early clinical development. We anticipate that we will aim to retain commercial rights in North America for any of our product candidates for which we may in the future receive marketing approvals. We may also seek to retain commercial rights in Europe for any of our product candidates for which we may in the future receive marketing approvals. We currently anticipate that, if and when appropriate, we will seek to access the North American or European oncology markets through a focused, specialized, internal sales force.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused internal sales and marketing team in North America to sell our products. We may also build a focused internal sales and marketing team in Europe to sell our products. We believe that such an approach will enable us to address the community of oncologists who are the key specialists in treating the patient populations for which our current product candidates are being developed. Outside of regions where we maintain commercial rights, we may enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval in foreign jurisdictions.

We also aim to build a marketing and sales management force to create and implement marketing strategies for any products that we may in the future market through our own sales teams and to oversee and support our sales force. We anticipate that our goals for any such marketing force include developing educational initiatives with respect to any approved products and establishing relationships with thought leaders in relevant fields of medicine.

We currently expect that any third parties with which we may collaborate in the future on the development of any commercial companion diagnostics for use with our therapeutic products will most likely hold the commercial rights to those diagnostic products. We expect that we would coordinate closely with any future diagnostic collaborators in connection with the marketing and sale of such diagnostic products and our related therapeutic products.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing as well as for commercial manufacture of any products that we may commercialize. Under our license agreement with Janssen, Janssen has provided us with its existing inventory of clinical supply of tipifarnib, which we believe will support our ongoing and planned Phase 2 clinical trials of tipifarnib. Janssen also provided us with its existing inventory of the crude drug substance and bulk key intermediate for manufacture of drug substance for tipifarnib. If needed, we aim to engage, by entering into a supply agreement or through another arrangement, third party manufacturers to provide us with additional tipifarnib clinical supply. For all our product candidates, we aim to identify and qualify manufacturers to provide the active pharmaceutical ingredient, or API, and fill-and-finish services prior to submission of an NDA to the FDA.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we or our collaborators may develop.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our product candidates and our core technologies, including novel biomarker and diagnostic discoveries and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary or intellectual property rights. We expect that we will seek to protect our proprietary and intellectual property position by, among other methods, licensing or filing our own U.S., international and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

We currently, and expect that we will continue to, file or license patent applications directed to our key product candidates in an effort to establish intellectual property positions regarding composition-of-matter of these product candidates, as well as biomarkers that may be useful in selecting the right patient population for use of any of our product candidates, formulations, processes and methods of using these product candidates in the treatment of various cancers. We own or in-license a patent portfolio consisting of over 30 patent families, including issued U.S. patents and their respective counterparts in a number of foreign jurisdictions, pending U.S. patent applications, pending applications under the Patent Cooperation Treaty and corresponding pending patent applications in a number of foreign jurisdictions. We have exclusively licensed from Janssen a portfolio of approximately 20 patent families. The in-licensed Janssen composition-of-matter and method-of-use patents expired in the United States and Europe in 2016. We have also exclusively licensed from Memorial Sloan Kettering Cancer Center a patent family pertaining to a method of use of tipifarnib. We have exclusively licensed from the University of Michigan or co-own multiple families of patent applications pertaining to our menin-MLL program. Other patent applications we own include composition-of-matter and method-of-use applications covering KO-947. We currently, and expect that we will continue to, file for patents in the United States with counterparts in major market countries in Europe and other key markets in the rest of the world.

In addition to the patent applications that we have filed to date, we plan to continue to expand our intellectual property portfolio by filing patent applications directed to dosage forms, methods of treatment and additional inhibitor compounds of oncology molecular targets and their derivatives. Specifically, we anticipate that we will seek patent protection in the United States and internationally for novel compositions of matter covering the compounds, the chemistries and processes for manufacturing these compounds, their intermediates and/or metabolites, the use of these compounds in a variety of therapies and the use of biomarkers for patient selection for these compounds. However, these or other patent applications that we may

file or license from third parties may not result in the issuance of patents, and any issued patents may cover limited claims that reduce their value and/or may be challenged, invalidated or circumvented. See “Risk Factors—Risks Related to Our Intellectual Property.”

In addition to patents, we also rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees and selected consultants, scientific advisors and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third-party.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant’s product. Upon approval, each of the patents listed in the application for the drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Any applicant who files an abbreviated new drug application, or ANDA, seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or Section 505(b)(2) application refers. The applicant may also elect to submit a “section viii” statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the NDA holder for the reference drug and/or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of an NDA for a listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or Section 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon FDA approval of an 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. Five-year NCE exclusivity does not block the submission, review or approval of a 505(b)(1) NDA.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug’s testing phase—the time between IND application and NDA submission—plus all of the review phase—the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term, including the extension may not exceed 14 years from the date of NDA approval.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and

Trademark Office, or U.S. PTO, must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by FDA. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to FDA of an IND which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to FDA as part of the IND.

FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the drug for a specific indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter clinical trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on

mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second clinical trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial, and the fees are typically increased annually.

FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, FDA begins an in-depth review. FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Most applications for standard review drug products are reviewed within 12 months from submission; most applications for priority review drugs are reviewed within eight months from submission. Priority review can be applied to drugs that FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP—a quality system regulating manufacturing—is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, for FDA to reconsider the application. If, or when, those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation and Accelerated Approval

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a Fast Track drug concurrent with, or after, the

filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

Under the Fast Track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to priority review by FDA.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with FDA, and FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track Designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA will grant orphan designation for that product for the orphan disease indication, assuming the same drug has not already been approved for the indication for which the sponsor is seeking orphan designation. If the same drug has already been approved for the indication for which the sponsor is seeking orphan designation, the sponsor must present a plausible hypothesis of clinical superiority to obtain orphan designation. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the FDA discloses the identity of the therapeutic agent and its potential orphan use.

Orphan designation may provide manufacturers with benefits such as research grants, tax credits, Prescription Drug User Fee Act application fee waivers, and eligibility for orphan drug exclusivity. If a product that has orphan designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or

disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan drug has exclusivity or obtain approval for the same product but for a different indication for which the orphan drug has exclusivity.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested prior to submission of an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

FDA Regulation of Companion Diagnostics

Our drug products may rely upon in vitro companion diagnostics for use in selecting the patients that we believe will respond to our cancer therapeutics. If safe and effective use of a therapeutic product depends on an in vitro diagnostic, or IVD, FDA generally will require approval or clearance of the diagnostic at the same time that FDA approves the therapeutic product. This policy is described in an August 2014 FDA guidance document.

FDA has required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a premarket approval, or PMA, for that diagnostic simultaneously with approval of the drug. We believe that FDA will require PMA approval of one or more in vitro companion diagnostics to identify patient populations suitable for our cancer therapies. The review of these in vitro companion diagnostics in conjunction with the review of our cancer treatments

involves coordination of review by FDA's Center for Drug Evaluation and Research and by FDA's Center for Devices and Radiological Health.

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If FDA's evaluation of the PMA application is favorable, FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If FDA concludes that the applicable criteria have been met, FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA. FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of submissions for new products, or withdrawal of PMA approvals.

Clinical Trials and IDEs

A clinical trial is almost always required to support a PMA application. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device.

All clinical studies of investigational devices must be conducted in compliance with the FDA's requirements. If an investigational device could pose a significant risk to patients pursuant to FDA regulations, the FDA must approve an IDE application prior to initiation of investigational use. IVD trials usually do not require an IDE, as the FDA does not judge them to be a significant risk because the results do not affect the patients in the study. However, for a clinical trial where the IVD result directs the therapeutic care of patients with cancer, we believe that the FDA may consider the investigation to present significant risk and require an IDE application.

An IDE application must be supported by appropriate data, such as laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The FDA typically grants IDE approval for a specified number of patients. A non-significant risk device does not require FDA approval of an IDE. Both significant risk and non-significant risk investigational devices require approval from IRBs at the study centers where the device will be used.

During the critical trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, clinical trial monitoring, reporting and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and

record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with applicable requirements.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

Additional Regulations and Environmental Matters

In addition to FDA restrictions on marketing of pharmaceutical products, we are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws, which generally will not be applicable to us or our product candidates unless and until we obtain FDA marketing approval for any of our product candidates, include transparency laws, anti-kickback statutes, false claims statutes and regulation regarding providing drug samples, among others.

The federal Anti-Kickback Statute prohibits, among other things, individuals and entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for either the referral of an individual or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Violations of the federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

Federal false claims laws and civil monetary penalties, including the False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

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 their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information used and disclosed by covered entities and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Many states and foreign jurisdictions also have laws and regulations that govern the privacy and security of individually identifiable health information, and such laws often vary from one another and from HIPAA.

The federal Physician Payments Sunshine Act requires certain manufacturers of 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 or other transfers of value made to physicians and teaching hospitals, and certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by the physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. 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. Our activities may also be certain state laws regarding the privacy and security of health information that may not be preempted by HIPAA, as well as additional tracking and reporting obligations regarding payments to healthcare providers and marketing expenditures.

Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including potentially significant administrative, criminal and civil penalties, damages, fines, individual imprisonment, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations

In addition to regulatory schemes that apply, or may in the future apply, to our business, we are or may become subject to various environmental, health and safety laws and regulations governing, among other things, laboratory procedures and any use and disposal by us of hazardous or potentially hazardous substances used in connection with our research and development activities. We do not presently expect such environmental, health and safety laws or regulations to materially impact our present or planned future activities.

Coverage and Reimbursement

Sales of any of our product candidates that may be approved will depend, in part, on the extent to which the cost of the product will be covered by third party payors. Third party payors may limit coverage to an approved list of products, or formulary, which might not include all drug products approved by the FDA for an indication. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. 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. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Any product candidates for which we obtain marketing approval may not be considered medically necessary or cost-effective by third party payors, and we may need to conduct expensive pharmacoeconomic studies in the future to demonstrate the medical necessity and/or cost effectiveness of any such product. Nonetheless, our product candidates may not be considered medically necessary or cost effective. The U.S. government, state legislatures and foreign governments have shown increased interest in implementing cost containment programs to limit government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Continued interest in and adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product candidates we are developing.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the

United States, the pharmaceutical industry has been a specific focus of these efforts and has been significantly affected by major legislative initiatives. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 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 several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations. Recently there has been heightened governmental scrutiny over the manner by which manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products.

In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

Employees

As of December 31, 2016, we had 22 full-time employees and three part-time employees, including nine employees with M.D. or Ph.D. degrees. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

Our corporate headquarters are located at 11119 North Torrey Pines Road, Suite 125, La Jolla, California 92037, and our telephone number is (858) 500-8800. We also occupy offices in Cambridge, Massachusetts. We maintain a website at www.kuraoncology.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report.

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our November 2015 public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (3) the day we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as measured as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. References herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

RISK FACTORS

Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference into this Annual Report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.

Risks Related to Our Financial Position and Need For Additional Capital

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

We expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through equity and debt financings. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially if and as we:

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

- the success of our clinical trials through all phases of clinical development;
- delays in the commencement, enrollment and timing of clinical trials;
- our ability to secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;
- our 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 contract research organizations, or CROs, to adhere to clinical study and other regulatory requirements;
- the ability of third-party manufacturers to manufacture our product candidates and key ingredients needed to conduct clinical trials and, if approved, successfully commercialize our products;
- the costs to us, and our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of any future intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

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

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

We are 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 for our product candidates and undertaking clinical studies of our most advanced product candidate, tipifarnib. We have not yet demonstrated our ability to 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. In April 2016, we entered into the loan agreement with the lenders providing for up to \$20.0 million in term loans. Under the terms of the loan agreement, the lenders have initially provided us with a term loan of \$7.5 million, or Term A Loan, with an additional \$12.5 million available at any time between December 31, 2016 and May 1, 2017, or Term B Loan, subject to our successful advancement of KO-947 into Phase 1 clinical trials.

In January 2017, we entered into an at the market issuance sales agreement, or ATM facility, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$25.0 million. Other than our term loan facility and ATM facility, 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.

While any amounts are outstanding under our term loan facility, we are subject to affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. If we default under our term loan facility, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default under our term loan facility upon the occurrence of an event of default, which includes our failure to satisfy our payment obligations under the loan agreement, the breach of certain of our other covenants under the loan agreement or the occurrence of a material adverse change, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

Risks Related to the Discovery and Development of Our Product Candidates

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

The discovery and development of targeted 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, a Phase 2 clinical trial in PTCL in September 2015, a Phase 2 clinical trial in patients with lower risk MDS in May 2016 and a Phase 2 clinical trial in patients with CMML in October 2016. Our product candidate in our ERK program, KO-947, is anticipated to enter clinical development in the first half of 2017, and menin-MLL program, is in preclinical development. Each of our product candidates will require 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, KO-947 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 at the various doses and schedules we are using or plan to use 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 clinical 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 clinical trials for tipifarnib.

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

In addition to the potentially small populations for our clinical trials of tipifarnib, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study including the number and frequency of study required procedures and tests, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

Enrollment in our Phase 2 clinical trial of tipifarnib in patients with HRAS mutant SCCHN is proceeding slower than anticipated. We believe this may be primarily due to two factors. First, with the recent approvals in the United States of the immune-oncology agents nivolumab and pembrolizumab, many SCCHN patients are now being treated with one of these agents after failure of first line treatments such as chemotherapy and/or cetuximab. Second, many physicians who treat SCCHN patients do not routinely screen their patients for genetic mutations, such as HRAS, which we believe is because, to date, targeted therapies have not been available to treat SCCHN patients. To seek to address these issues, we are expanding the number of clinical sites in Europe, where the immune-oncology agents have not yet been approved, and in the United States, and are contracting with third party laboratories to facilitate the genetic screening of patients for our clinical sites. These efforts will result in an increase in costs for this Phase 2 clinical trial, and there is no guarantee that these efforts will be effective in accelerating enrollment in this clinical trial.

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 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 subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. Results from clinical trials conducted at a single clinical site may not be predictive of results from additional clinical sites or from subsequent clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, the FDA issued a non-approval letter for tipifarnib in acute myeloid 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. We experienced a delay in completing the manufacture of clinical supplies of KO-947, which resulted in a delay in submitting an IND for KO-947. We currently anticipate commencing a Phase 1 clinical trial of KO-947 in the first half of 2017. If the FDA or IRBs have comments on our study plans for our ongoing or planned Phase 2 clinical trials of tipifarnib or our planned Phase 1 clinical trial of KO-947 that we are required to address, such studies may be delayed, or may not start at all. Clinical trials may be delayed, suspended or prematurely terminated at any time by us or by the FDA or other similar regulatory agency if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including risk of death, or if compounds are not manufactured in compliance with cGMP regulations or with acceptable quality. 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:

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

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to redesign or modify our clinical trial protocols, conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients whose tumors harbor the specific genetic alterations that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that 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 clinical trials, to include patients whose tumors harbor the applicable molecular and/or 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, to show early and statistically significant evidence of clinical efficacy. If we are unable to identify genetic alterations, or biomarkers, that are predictive of response to our product candidates, or we are unable to include patients whose tumors harbor the applicable genetic alterations in our clinical trials, or if our product candidates fail to work as we expect, our ability to assess the therapeutic effect, seek participation in FDA expedited review and approval programs, including Breakthrough Therapy, Fast Track Designation, Priority Review and Accelerated Approval, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised, resulting in longer development times, larger clinical trials and a 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 licensed the rights to develop our lead product candidate, tipifarnib, from Janssen in December 2014, and the development of tipifarnib prior to our license was conducted wholly by Janssen or any third parties with which it had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. Because we had no input on Janssen's development activities relating to tipifarnib, we may discover that all or certain elements of the clinical trials and studies 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.

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

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

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

We have not yet initiated clinical trials of KO-947, and it is likely that there may be side effects associated with its use in humans. Any observed drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Additionally, if results of our clinical trials for tipifarnib, KO-947 or other product candidates reveal an unacceptable frequency and severity of serious adverse events or side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory agencies could require us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of those compounds. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

As one of the central elements of our business strategy and clinical development approach, we seek to screen and identify subsets of patients with a genetic alteration who may derive meaningful benefit from our 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.

In our Phase 2 clinical trial of tipifarnib in advanced cancers with HRAS mutations, patients are being enrolled based on information from the clinical sites on the patients' tumor HRAS mutation status. Typically, this information is being obtained by the clinical sites from NGS panels used by the site to characterize patients' tumors. In some disease indications including HRAS mutant squamous cell head and neck cancer, it is not routine to screen all patients. In such cases, we may facilitate screening at third party CROs. This may result in additional cost and longer timelines. We are contracting with third party laboratories to facilitate screening of patients in our HRAS mutant SCCHN clinical trial and expect to incur additional costs and longer timelines as a result. If the results of our Phase 2 clinical trials are positive and we validate our biomarker hypotheses in those clinical trials, we plan to partner development and validation of companion diagnostic tests to aid in the selection of patients in subsequent clinical trials of tipifarnib and to prepare and submit an IDE for use of the companion diagnostic in the clinical trial. Any delay or failure by us or our third-party collaborators to develop or obtain IDE approval for use of companion diagnostics in our clinical trials of tipifarnib could delay or prevent us from commencing or completing our clinical trials. We expect that the companion diagnostic tests will either be a qualitative polymerase chain reaction-based assay or an NGS-based assay. The results of NGS panels being currently used at sites may not be accurate or consistent across sites, and our development of tipifarnib or a companion diagnostic may be delayed or complicated by a change in assay methodology.

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 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 Our Dependence on Third Parties

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

We rely 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 clinical trial. Moreover, the FDA and other regulatory authorities require us to comply with good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

We do not own or operate facilities for the manufacture of our product candidates, and we do not have any manufacturing personnel. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. 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. We rely, and expect to continue to rely, on third parties, for the manufacture of additional clinical supplies of tipifarnib and our other product

candidates for preclinical and clinical testing. We will rely on third parties as well for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of drug formulation and manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Our initial liquid formulation of KO-947 for intravenous dosing did not demonstrate stability characteristics consistent with our specifications, which resulted in a delay in the completion of our manufacturing activities for clinical supplies of KO-947 and a delay in submitting an IND for KO-947 as we had to continue our formulation development work to develop a lyophilized formulation of KO-947 for use in clinical trials.

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- 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.

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 expired in the United States and in countries in Europe in 2016, our commercial strategy for tipifarnib relies on obtaining other patents related to tipifarnib and on non-patent regulatory exclusivity. In the United States, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon FDA approval of an NDA for an 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 abbreviated new drug application seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that the FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. EB Pharma has licensed rights from Janssen to develop tipifarnib in virology indications. If EB Pharma obtains regulatory approval for tipifarnib in a virology indication before we obtain regulatory approval in one of our oncology or other non-virology indications, the five-year exclusivity period would commence on the date upon which EB Pharma obtains regulatory approval, and as a result, the period of regulatory exclusivity to which we may be entitled may be reduced or eliminated and the commercial prospects for tipifarnib would be harmed as a result.

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

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

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan 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 intend to 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 to grant this designation. Even if we believe a specific product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain drug approval.

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

We do not currently have Breakthrough Therapy Designation for any of our product candidates, but we 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, 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;
- 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 HITECH Act, and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information on covered entities and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of certain drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals, as well as certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians or their immediate family; 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, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion 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 ACA, a sweeping law intended to broaden access to health insurance, improve quality, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the 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.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Most recently, in January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed

an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We cannot predict how the ACA, its possible repeal, or any legislation that may be proposed to replace the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, that due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-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 the Commercialization of Our Product Candidates

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours, such as the recently approved immune-oncology therapies, in which there is increasing awareness and interest. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

We currently have no marketing and sales force. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. 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.

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. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. We or our collaborators may need to conduct expensive

pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain 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 clinical trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

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

Risks Related to Our Intellectual Property

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

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, confidentiality agreements, and license agreements to protect the intellectual property related to our current product candidates and development programs. If the breadth or strength of protection provided by any patents, patent applications or future patents we may own, license, or pursue with respect to any of our current or future product candidates or products is threatened, it could threaten our ability to commercialize any of our current or future product candidates or products. Further, if we encounter delays in our development efforts, the period of time during which we could market any of our current or future product candidates or products under any patent protection we obtain would be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates or products, patents protecting such candidates might expire before or shortly after such product candidates or products are commercialized.

Our patent rights may not protect our patent protected products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights. For example, our patent rights in tipifarnib are limited in ways that affect our ability to exclude third parties from competing against us. In particular, the patent term for the composition of matter patents covering the API of tipifarnib recently expired in the United States and countries in Europe. 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 United States 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. 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 clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We expect that following expiration of 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 all indications other than virology, for our lead product candidate, tipifarnib. We have also in-licensed rights to potential product candidates in other programs in our pipeline. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of the Janssen agreement and the rights we license under it and our other in-license agreements. The Janssen license agreement provides that we are subject to diligence obligations relating to the commercialization and development of tipifarnib, milestone payments, royalty payments and other obligations. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of our license agreement with Janssen, or any of our other license agreements or license agreements we may enter into on which our business or product candidates are dependent, Janssen or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates, including, with respect to our license agreement with Janssen, tipifarnib. The loss of the rights licensed to us under our license agreement with Janssen, or our other license agreements or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

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

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, 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. Even if our owned and licensed patents might provide such protection or competitive advantage, we may not have the resources to effectively enforce our rights under such patents, which can be expensive and time-consuming. Further, our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

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

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

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

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to

our products and technology, including interference or derivation proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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

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

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

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

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

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

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

Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

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

We are an early-stage clinical development company with a limited operating history, and, as of December 31, 2016, we had only 25 employees. We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our President and Chief Executive Officer, Antonio Gualberto, M.D., Ph.D., our Chief Medical Officer, and Pingda Ren, Ph.D., our Senior Vice President, Chemistry and Pharmaceutical Sciences, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. Additionally, Dr. Wilson currently also serves as President and Chief Executive Officer of Avidity Biosciences, LLC. As a result, Dr. Wilson is not able to devote all of his business time and attention to our business. Conflicts may arise in the future if there are competing demands on Dr. Wilson’s time and attention and our business may be harmed as a result.

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

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The United Kingdom’s referendum to leave the European Union or “Brexit,” has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom’s relationship with the European Union. During this

period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our financial condition.

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

Despite the implementation of security measures, our internal computer systems and those of our CROs, collaborators and third-parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

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

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

Risks Related to Ownership of our Common Stock

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

Our common stock has been listed on the Nasdaq Global Select Market under the symbol “KURA” since November 5, 2015. From September 16, 2015 through November 4, 2015, our common stock was quoted for trading on the OTC Markets—OTCQB tier, or OTCQB, in very limited volume under the symbol “KURO.” Prior to September 16, 2015, our common stock was not publicly-traded. The high and low price per share of our common stock as reported by Nasdaq during the period from November 5, 2015 until December 31, 2016, were \$9.06 and \$2.50, respectively. The high and low bid quotations per share of our common stock as reported by the OTCQB during the period from September 16, 2015 through November 4, 2015 were \$25.00 and \$10.00, respectively. 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.

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

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

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

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We filed a registration statement with the SEC, which was declared effective on July 21, 2015, and subsequently filed a post-effective amendment to such registration statement with the SEC, which was declared effective on April 14, 2016, to register the resale of 13,947,599 shares of our common stock, which represents a substantial portion of the shares of our common stock issued in connection with the Merger. The shelf registration statement permits the resale of these shares at any time, subject to restrictions under applicable law. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to the shelf registration statement, the selling stockholders named in such registration statement will continue to offer shares covered by the shelf registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the shelf registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

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

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

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

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

We are an emerging growth company 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 Jumpstart Our Business Startups Act and a “smaller reporting company” as defined in applicable rules under the Securities Exchange Act of 1934, as amended, or 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 regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and financial statements, commonly known as an “auditor discussion and analysis”; we are not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders; we are not required to comply with the requirement of auditor attestation of management’s assessment of internal control over financial reporting, which is required for some other public reporting companies by Section 404 of the Sarbanes-Oxley Act; we are eligible for reduced disclosure obligations regarding executive compensation in our periodic and annual reports; and we are eligible for reduced financial statement disclosure in any registration statements under the Securities Act or reports under the Exchange Act that we may file. For as long as we continue to be an emerging growth company 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 significant amount of our outstanding equity securities and will be able to exert substantial control over us.

Our executive officers and directors beneficially own a significant 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, warrants, or otherwise, could result in dilution to the percentage ownership of our stockholders and could cause our stock price to fall.

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

If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders or the perception that such sales could occur could cause the market price of our common stock to decline. In January 2017, we entered into an ATM facility with Cowen, under which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$25.0 million. To date, we have not yet sold any shares of our common stock under the ATM facility.

Pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of December 31, 2016, we had 708,628 shares of common stock reserved for future issuance under our 2014 Plan and options to purchase up to an aggregate of 1,201,591 shares of common stock outstanding. The number of shares available for future grant under our 2014 Plan will automatically increase on January 1 of each year by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2017, an automatic increase pursuant to the 2014 Plan occurred, resulting in 854,709 additional shares available for future grant under the 2014 Plan. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2015 Employee Stock Purchase Plan, or ESPP. As of December 31, 2016, we had 238,705 shares of common stock reserved for future issuance under our ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the

preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2016, the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in January 2017. In connection with the Term A Loan, we issued to the lenders warrants to purchase up to 67,976 shares of our common stock at an exercise price of \$3.31 per share and if we borrow under Term B Loan, upon the funding of Term B Loan, we will issue to the lenders additional warrants to purchase shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

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

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- 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, as amended, and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our 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, 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 March 2015 private placement and November 2015 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.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We occupy approximately 1,560 rentable square feet of office space in La Jolla, California under a sublease with Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC), or Wellspring. In December 2016, we signed a new sublease for office space in San Diego, California to replace the sublease in La Jolla, California that will commence on the later of (i) June 1, 2017 or (ii) the date on which Wellspring's landlord delivers the premises subject to the master lease to Wellspring with certain improvements substantially completed. The new sublease will expire in October 2019. We also occupy approximately 3,766 square feet of office space in Cambridge, Massachusetts under a lease that expires in August 2020. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

We are not currently a party to, nor is our property the subject of, any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

From September 16, 2015 through November 4, 2015, our common stock was quoted on the OTCQB under the symbol "KURO." Since November 5, 2015, our common stock has been listed on the Nasdaq Global Select Market under the symbol "KURA" and ceased being quoted on the OTCQB. The high and low bid quotations per share of our common stock as reported by the OTCQB and the high and low sales prices per share of our common stock as reported by Nasdaq for the applicable periods when our common stock was quoted on the OTCQB or listed on the Nasdaq Global Select Market, as applicable, since our common stock commenced public trading are set forth below:

	High	Low
2015		
Third Quarter*	\$ 15.00	\$ 14.00
Fourth Quarter	\$ 25.00	\$ 6.72
2016		
First Quarter	\$ 8.90	\$ 3.22
Second Quarter	\$ 4.32	\$ 2.54
Third Quarter	\$ 7.24	\$ 2.50
Fourth Quarter	\$ 6.75	\$ 4.00

*There was no market for our common stock prior to September 16, 2015.

Holder of Record

As of March 10, 2017, there were approximately 283 holders of record of our common stock, which does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers, and other fiduciaries.

Dividend Policy

We have never paid cash dividends on any of our capital stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our term loan facility, subject to customary exceptions. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Use of Proceeds

On November 4, 2015, the SEC declared effective the registration statement on Form S-1 (File No. 333-207534) for our public offering of our common stock. Pursuant to the registration statement, we registered the offer and sale of up to \$69.0 million of shares of our common stock. On November 10, 2015, we sold 6,250,000 shares of our common stock at a public offering price of \$8.00 per share and on November 13, 2015, we sold 633,467 shares of our common stock at a public offering price of \$8.00 per share pursuant to the partial exercise of the underwriters' option to purchase additional shares for an aggregate gross offering price of approximately \$55.1 million. The offering has terminated and consequently we may not sell under that registration statement the remaining approximately \$13.9 million of shares of common stock. Citigroup Global Markets Inc. and Leerink Partners LLC acted as joint book-running managers for the offering and JMP Securities LLC and Oppenheimer & Co. Inc. acted as co-lead managers for the offering. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$50.3 million. None of the

underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

As of December 31, 2016, we have used approximately \$20.7 million of the net proceeds from the public offering (i) to fund our (a) four ongoing clinical trials for our lead product candidate, tipifarnib; (b) ongoing ERK inhibitor program; and (c) companion diagnostic program for tipifarnib, (ii) to fund research for other product candidates and (iii) for working capital and other general corporate purposes. Pending their use, we have invested the net proceeds from the public offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

Item 6. Selected Financial Data.

Not required for smaller reporting companies.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of the financial condition and results of operations of Kura Oncology, Inc. and Prior Kura (as defined below) should be read in conjunction with the financial statements and the notes to those statements appearing in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, assumptions and uncertainties. Important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis include, but are not limited to, those set forth in "Item 1A. Risk Factors" in this Annual Report. All forward-looking statements included in this Annual Report are based on information available to us as of the time we file this Annual Report and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

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 our reverse merger transaction which took place on March 6, 2015, or the Merger, 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 committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We intend to advance our product candidates through a combination of internal development and strategic partnerships and maintain significant development and commercial rights.

Our lead product candidate, tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase. Tipifarnib has been studied in more than 5,000 cancer patients and has demonstrated compelling and durable anti-cancer activity in certain patients with a manageable side effect profile. We are evaluating tipifarnib in four Phase 2 clinical trials: the first in patients with locally advanced solid tumors that carry mutations in the HRAS gene; the second in patients with PTCL; the third in patients with lower risk MDS; and the fourth in patients with CMML. Our goals with our ongoing Phase 2 clinical trials of tipifarnib are to confirm the clinical activity of tipifarnib in each disease indication, to validate biomarker hypotheses and to optimize dose and schedule for each disease to build a data package supporting advancement to pivotal study.

Our second product candidate is KO-947, a potent and selective small molecule inhibitor of ERK which we are advancing as a potential treatment for patients with tumors that have mutations in, or other dysregulation of, the MAPK signaling pathway. KO-947 demonstrates prolonged pathway inhibition, both in cells, or in vitro, and in animal models, or in vivo, enabling the potential for intermittent dosing on schedules up to once weekly. Additionally, the drug properties of KO-947 support an intravenous formulation, which may allow for higher drug concentration, and potentially improved tolerability in the clinic. We submitted an IND application for KO-947 to the FDA, which became effective in December 2016, and we anticipate initiation of our Phase 1 clinical trial of KO-947 in the first half of 2017.

Our third program is KO-539, a potent and selective small molecule inhibitor of the menin-MLL protein-protein interaction. Chromosomal translocations of the MLL gene play a causative role in the onset, development and progression of a subset of acute leukemias, and the activity of the MLL fusion proteins are critically dependent on binding the protein menin. Our preclinical data demonstrates that inhibitors of the menin-MLL interaction induced robust and durable regressions in multiple models of MLL-fusion leukemias. We nominated KO-539 as a development candidate for this program in December 2016.

Our accumulated deficit was \$53.9 million as of December 31, 2016. 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 additional capital 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 December 31, 2016, we had cash, cash equivalents and short-term investments of \$67.8 million. In April 2016, we received approximately \$7.5 million in net proceeds from our term loan facility, with an additional \$12.5 million available between December 31, 2016 and May 1, 2017, subject to our successful advancement of KO-947 into Phase 1 clinical trials. Although we expect our existing cash, cash equivalents and short-term investments will be sufficient to fund

our current operations into the second half of 2018, our development programs will require significant additional funds. We may also need to raise additional funds sooner than expected to pursue other development activities related to our pipeline programs. We may seek to obtain additional financing in the future through equity or debt financings or through collaborations, strategic partnerships or licensing arrangements with other companies.

We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan.

Loan and Security Agreement

In April 2016, we entered into a loan and security agreement, or loan agreement, with Oxford Finance LLC and Silicon Valley Bank, collectively referred to as the lenders, providing for up to \$20.0 million in a series of term loans. Upon entering into the loan agreement, the lenders provided us with a term loan of \$7.5 million. Under the terms of the loan agreement, we may borrow up to an additional \$12.5 million at any time between December 31, 2016 and May 1, 2017, subject to our successful advancement of KO-947 into Phase 1 clinical trials.

ATM Facility

In January 2017, we entered into an ATM facility under which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$25.0 million. We have not yet sold any shares of our common stock under the ATM facility.

Financial Operations Overview

Research and Development Expenses

We focus on the research and development of our product programs. Our research and development expenses consist of costs associated with our research activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, preclinical study fees, manufacturing costs for non-commercial products, costs for the development of our earlier-stage programs and research supply, equipment and facility costs. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses (in other research and development projects or otherwise) and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of December 31, 2016, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

Since inception through December 31, 2016, we had incurred an aggregate of approximately \$40.8 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 clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;

- the number of doses that patients receive;
- the number of patients that participate in the clinical trials;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of analyses and tests performed during the clinical trial;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

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

Other Income (Expense)

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

Results of Operations

Comparison of Fiscal Years Ended December 31, 2016 and 2015

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

	Years Ended December 31,		Increase (Decrease)
	2016	2015	
Research and development expenses	\$ 20,404	\$ 17,777	\$ 2,627
General and administrative expenses	7,963	6,088	1,875
Other income, net	807	1,240	(433)

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

	Years Ended December 31,		Increase (Decrease)
	2016	2015	
External research and development expenses:			
Tipifarnib	\$ 6,290	\$ 2,922	\$ 3,368
KO-947	3,145	5,203	(2,058)
Discovery and preclinical stage programs, collectively	5,713	4,123	1,590
Internal research and development expenses	5,256	5,529	(273)
Total research and development expenses	<u>\$ 20,404</u>	<u>\$ 17,777</u>	<u>\$ 2,627</u>

The increase in external research and development expense for tipifarnib is primarily due to increases of \$2.8 million in clinical development expenses related to our ongoing Phase 2 clinical trials and \$0.5 million in manufacturing activities. The decrease in external research and development expense for KO-947 is due to the decrease in expenses as we completed our IND-enabling activities. The increase in external research and development expenses for our discovery and preclinical stage product programs is primarily due to increases in expenses related to our menin-MLL program as we ramped up studies in preparation for the nomination of KO-539 as a development candidate in December 2016. Internal research and development

expenses include employee salaries and related expenses, share-based compensation expense, facilities expense, overhead expenses and other outside expenses. We expect our research and development expenses to increase in future periods as we continue clinical development activities for our tipifarnib and KO-947 product candidates and further research and development of our other programs.

General and Administrative Expenses. The increase in general and administrative expenses for the year ended December 31, 2016 compared to the prior year was primarily due to increases of \$0.5 million in personnel costs, \$0.5 million in share-based compensation, \$0.4 million in legal, professional fees and compliance expenses and \$0.2 million in patent related costs. We expect our general and administrative expenses to increase in future periods to support our planned increase in research and development activities.

Other income, net. The decrease in other income, net, for the year ended December 31, 2016 compared to the prior year was primarily due to an increase of \$0.5 million in interest expense and a decrease of \$0.3 million in management fee income, offset in part by an increase of \$0.4 million in interest income on our short-term investments.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through equity and debt financings. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. As of December 31, 2016, we had an accumulated deficit of \$53.9 million. We have incurred operating losses since inception and negative cash flows from operating activities.

In April 2016, we entered into a loan agreement with Oxford Finance LLC and Silicon Valley Bank, or collectively referred to as the lenders, providing for up to \$20.0 million in a series of term loans. Under the loan agreement, we have borrowed \$7.5 million, or Term A Loan, and may borrow up to an additional \$12.5 million at any time between December 31, 2016 and May 1, 2017, or Term B Loan, and together with Term A Loan, the Term Loans, subject to our successful advancement of KO-947 into Phase 1 clinical trials. All of the Term Loans mature on November 1, 2020, or Maturity Date. Repayment on the Term Loans is interest only through May 1, 2018, followed by 30 equal monthly payments of principal plus accrued interest commencing on June 1, 2018. The per annum interest rate for any outstanding Term Loans is the greater of (i) 7.75% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.25%. In addition, a final payment of 7.50% of the amounts of the term loans drawn will be due on the earlier of the Maturity Date, acceleration or prepayment of the Term Loans. If we elect to prepay the Term Loans, a prepayment fee equal to 1%, 2% or 3% of the principal balance also will be due, depending upon when the prepayment occurs. We will also be required to pay an unused fee on the earlier of May 2, 2017 or prior repayment of the Term Loans in an amount equal to (a) 2.00% multiplied by (b) \$20.0 million minus the aggregate amount of the term loans drawn on or before May 1, 2017. See Note 8, Long-Term Debt, in the Notes to Financial Statements of this Annual Report for further details of the term loan facility. Our obligations under the loan agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. Our intellectual property is subject to negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

In January 2017, we entered into an ATM facility with Cowen, under which we may offer and sell, from time to time, in our sole discretion, shares of common stock having aggregate proceeds of up to \$25.0 million through Cowen as our sales agent. We have not yet sold any shares of our common stock under the ATM facility.

As of December 31, 2016, we had cash, cash equivalents and short-term investments of \$67.8 million. Although we believe that our existing cash resources, including the proceeds and funds available under our term loan facility and ATM facility, will be sufficient to fund our current operations into the second half of 2018, 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, strategic partnerships or licensing arrangements 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.

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

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

	Years Ended December 31,	
	2016	2015
Net cash used in operating activities	\$ (25,349)	\$ (17,925)
Net cash provided by (used in) investing activities	12,178	(70,626)
Net cash provided by financing activities	7,453	102,870

Operating Activities – The increase in net cash used in operating activities was primarily due to a \$4.9 million higher net loss for the year ended December 31, 2016 compared to the prior year and a \$3.3 million increase in payments of accounts payable and accrued expenses, offset by a \$1.0 million upfront payment related to the tipifarnib license agreement in the prior year.

Investing Activities – The increase in net cash provided by investing activities for the year ended December 31, 2016 was primarily due to a \$62.6 million increase in maturities of marketable securities and a \$20.1 million decrease in purchases of marketable securities.

Financing Activities – Net cash provided by financing activities for the year ended December 31, 2016 consisted of \$7.5 million in net proceeds from the issuance of long-term debt. Net cash provided by financing activities for the year ended December 31, 2015 consisted of an aggregate of approximately \$97.9 million in net proceeds from the sale of common stock in our March 2015 private placement and our November 2015 public offering and \$5.0 million in proceeds from the issuance of convertible notes.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Management's discussion and

analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these 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 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 Note 2 to Financial Statements of this Annual Report, we believe the following accounting policies are critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our 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.

Clinical Trial Costs and Accruals

We accrue clinical trial costs based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on enrollment, the completion of clinical trials and other events. We follow this method because we believe reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, our estimated accrued expenses have approximated actual expense incurred; however, material differences could occur in the future.

Share-Based Payments

We account for share-based compensation expense related to stock options granted to employees, members of our board of directors, and non-employee consultants by estimating the fair value of each stock option on the date of grant using the Black-Scholes options-pricing model, or Black-Scholes model. The Black-Scholes model requires the use of subjective assumptions, including fair value of the underlying common stock, volatility, expected term, risk free interest rate, and the expected dividend yield. 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 actual forfeitures. In accordance with authoritative guidance, the fair value of non-employee share-based awards is remeasured as the awards vest, and the resulting change in value, if any, is recognized as expense during the period the related services are rendered.

Recently Adopted Accounting Pronouncements

See Note 3, Recent Accounting Pronouncements, in the Notes to Financial Statements of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

The financial statements required pursuant to this item are included in Item 15 of this Annual Report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 period covered by this Annual 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.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report does not include an attestation report of our independent registered public accounting firm due to a transition period established by the JOBS Act for emerging growth companies.

Change in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with management's evaluation of such internal control that occurred during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to material affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in the sections headed “Election of Directors” and “Executive Officers” in our definitive proxy statement for our 2017 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016, and is incorporated herein by reference.

We have adopted a written code of ethics for directors, officers (including our principal executive officer and our principal financial and accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at www.kuraoncology.com under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation.

The information required by this item will be set forth in the sections headed “Executive Compensation” and “Non-Employee Director Compensation” in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in the sections headed “Certain Relationships and Related Party Transactions” and “Information Regarding the Board of Directors and Corporate Governance” in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section headed “Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. *Financial Statements.* We have filed the following documents as part of this Annual Report:

[Report of Independent Registered Public Accounting Firm](#)
[Balance Sheets](#)
[Statements of Operations and Comprehensive Loss](#)
[Statements of Stockholders' Equity \(Deficit\)](#)
[Statements of Cash Flows](#)
[Notes to Financial Statements](#)

Page
F-2
F-3
F-4
F-5
F-6
F-7

2. *Financial Statement Schedules.*

There are no financial statement schedules provided because the information called for is either not required or is shown either in the financial statements or the notes thereto.

3. *Exhibits*

The exhibits listed in the accompanying Exhibit Index are incorporated herein by reference.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Kura Oncology, Inc.

Date: March 14, 2017

By: /s/ Troy E. Wilson, Ph.D., J.D.

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

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Troy E. Wilson, Ph.D., J.D. and Heidi Henson, and each of them, as his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Troy E. Wilson, Ph.D., J.D.</u> Troy E. Wilson, Ph.D., J.D.	President, Chief Executive Officer and Chairman of the Board of Directors <i>(Principal Executive Officer)</i>	March 14, 2017
<u>/s/ Heidi Henson</u> Heidi Henson	Chief Financial Officer and Secretary <i>(Principal Financial Officer and Principal Accounting Officer)</i>	March 14, 2017
<u>/s/ Faheem Hasnain</u> Faheem Hasnain	Director	March 14, 2017
<u>/s/ Robert E. Hoffman</u> Robert E. Hoffman	Director	March 14, 2017
<u>/s/ Thomas Malley</u> Thomas Malley	Director	March 14, 2017
<u>/s/ Steven H. Stein, M.D.</u> Steven H. Stein, M.D.	Director	March 14, 2017

KURA ONCOLOGY, INC.

INDEX TO FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets as of December 31, 2016 and 2015</u>	F-3
<u>Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2016 and 2015</u>	F-4
<u>Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2016 and 2015</u>	F-5
<u>Statements of Cash Flows for the Years Ended December 31, 2016 and 2015</u>	F-6
<u>Notes to Financial Statements</u>	F-7

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Kura Oncology, Inc.

We have audited the accompanying balance sheets of Kura Oncology, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Kura Oncology, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
March 14, 2017

KURA ONCOLOGY, INC.
BALANCE SHEETS
(In thousands, except par value data)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,725	\$ 15,443
Short-term investments	58,065	70,303
Accounts receivable, related party	295	430
Prepaid expenses and other current assets	725	693
Total current assets	68,810	86,869
Property and equipment, net	40	71
Other long-term assets	971	319
Total assets	\$ 69,821	\$ 87,259
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,681	\$ 4,118
Accounts payable and accrued expenses, related party	770	937
Total current liabilities	5,451	5,055
Long-term debt, net	7,324	—
Other long-term liabilities	170	101
Total liabilities	12,945	5,156
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized; 21,368 and 21,371 shares issued as of December 31, 2016 and 2015, respectively; and 19,348 and 18,138 shares outstanding as of December 31, 2016 and 2015, respectively, excluding 2,020 and 3,233 shares subject to repurchase as of December 31, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	110,748	108,484
Accumulated other comprehensive loss	(18)	(87)
Accumulated deficit	(53,856)	(26,296)
Total stockholders' equity	56,876	82,103
Total liabilities and stockholders' equity	\$ 69,821	\$ 87,259

See accompanying notes to financial statements.

KURA ONCOLOGY, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	Years Ended December 31,	
	2016	2015
Operating Expenses:		
Research and development	\$ 16,575	\$ 13,905
Research and development, related party	3,829	3,872
General and administrative	7,861	6,019
General and administrative, related party	102	69
Total operating expenses	<u>28,367</u>	<u>23,865</u>
Other Income (Expense):		
Management fee income, related party	885	1,200
Interest income	499	128
Interest expense	(577)	(42)
Interest expense, related party	—	(46)
Total other income	<u>807</u>	<u>1,240</u>
Net loss	<u>\$ (27,560)</u>	<u>\$ (22,625)</u>
Net loss per share, basic and diluted	<u>\$ (1.47)</u>	<u>\$ (2.28)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>18,701</u>	<u>9,933</u>
Comprehensive Loss:		
Net loss	\$ (27,560)	\$ (22,625)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	69	(87)
Comprehensive loss	<u>\$ (27,491)</u>	<u>\$ (22,712)</u>

See accompanying notes to financial statements.

KURA ONCOLOGY, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Unrealized Gain (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Par Value</u>				
Balance at December 31, 2014	411	\$ —	\$ 238	\$ —	\$ (3,671)	\$ (3,433)
Issuance of common stock, net of offering costs	15,164	2	97,868	—	—	97,870
Issuance of common stock for license fee	79	—	500	—	—	500
Conversion of notes payable and accrued interest	1,205	—	7,615	—	—	7,615
Restricted stock awards vested	1,279	—	4	—	—	4
Share-based compensation expense	—	—	2,259	—	—	2,259
Unrealized loss on marketable securities	—	—	—	(87)	—	(87)
Net loss	—	—	—	—	(22,625)	(22,625)
Balance at December 31, 2015	<u>18,138</u>	<u>2</u>	<u>108,484</u>	<u>(87)</u>	<u>(26,296)</u>	<u>82,103</u>
Restricted stock awards vested	1,210	—	3	—	—	3
Share-based compensation expense	—	—	2,089	—	—	2,089
Unrealized gain on marketable securities	—	—	—	69	—	69
Issuance of warrants in connection with debt facility	—	—	172	—	—	172
Net loss	—	—	—	—	(27,560)	(27,560)
Balance at December 31, 2016	<u>19,348</u>	<u>\$ 2</u>	<u>\$ 110,748</u>	<u>\$ (18)</u>	<u>\$ (53,856)</u>	<u>\$ 56,876</u>

See accompanying notes to financial statements.

KURA ONCOLOGY, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2016	2015
Operating Activities		
Net loss	\$ (27,560)	\$ (22,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,089	2,259
Non-cash license fee expense	—	500
Change in value of derivative liability	—	268
Non-cash interest expense	42	37
Non-cash interest expense, related party	—	42
Depreciation expense	31	20
Amortization of discount on marketable securities	129	171
Changes in operating assets and liabilities:		
Accounts receivable, related party	135	(400)
Prepaid expenses and other current assets	(32)	(650)
Other long-term assets	(652)	(164)
Accounts payable and accrued expenses	471	2,812
Accounts payable and accrued expenses, related party	(167)	803
Other long-term liabilities	165	(998)
Net cash used in operating activities	<u>(25,349)</u>	<u>(17,925)</u>
Investing Activities		
Maturities of marketable securities	68,605	6,000
Purchases of marketable securities	(56,427)	(76,562)
Purchases of property and equipment	—	(64)
Net cash provided by (used in) investing activities	<u>12,178</u>	<u>(70,626)</u>
Financing Activities		
Proceeds from issuance of long-term debt, net	7,453	—
Proceeds from issuance of common stock, net	—	97,870
Proceeds from issuance of convertible notes	—	4,290
Proceeds from issuance of convertible notes, related party	—	710
Net cash provided by financing activities	<u>7,453</u>	<u>102,870</u>
Net (decrease) increase in cash and cash equivalents	<u>(5,718)</u>	<u>14,319</u>
Cash and cash equivalents at beginning of period	15,443	1,124
Cash and cash equivalents at end of period	<u>\$ 9,725</u>	<u>\$ 15,443</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 352	\$ —
Supplemental non-cash disclosures:		
Warrants issued in connection with debt facility	\$ 172	\$ —
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 financial statements.

KURA ONCOLOGY, INC.
Notes to Financial Statements

1. Organization and Basis of Presentation

Kura Oncology, Inc., is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes by identifying those patients most likely to benefit from treatment.

References in these Notes to 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, or Zeta, a public shell company, for the periods following the Merger.

Effective March 6, 2015, or the Effective Time, we completed a reverse merger, or the Merger, with a wholly owned subsidiary of 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. 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. We issued an aggregate of 14,508,177 shares of our common stock upon such exchange of the Prior Kura common stock outstanding. The Merger was accounted for as a reverse merger and a capital transaction. Prior Kura is the acquirer for accounting purposes and Zeta is the acquired company.

Immediately prior to the Merger, on March 6, 2015, Prior Kura sold to investors 9,485,566 shares of its common stock at a price of \$6.32 per share, or Private Placement, for net proceeds of approximately \$55.8 million, which included approximately \$7.5 million in principal and \$115,000 in accrued interest from the conversion of the then outstanding convertible promissory notes.

2. Summary of Significant Accounting Policies

Use of Estimates

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

Reported amounts and note disclosures reflect the overall economic conditions that are most likely to occur and anticipated measures management intends to take. Actual results could differ materially from those estimates. All revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. We operate in a single industry segment which is the discovery and development of precision medicines for the treatment of cancer. Our chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

Cash and Cash Equivalents

Cash and cash equivalents consist of checking, money market and 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.

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. 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. Dividend and interest income is recognized as interest income on the statements of operations and comprehensive loss when earned. Short-term investments are classified as available-for-sale securities and carried at fair value with unrealized gains and losses recorded in other comprehensive loss and included as a separate component of stockholders' equity. 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 comprehensive loss and included in interest income on the 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;
- 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.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We maintain deposits in federally insured financial institutions in excess of federally insured limits. We have established guidelines to limit our exposure to credit risk by placing investments with high credit quality financial institutions, diversifying our investment portfolio and placing investments with maturities that maintain safety and liquidity.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets which is three years for each asset class.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset, including its eventual residual value, is compared to the carrying value to determine whether impairment exists. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. While our current and historical operating losses and negative cash flows are indicators of impairment, we believe that future cash flows to be received support the carrying value of our long-lived assets and, accordingly, have not recognized any impairment losses through December 31, 2016.

Research and Development Expenses

Research and development expenses consist of costs associated with our research activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, preclinical study fees, manufacturing costs for non-commercial products, costs for the development of our earlier-stage programs and research supply, equipment and facility costs. All such costs are charged to research and development expense as incurred when these expenditures have no alternative future uses. We are obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as expense as the related goods are delivered or the related services are performed or such time when we do not expect the goods to be delivered or services to be 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. As of December 31, 2016, 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 financial statements by matching those expenses with the period in which services and efforts are expended. As part of the process of preparing our 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.

Patent Costs

We expense all costs as incurred in connection with patent applications, including direct application fees, and the legal and consulting expenses related to making such applications, and such costs are included in general and administrative expenses on the statements of operations and comprehensive loss.

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 actual forfeitures. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model, or Black-Scholes 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 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.

Income Taxes

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

Comprehensive Income (Loss)

Comprehensive income (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 income (loss) consists solely of unrealized gains and losses on marketable securities.

Net Loss per Share

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

For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the antidilutive effect of the securities. Because of our net loss, unvested restricted stock awards, outstanding stock options and outstanding warrants are excluded from the calculation of diluted net loss per common share for the years ended December 31, 2016 and 2015, due to the anti-dilutive effect of the securities. The following table summarizes the number of potentially dilutive securities that were excluded from our calculation of diluted net loss per share for the years ended December 31, 2016 and 2015:

	Years Ended December 31,	
	2016	2015
Unvested restricted stock awards	2,020,266	3,232,350
Stock options	1,201,591	574,312
Warrants	67,976	—
Total	3,289,833	3,806,662

3. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards 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. 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 in the first quarter of 2018. We plan to adopt the accounting standard using the modified retrospective transition approach. The modified retrospective transition approach will recognize any changes from the beginning of the year of initial application through reteiled earnings with no restatement of comparative periods. We currently do not have any revenue contracts with customers and will review any new contracts entered into prior to the adoption of the new standard. The adoption of this guidance is not expected to have an impact on our financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires lessees to recognize a right-to-use asset and a lease obligation for all leases. Lessees are permitted to make an accounting policy election to not recognize an asset and liability for leases with a term of 12 months or less. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures, including significant judgments made by management, will be required. This pronouncement is effective for fiscal years beginning after December 15, 2018 and interim periods within those annual periods. Early adoption is permitted. The guidance is required to be adopted at the earliest period presented using a modified retrospective approach. We plan to adopt the accounting standard in the first quarter of 2019 and will evaluate any existing leases at that time and recognize a right-to-use asset and lease obligation for all leases with terms greater than 12 months on our financial statements.

4. Investments

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

The following tables summarize, by major security type, our investments that are measured at fair value on a recurring basis as of December 31, 2016 and 2015, in thousands:

	Maturities (years)	As of December 31, 2016			Fair Value
		Amortized Cost	Unrealized Gains	Unrealized Losses	
Cash equivalents:					
Money market funds	1 or less	\$ 5,762	\$ —	\$ —	\$ 5,762
Commercial paper	1 or less	2,000	—	—	2,000
Total cash equivalents		7,762	—	—	7,762
Short-term investments:					
U.S. Treasury securities	2 or less	28,006	5	(9)	28,002
Commercial paper	1 or less	14,273	—	—	14,273
Corporate debt securities	2 or less	13,603	—	(14)	13,589
Government sponsored enterprise securities	1 or less	2,201	—	—	2,201
Total short-term investments		58,083	5	(23)	58,065
Total		\$ 65,845	\$ 5	\$ (23)	\$ 65,827

	Maturities (years)	As of December 31, 2015			Fair Value
		Amortized Cost	Unrealized Gains	Unrealized Losses	
Cash equivalents:					
Money market funds	1 or less	\$ 12,984	\$ —	\$ —	\$ 12,984
Short-term investments:					
U.S. Treasury securities	2 or less	16,007	—	(18)	15,989
Commercial paper	1 or less	18,367	—	—	18,367
Corporate debt securities	2 or less	22,758	—	(48)	22,710
Government sponsored enterprise securities	2 or less	13,258	—	(21)	13,237
Total short-term investments		70,390	—	(87)	70,303
Total		\$ 83,374	\$ —	\$ (87)	\$ 83,287

The available-for-sale investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. As of December 31, 2016 and 2015, \$50.3 million and \$57.6 million of our short-term investments had maturities less than one year, respectively, and \$7.8 million and \$12.7 million had maturities between one to two years, respectively. There were no realized gains or losses for the years ended December 31, 2016 and 2015. As of December 31, 2016 and 2015, \$32.8 million and \$51.9 million of our marketable securities were in gross unrealized loss positions, respectively, all of which had been in such position for less than 12 months. We reviewed our

marketable securities as of December 31, 2016 and determined that the unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that all securities have been in an unrealized loss position for less than 12 months. In addition, we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis. As such, we did not recognize any such impairment in our financial statements as of December 31, 2016 and 2015.

5. Fair Value Measurements

As of December 31, 2016 and 2015, we had cash equivalents and 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 December 31, 2016 and 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 U.S. Treasury securities, which were measured at fair value using Level 1 inputs, and corporate debt securities, commercial paper and government sponsored enterprise securities, which were measured at fair value using Level 2 inputs. We determine the fair value of Level 2 related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. We validate the fair values of Level 2 financial instruments by comparing these fair values to a third-party pricing source. No transfers between levels have occurred during the periods presented.

The following tables summarize, by major security type, our cash equivalents and short-term investments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy as of December 31, 2016 and 2015, in thousands:

	As of December 31, 2016		
	Balance	Level 1	Level 2
Cash equivalents:			
Money market funds	\$ 5,762	\$ 5,762	\$ —
Commercial paper	2,000	—	2,000
Total cash equivalents	7,762	5,762	2,000
Short-term investments:			
U.S. Treasury securities	28,002	28,002	—
Commercial paper	14,273	—	14,273
Corporate debt securities	13,589	—	13,589
Government sponsored enterprise securities	2,201	—	2,201
Total short-term investments	58,065	28,002	30,063
Total	\$ 65,827	\$ 33,764	\$ 32,063
	As of December 31, 2015		
	Balance	Level 1	Level 2
Cash equivalents:			
Money market funds	\$ 12,984	\$ 12,984	\$ —
Short-term investments:			
U.S. Treasury securities	15,989	15,989	—
Commercial paper	18,367	—	18,367
Corporate debt securities	22,710	—	22,710
Government sponsored enterprise securities	13,237	—	13,237
Total short-term investments	70,303	15,989	54,314
Total	\$ 83,287	\$ 28,973	\$ 54,314

We believe that our term loan facility bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the term loan facility approximates fair value. The fair value of our term loan facility is determined using Level 2 inputs in the fair value hierarchy. See Note 8, Long-Term Debt, for further discussion of our term loan facility.

6. Property and Equipment, Net

Property and equipment consisted of the following, in thousands:

	December 31,	
	2016	2015
Computer equipment	\$ 85	\$ 85
Software	7	7
Property and equipment, gross	92	92
Less: accumulated depreciation	(52)	(21)
Property and equipment, net	<u>\$ 40</u>	<u>\$ 71</u>

Depreciation expense was \$31,000 and \$20,000 for the years ended December 31, 2016 and 2015, respectively.

7. Accounts Payable and Accrued Liabilities

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

	December 31,	
	2016	2015
Accounts payable	\$ 638	\$ 902
Accrued compensation and benefits	1,907	1,282
Other accrued expenses	2,136	1,934
Total accounts payable and accrued expenses	<u>\$ 4,681</u>	<u>\$ 4,118</u>

8. Long-Term Debt

On April 27, 2016, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or the Lenders, pursuant to which the Lenders provided a term loan facility of up to \$20.0 million. Upon entering into the Loan Agreement, we borrowed \$7.5 million from the Lenders, or Term A Loan. We may, at our sole discretion, borrow up to an additional \$12.5 million at any time between December 31, 2016 and May 1, 2017, or Term B Loan, and together with the Term A Loan, the Term Loans, subject to our successful advancement of KO-947, a small molecule inhibitor of extracellular signal regulated kinase, into Phase 1 clinical trials. In addition, each Term B Loan must be in an amount equal to the lesser of \$5.0 million or the amount that is remaining under the Term B Loan.

All of the Term Loans will mature on November 1, 2020, or Maturity Date. Repayment of the Term Loans is interest only through May 1, 2018, followed by 30 equal monthly payments of principal plus accrued interest commencing on June 1, 2018. The per annum interest rate for any outstanding Term Loans is the greater of (i) 7.75% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.25%. The interest rate as of December 31, 2016 was 7.75%. In addition, a final payment of 7.50% of the amounts of the Term Loans drawn will be due on the earlier of the Maturity Date, acceleration of any Term Loan, or prepayment of the Term Loans. In connection with the Term A Loan, a final payment of approximately \$563,000 will be due and is being accrued through interest expense using the effective interest method. If we elect to prepay the Term Loans, a prepayment fee equal to 1%, 2% or 3% of the principal balance will also be due, depending upon when the prepayment occurs. We will also be required to pay an unused fee on the earlier of May 2, 2017 or prior repayment of the Term Loans in an amount equal to (a) 2.00% multiplied by (b) \$20.0 million minus the aggregate amount of the Term Loans drawn on or before May 1, 2017.

We are subject to customary affirmative and restrictive covenants under the term loan facility. Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our current and future assets, other

than our intellectual property. We have also agreed not to encumber our intellectual property assets, except as permitted by the Loan Agreement.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the Loan Agreement and the occurrence of a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of Lenders' lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement. The conditional exercisable call option related to the event of default is considered to be an embedded derivative which is required to be bifurcated and accounted for as a separate financial instrument. In the periods presented, the value of the embedded derivative is not material, but could become material in future periods if an event of default became more probable than is currently estimated. As of December 31, 2016, we were in compliance with all material covenants under the Loan Agreement and there had been no material adverse change.

In connection with the Term A Loan, we issued to the Lenders warrants to purchase up to 67,976 shares of our common stock at an exercise price of \$3.31 per share, or the Warrants. The Warrants are exercisable, in whole or in part, and will terminate on the earlier of April 27, 2026 or the closing of certain merger or consolidation transactions. The Warrants were valued using the Black-Scholes model with the following assumptions: volatility of 70.92%, expected term of ten years, risk-free interest rate of 2.11% and a zero dividend yield. The fair value of the Warrants was approximately \$172,000 upon issuance, which was recorded as a debt discount and is being amortized to interest expense using the effective interest method through the scheduled maturity date.

If we borrow under the Term B Loan, upon the funding of the Term B Loan, we will issue to the Lenders additional warrants to purchase shares of our common stock equal to 3.00% of each Term B Loan amount divided by the lower of (i) the ten day average closing price of our common stock reported on the Nasdaq Global Select Market prior to funding or (ii) the closing price of our common stock reported on the Nasdaq Global Select Market on the day prior to funding. Such lower amount of (i) and (ii) above will also be the exercise price per share for such warrants. The terms of such warrants would be substantially the same as those contained in the Warrants.

The following table summarizes future minimum payments under the term loan facility as of December 31, 2016, in thousands:

Year Ending December 31,	
2017	\$ 607
2018	2,323
2019	3,355
2020	3,424
Total future minimum payments	<u>9,709</u>
Less: interest payments	<u>(2,209)</u>
Principal amount of long-term debt	7,500
Less: Unamortized discount	<u>(176)</u>
Long-term debt, net of unamortized discount	7,324
Current portion of long-term debt	<u>—</u>
Long-term debt, net	<u><u>\$ 7,324</u></u>

9. 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. In connection with the Private Placement, the total amount 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. In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under the note 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 of which \$710,000 were with certain officers and certain officers' related parties. In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under the note was automatically converted into 479,667 shares of our common stock.

JJDC Convertible Note

In accordance with the license agreement with Janssen Pharmaceutica NV, a foreign entity headquartered in Belgium and an affiliate of Johnson & Johnson, Inc., or Janssen, in January 2015 we entered into a Convertible Promissory Note with Janssen's affiliated company, Johnson & Johnson Innovation – JJDC, Inc., for \$1.0 million. In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under the note 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. In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under the note was automatically converted into 158,852 shares of our common stock.

10. License Agreements

Janssen License Agreement

In December 2014, we entered into a license agreement with Janssen, which was amended in June 2016, under which we received certain intellectual property rights related to tipifarnib in all indications other than virology for a non-refundable \$1.0 million upfront license fee and payments upon achievement of certain development and sales-based milestones. Tipifarnib is a clinical stage compound and all ongoing development, regulatory and commercial work will be completed fully and at our sole expense. Under the license agreement, Janssen has a first right to negotiate for an exclusive license back from us to develop and commercialize tipifarnib on terms to be negotiated in good faith. Janssen may exercise this right of first negotiation during a 60-day period following delivery of clinical data as specified in the agreement.

The agreement will terminate upon the last-to-expire patent rights or last-to-expire royalty term, or may be terminated by us with 180 days written notice of termination. Either party may terminate the agreement in the event of material breach of the agreement that is not cured within 45 days. Janssen may also terminate the agreement due to our lack of diligence that is not cured within a three-month period.

The upfront license fee was recorded as research and development expense for the period from August 22, 2014 (Inception) to December 31, 2014 and paid in January 2015. Subsequent to such payment, in accordance with the agreement, we entered into a convertible promissory note with Johnson & Johnson Innovation—JJDC, Inc. as described in Note 9.

The University of Michigan License Agreement

In December 2014, we entered into a license agreement with the Regents of the University of Michigan, or the University of Michigan, which was amended in March 2015, July 2015, September 2016 and February 2017, 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 several 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. The University of 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 our Private Placement, 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 year ended December 31, 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 the University of 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.

The University of California San Francisco License Agreement

In November 2014, we entered into a license agreement with The Regents of the University of California San Francisco, or UCSF, which was amended in April 2015, under which we received certain license rights. The agreement provided for an upfront payment as well as contingent milestone payments. Additionally, the agreement provided for a one-time 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. Upon completion of the qualified financing event in March 2015 and the public offering completed in November 2015, the indexed milestone payment was determined to be \$464,000 and was paid in full as of December 31, 2016. The license agreement with UCSF was terminated effective as of January 8, 2017.

Future Milestone Payments under License Agreements

Collectively, all of our license agreements provide for specified development, regulatory and sales-based milestone payments up to a total of \$79.4 million payable upon occurrence of each stated event, of which \$425,000 relates to the initiation of certain development activities, \$28.2 million relates to the achievement of specified regulatory approvals for the first indication and up to \$50.8 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 December 31, 2016, 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.

Araxes Asset Purchase Agreement

In December 2014, we entered into an asset purchase agreement with Araxes, which was amended and restated in February 2015, under which we purchased certain early stage patent rights related to compounds in the field of oncology for a purchase price of \$500,000 payable under a convertible promissory note. All ongoing development, regulatory and commercial work will be completed fully and at our sole expense. The agreement allows for contingent milestone payments of \$9.7 million throughout development and commercialization of the asset, of which \$1.2 million relates to the initiation of certain development activities, and \$8.5 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. Additional payments will be due for each subsequent indication if specified regulatory approvals are achieved. We will recognize the milestones as expense when each event occurs. Furthermore, if the program is successfully commercialized, we will be required to pay tiered royalties on annual net product sales ranging in the low single digits, depending on the volume of sales. All milestone payments under the agreement will be recognized upon completion of the required events because the triggering events will not be considered to be probable until they are achieved. As of December 31, 2016, we paid a \$100,000 milestone payment to Araxes upon the filing of the investigational new drug application, or IND, for KO-947 in the fourth quarter of 2016.

11. Commitments and Contingencies

Sponsored Research Agreement with the University of Michigan

In February 2015, we entered into a sponsored research agreement with the University of Michigan under which we agreed to sponsor up to \$2.7 million of research at the University of Michigan over a three-year period. We 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. Any costs incurred for the sponsored research agreement will be expensed as incurred. For the years ended December 31, 2016 and 2015, we recorded approximately \$1.0 million and \$0.9 million, respectively, in research and development expense under this sponsored research agreement.

Operating Leases

In August 2014, we entered into a sublease agreement, or the Sublease, with Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC), or Wellspring, a wholly owned subsidiary of our affiliated company Araxes for office space located on North Torrey Pines Road in La Jolla, California. The Sublease was amended effective September 1, 2014 to provide for a monthly rent of \$4,820 per month. The Sublease includes rent escalation of 3.0% per year. In addition to the base monthly rent, we are obligated to pay for operating expenses, taxes, insurance and utilities applicable to the subleased property. Pursuant to the terms of the Sublease, as amended again in June 2016, the Sublease would have expired on October 31, 2019. In December 2016, we entered into a third amendment to Sublease pursuant to which the Sublease will expire on the later of (i) June 8, 2017 or (ii) seven days after the date on which Wellspring's landlord delivers the new subleased premises to Wellspring as described below.

In December 2016, we entered into a new sublease, or the New Sublease, with Wellspring for 5,216 square feet of office space located on Science Park Road in San Diego, California for a monthly rent of approximately \$16,000 per month and security deposit of approximately \$16,000. The New Sublease includes rent escalation of 3.0% per year. In addition to the base monthly rent, we will be obligated to pay for operating costs, amenities fees and all other costs applicable to the subleased property. The terms of the new sublease will commence on the later of (i) June 1, 2017 or (ii) the date on which Wellspring's landlord delivers certain premises under Wellspring's master lease to Wellspring with certain improvements substantially completed. The New Sublease will expire on October 31, 2019.

In August 2015, we entered into a lease agreement for approximately 3,766 square feet of office space located in Cambridge, Massachusetts. We paid a security deposit of approximately \$44,000. The lease is subject to a 60 month term expiring on August 1, 2020, with initial monthly rent of approximately \$21,000 per month, and subject to a 1.4% annual rent increase. Total base rent payable over the lease period is \$1.3 million. In addition to base monthly rent, we are obligated to pay for taxes, insurance and utilities applicable to the leased property.

Future minimum payments required under the facility leases as of December 31, 2016 are summarized as follows, in thousands:

Year Ending December 31,		
2017	\$	406
2018		461
2019		436
2020		159
Total future minimum lease payments	\$	1,462

Rent expense for the years ended December 31, 2016 and 2015 was \$342,000 and \$267,000, respectively.

Charitable Gift

We are obligated to make a charitable gift of \$285,000 to the Leukemia and Lymphoma Society in connection with the University of Michigan agreement described in Note 10 to be paid in three equal parts: the first part was due and paid in January 2015, the second part was due and paid in January 2016 and the final part was due and paid in January 2017. As of December 31, 2016, \$95,000 was included in accounts payable and accrued expenses on the balance sheets. As of December 31, 2015, \$95,000 was included in accounts payable and accrued expenses and \$95,000 in other long-term liabilities on the balance sheets.

Litigation

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.

12. Stockholders' Equity

Immediately prior to the Merger, on March 6, 2015, Prior Kura sold an aggregate of 9,485,566 shares of its common stock at a price of \$6.32 per share, for net proceeds of approximately \$55.8 million, net of \$4.1 million in fees. The Private Placement represented a qualified financing conversion event pursuant to Prior Kura's then outstanding convertible promissory notes. As such, upon the closing of the Private Placement, an aggregate of \$7.5 million in principal under such convertible promissory notes and \$115,000 in accrued interest through February 28, 2015 automatically converted into 1,204,870 shares of our common stock (which shares and net proceeds are included in the amounts set forth above). 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.

In November 2015, we completed a public offering in which we sold an aggregate of 6,883,467 shares of common stock at a price of \$8.00 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$50.3 million.

13. Equity Incentive Plan

Under our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, a total of 5,975,000 shares of common stock were initially reserved for issuance. As of December 31, 2016, there were 708,628 shares of common stock reserved for future equity awards under the 2014 Plan. The number of shares available for future grant under our 2014 Plan will automatically increase on January 1 of each year by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2016 and 2017, an automatic increase pursuant to the 2014 Plan occurred, resulting in 854,822 and 854,709 additional shares available for future grant under the 2014 Plan, respectively. 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 our employees and other service providers.

In addition, as of December 31, 2016, we had 238,705 shares of common stock reserved for future issuance under our 2015 Employee Stock Purchase Plan, or ESPP, which has not been implemented as of December 31, 2016. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2016, our board of directors elected not to increase the total number of shares of our common stock reserved for issuance under the ESPP in January 2017.

Stock Options

The exercise price of all stock options granted was equal to no less than the estimated fair market value of such stock on the date of grant. Stock options generally vest over a three to four-year period. The maximum contractual term for all options is ten years. The following is a summary of stock option activity for the year ended December 31, 2016, in thousands (except per share and years data):

	Number of Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	574	\$ 9.10		
Granted	703	\$ 4.72		
Canceled/forfeited	(75)	\$ 11.64		
Outstanding at December 31, 2016	1,202	\$ 6.38	8.9	\$ 840
Exercisable at December 31, 2016	331	\$ 6.92	8.7	\$ 148

The assumptions used to estimate the fair value of stock options granted to employees in the years ended December 31, 2016 and 2015 using the Black-Scholes model were as follows:

	Years Ended December 31,	
	2016	2015
Weighted-average grant date fair value per share	\$ 3.09	\$ 4.16
Expected volatility	73.8% — 76.6%	70.8% — 72.8%
Expected term (in years)	5.50 — 6.08	6.00 — 6.08
Risk free interest rate	1.5% — 1.7%	1.7% — 1.8%
Expected dividend yield	—	—

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 adopted ASU 2016-09 in 2016, and as a result, apply actual forfeitures as they occur.

For the years ended December 31, 2016 and 2015, we recognized \$1.1 million and \$399,000 expense related to options, respectively. As of December 31, 2016, unrecognized estimated compensation expense related to options was \$2.7 million, which is expected to be recognized over the weighted-average remaining requisite service period of approximately 2.7 years.

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 December 31, 2016, there were 2,020,266 shares subject to repurchase, of which 1,697,556 shares were related to employee stock awards, and 322,710 shares were related to non-employee stock awards.

The following is a summary of restricted stock awards activity for the year ended December 31, 2016, in thousands (except per share data):

	Number of Shares	Employee	Non-employee	Weighted-Average Grant Date Fair Value of Employee Awards
Unvested at December 31, 2015	3,233	2,717	516	\$ 0.002
Granted	—	—	—	\$ —
Vested	(1,210)	(1,017)	(193)	\$ 0.002
Forfeited	(3)	(3)	—	\$ 0.002
Unvested at December 31, 2016	<u>2,020</u>	<u>1,697</u>	<u>323</u>	\$ 0.002
Vested at December 31, 2016	<u>2,899</u>	<u>2,375</u>	<u>524</u>	\$ 0.002

For the years ended December 31, 2016 and 2015, we recognized expense related to restricted stock awards totaling \$1.0 million and \$1.9 million, respectively, of which \$856,000 and \$1.7 million in expense related to non-employee restricted stock awards, respectively. As of December 31, 2016, unrecognized estimated compensation expense related to employee restricted stock awards was \$227,000, which is expected to be recognized over the weighted-average remaining requisite service period of approximately 1.7 years.

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

	Years Ended December 31,	
	2016	2015
Research and development	\$ 1,293	\$ 1,916
General and administrative	796	343
Total share-based compensation expense	<u>\$ 2,089</u>	<u>\$ 2,259</u>

14. Related Party Transactions

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, of which \$710,000 were with certain officers and certain officers' related parties. In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under the notes 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 transactions with Araxes for the years ended December 31, 2016 and 2015:

- *Asset Purchase Agreement*

Under our asset purchase agreement with Araxes, we paid a \$100,000 milestone payment to Araxes upon the filing of the IND for KO-947 in the fourth quarter of 2016.

- *Convertible Promissory Notes*

In connection with the Private Placement, the total amount of unpaid principal and accrued interest as of February 28, 2015 under a convertible note issued to Araxes in connection with (i) the Araxes asset purchase was automatically converted into 80,293 shares of our common stock and (ii) an Araxes \$2.0 million loan was automatically converted into 326,443 shares of our common stock.

- *Facility Sublease*

We sublease office space in La Jolla, California from Wellspring. Rent expense related to the Sublease for the years ended December 31, 2016 and 2015 was \$65,000 and \$58,000, respectively. Pursuant to the terms of the Sublease, as amended in June 2016, the Sublease would have expired on October 31, 2019. In December 2016, we entered into a third amendment to Sublease pursuant to which the Sublease will expire on the later of (i) June 8, 2017 or (ii) seven days after the date on which Wellspring's landlord delivers the premises to Wellspring.

In December 2016, we entered into the New Sublease with Wellspring for office space in San Diego, California. The terms of the New Sublease will commence on the later of (i) June 1, 2017 or (ii) the date on which Wellspring's landlord delivers the premises subject to Wellspring's master lease to Wellspring with certain improvements substantially completed. The New Sublease will expire on October 31, 2019. See Note 11, Commitments and Contingencies, for further details of the terms of the Sublease and New Sublease.

- *Management Fees*

We have a management services agreement with Araxes pursuant to which Araxes pays us a fixed fee of \$65,000 per month for management services. In addition, the agreement allows for Araxes to reimburse us an amount equal to the number of full time equivalents, or FTE, performing research and development services for Araxes, at an annual FTE rate of approximately \$350,000, plus actual expenses as reasonably incurred. The initial term of this agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the years ended December 31, 2016 and 2015, we recorded reimbursements of \$358,000 and \$330,000, respectively, for research and development services provided to Araxes, which was recorded as a reduction to research and development expenses on the statements of operations and comprehensive loss. As of December 31, 2016 and 2015, \$295,000 and \$430,000 related to management fees and reimbursements of research and development services, respectively, are included in accounts receivable, related party on the balance sheets.

- *Services Agreement*

We have a services agreement with Wellspring 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. The initial term of this services agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the years ended December 31, 2016 and 2015, we recognized \$4.0 million and \$4.1 million, respectively, from research and development services provided to us under this agreement as research and development expense, related party on the statements of operations and comprehensive loss. As of December 31, 2016 and 2015, \$770,000 and \$911,000, respectively, related to research and development services under this agreement are included in accounts payable and accrued expenses, related party on the balance sheets.

15. Employee Benefit Plan

We have a defined contribution 401(k) plan for all employees. Under the terms of the plan, employees may make voluntary contributions as a percentage or defined amount of compensation. We did not provide a matching contribution program in 2015. Beginning in 2016, we provide a safe harbor contribution of 3.0% of the employee's compensation, not to exceed eligible limits. For the year ended December 31, 2016, we incurred \$176,000 in expenses related to the safe harbor contribution.

16. Income Taxes

We file tax returns as prescribed by the tax laws of the jurisdictions in which we operate. In the normal course of business, our 2014 through 2016 tax years will be subject to examination by the federal and state jurisdictions where applicable. We have not been, nor are we currently, under examination by the federal or any state tax authority.

Our effective income tax rate differs from the statutory federal rate of 34% for the years ended December 31, 2016 and 2015, due to the following, in thousands:

	Years Ended December 31,	
	2016	2015
Income taxes at statutory federal rate	\$ (9,370)	\$ (7,693)
State income tax, net of federal benefit	(1,823)	(1,412)
Share-based compensation	564	712
Research and development tax credits	(560)	(544)
Other	50	29
Valuation allowance	11,139	8,908
Income tax expense	\$ —	\$ —

Significant components of our deferred tax assets at December 31, 2016 and 2015 are shown below, in thousands:

	December 31,	
	2016	2015
Deferred tax assets		
Net operating loss carryforwards	\$ 18,321	\$ 7,975
Intangibles	982	999
Research and development tax credit carryforwards	971	573
Accruals	809	662
Other	371	106
Total deferred tax assets	21,454	10,315
Less valuation allowance	(21,454)	(10,315)
Net deferred tax assets	\$ —	\$ —

At December 31, 2016, we had federal and state net operating loss, or NOL, carryforwards of \$44.8 million and \$54.4 million, respectively. The federal loss carryforwards begin to expire in 2034, unless previously utilized. We have \$54.1 million of state losses that begin to expire in 2034 and \$310,000 of state loss carryforwards that begin to expire in 2030, unless previously utilized. We also have federal and state research and development credit carryforwards of \$857,000 (net of \$250,000 to be utilized as a payroll tax offset) and \$629,000, respectively. The federal research and development credits will begin to expire in 2034, unless previously utilized. Of the state research and development credits, \$593,000 will carryforward indefinitely and \$36,000 will begin to expire in 2031, unless previously utilized. Pursuant to Section 41(h) of the Internal Revenue Code of 1986, as amended, or IRC, which was added as part of the Protecting Americans from Tax Hikes Act of 2015, we qualify to elect up to \$250,000 of 2016 federal research and development credits to be utilized as an offset against future payroll taxes. We plan to make the election on our 2016 federal tax return and have recognized benefit of \$250,000 as an offset to our 2016 research and development expenses.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use existing deferred tax assets. Based on the weight of the evidence, including our limited existence and losses since inception, management has determined that it is more likely than not that the deferred tax assets will not be realized. The valuation allowance increased by \$11.1 million and \$8.9 million from December 31, 2015 to December 31, 2016 and from December 31, 2014 to December 31, 2015, respectively.

Pursuant to Sections 382 and 383 of the IRC annual use of our NOL or research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We completed a study to assess whether an ownership change, as defined by IRC Section 382, had occurred from our formation through March 31, 2016. Based upon the study, we determined that an ownership change occurred on March 6, 2015 concurrent with the Private Placement and the Merger. The analysis concluded the annual utilization limitation will be

sufficient to utilize our pre-ownership change NOLs and research and development credits prior to expiration. Future ownership changes may limit our ability to utilize remaining tax attributes. Any carryforwards that will expire prior to utilization as a result of such additional limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance.

In accordance with authoritative guidance, the impact of an uncertain income tax position is recognized at the largest amount that is “more likely than not” to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table summarizes the activity related to our unrecognized tax benefits, in thousands:

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Gross unrecognized tax benefits at the beginning of the year	\$ 167	\$ —
Increases from tax positions taken in the current year	191	167
Gross unrecognized tax benefits at the end of the year	<u>\$ 358</u>	<u>\$ 167</u>

Our practice is to recognize interest and penalties related to income tax matters in income tax expense. We did not have any accrued interest or penalties included on the balance sheets and have not recognized interest and penalties on the statements of operations and comprehensive loss for the years ended December 31, 2016 or 2015.

We do not expect that there will be a significant change in the unrecognized tax benefits over the next 12 months. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

17. Subsequent Event

Entry into ATM Facility

On January 27, 2017, we entered into an at the market issuance sales agreement, or ATM agreement, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time, in our sole discretion, shares of our common stock having an aggregate offering price of up to \$25.0 million through Cowen as our sales agent, or the ATM facility.

Cowen may sell common stock under the ATM facility by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended, including without limitation sales made by means of ordinary brokers’ transactions on the Nasdaq Global Select Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Cowen will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM facility, and also have provided Cowen with customary indemnification rights.

We are not obligated to make any sales of common stock under the ATM facility. The offering of shares of common stock pursuant to the ATM facility will terminate upon the earlier of (i) the sale of all common stock subject to the ATM facility, or (ii) termination of the ATM agreement in accordance with its terms.

INDEX TO EXHIBITS

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
2.1	Agreement and Plan of Merger, dated March 6, 2015, by and among the Registrant, Kura Operations, Inc. and Kura Oncology, Inc.		8-K (Exhibit 2.1)	3/12/2015	000-53058
2.2	Agreement and Plan of Merger, dated March 6, 2015, by and between the Registrant and Kura Oncology, Inc., relating to the name change of the Registrant.		8-K (Exhibit 2.2)	3/12/2015	000-53058
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.		8-K (Exhibit 3.1)	5/16/2016	001-37620
3.2	Amended and Restated Bylaws of the Registrant.		8-K (Exhibit 3.2)	5/16/2016	001-37620
4.1	Form of Common Stock certificate.		8-K (Exhibit 4.1)	3/12/2015	000-53058
4.2	Registration Rights Agreement, dated as of March 6, 2015, by and among Kura Oncology, Inc. and the Investors listed on Schedule A thereto.		8-K (Exhibit 4.2)	3/12/2015	000-53058
4.3	Warrant to Purchase Stock by Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
4.4	Warrant to Purchase Stock by Registrant on April 27, 2016 to Silicon Valley Bank.		10-Q (Exhibit 4.4)	8/10/2016	001-37620
10.1+	Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.		8-K (Exhibit 10.1)	3/12/2015	000-53058
10.2+	Form of Restricted Stock Purchase Agreement and Restricted Stock Purchase Award Notice under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan.		8-K (Exhibit 10.2)	3/12/2015	000-53058
10.3+	Kura Oncology, Inc. 2015 Employee Stock Purchase Plan.		8-K (Exhibit 10.3)	3/12/2015	000-53058
10.4+	Form of Indemnification Agreement by and between the Registrant and each of its directors and officers.		8-K (Exhibit 10.4)	3/12/2015	000-53058
10.5*	License Agreement, dated December 18, 2014, by and between the Registrant and Janssen Pharmaceutica NV.		8-K/A (Exhibit 10.6)	7/2/2015	000-53058
10.6*	Amended and Restated Asset Purchase Agreement, dated February 12, 2015, by and between the Registrant and Araxes Pharma LLC.		8-K (Exhibit 10.7)	3/12/2015	000-53058
10.7	Sublease, dated August 29, 2014, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).		8-K (Exhibit 10.8)	3/12/2015	000-53058

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.8	First Amendment to Sublease, dated December 18, 2014, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).		8-K (Exhibit 10.9)	3/12/2015	000-53058
10.9	2 nd Amendment to Sublease, dated June 9, 2016, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).		10-Q (Exhibit 10.4)	8/10/2016	001-37620
10.10	Third Amendment to Sublease, dated December 20, 2016, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).	X			
10.11	Sublease, dated December 20, 2016, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).	X			
10.12**	Patent License Agreement, effective as of December 22, 2014, by and between the Registrant and the Regents of the University of Michigan, as amended on March 3, 2015, July 22, 2015, September 29, 2016 and February 1, 2017.	X			
10.13+	Kura Oncology, Inc. Amended and Restated Non-Employee Director Compensation Policy.		S-1 (Exhibit 10.13)	10/20/2015	333-207534
10.14*	Services Agreement, effective as of October 1, 2014, by and between the Registrant and Wellspring Biosciences, Inc. (formerly Wellspring Biosciences LLC).		S-1/A (Exhibit 10.13)	6/2/2015	333-203503
10.15*	Management Services Agreement, effective as of October 1, 2014, by and between the Registrant and Araxes Pharma LLC.		S-1/A (Exhibit 10.14)	6/2/2015	333-203503
10.16	Office Lease Agreement, dated August 1, 2015, by and between the Registrant and 55 Cambridge Parkway, LLC.		S-1 (Exhibit 10.16)	10/20/2015	333-207534
10.17+	Amended and Restated Executive Employment Agreement, effective as of January 29, 2016, by and between the Registrant and Troy E. Wilson, Ph.D., J.D.		10-K (Exhibit 10.15)	3/17/2016	001-37620
10.18+	Amended and Restated Executive Employment Agreement, effective as of January 29, 2016, by and between the Registrant and Antonio Gualberto, M.D., Ph.D.		10-K (Exhibit 10.16)	3/17/2016	001-37620
10.19+	Amended and Restated Executive Employment Agreement, effective as of January 29, 2016, by and between the Registrant and Annette North.		10-K (Exhibit 10.17)	3/17/2016	001-37620
10.20	First Amendment to Management Services Agreement, effective as of April 1, 2016, by and between the Registrant and Araxes Pharma LLC.		10-Q (Exhibit 10.1)	8/10/2016	001-37620

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.21	Loan and Security Agreement, dated as of April 27, 2016, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank.		10-Q (Exhibit 10.2)	8/10/2016	001-37620
10.22	Amendment No. 1 to License Agreement, dated June 6, 2016, by and between the Registrant and Janssen Pharmaceutica NV.		10-Q (Exhibit 10.3)	8/10/2016	001-37620
10.23	Common Stock Sales Agreement, dated January 27, 2017, by and between the Registrant and Cowen and Company, LLC.		8-K (Exhibit 10.1)	1/27/2017	001-37620
23.1	Consent of Independent Registered Public Accounting Firm.	X			
24.1	Power of Attorney (see signature page).	X			
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.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Presentation Linkbase Document.	X			

+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

SUBLEASE

THIS SUBLEASE (“Sublease”), dated December 20, 2016, for reference purposes only, is entered into by and between **WELLSPRING BIOSCIENCES LLC**, a Delaware limited liability company (“Sublandlord”), and **KURA ONCOLOGY, INC.**, a Delaware corporation (“Subtenant”).

RECITALS

A. Sublandlord has entered into a lease of certain premises consisting of approximately 24,759 square feet in a building, located at 3033 Science Park Road, San Diego, CA, pursuant to that certain lease of even date herewith, between ARE-SD REGION No. 35, LLC, as landlord (the “Master Landlord”) and Sublandlord, as tenant (as amended or otherwise modified from time to time, the “Master Lease”), a copy of which is attached as **Exhibit A**, as more particularly described therein (the “Premises”). Capitalized terms used but not defined herein have the same meanings as they have in the Master Lease.

B. Sublandlord desires to sublease to Subtenant, and Subtenant desires to sublease from Sublandlord a portion of the Premises upon the terms and conditions provided for herein.

Now, THEREFORE, in consideration of the mutual covenants and conditions contained herein, Sublandlord and Subtenant covenant and agree as follows:

AGREEMENT

1. Subleased Premises. On and subject to the terms and conditions below, Sublandlord hereby leases to Subtenant, and Subtenant hereby leases from Sublandlord, a portion of the Premises described as follows:

(a) That portion of the Premises consisting of approximately 5,216 rentable square feet, as more particularly shown on the layout attached at **Exhibit B** hereto (the “Subleased Premises”).

(b) Additionally, Subtenant is hereby granted the right to the nonexclusive use of the Common Areas as defined in the Master Lease and subject to the provisions of the Master Lease applicable to such Common Areas. Subtenant covenants that its use of the Common Areas shall at all times comply with any all terms, conditions and provisions of the Master Lease and with any rules and regulations established by Master Landlord and/or Sublandlord from time to time. Additionally, Subtenant is hereby granted the right to the nonexclusive use of the common areas within the Premises, outlined on Exhibit B attached hereto, which include a break room, and conference room (the “Sub-Common Area”). Upon advance approval from Sublandlord, Subtenant may access the conference rooms located in the Premises (that are not included in the Subleased Premises or Sub-Common Areas). Subtenant covenants that its use of the Sub-Common Area and conference rooms shall at all times comply with any all terms, conditions and provisions of the

Master Lease and with any rules and regulations established by Master Landlord and/or Sublandlord from time to time.

(c) Subtenant is hereby granted the right to the non-exclusive use of the Amenities as defined in the Master Lease and subject to the provisions of the Master Lease applicable to such Amenities. Subtenant covenants that its use of the Amenities shall at all times comply with any and all terms, conditions and provisions of the Master Lease and with any rules and regulations established by Master Landlord and/or Sublandlord from time to time.

2. **Term.** The term of this Sublease shall commence on the date that is the later of (i) June 1, 2017 and (ii) the date that Landlord Delivers (as defined in the Master Lease) the premises subject to the Master Lease with Landlord's Work in such premises Substantially Completed (as such terms are defined in the Master Lease) ("Sublease Commencement Date") and shall expire on October 31, 2019 unless sooner terminated pursuant to any provision hereof (the "Term").

3. **Possession.** If for any reason Sublandlord cannot deliver possession of any of the Subleased Premises to Subtenant on the Sublease Commencement Date, Sublandlord shall not be subject to any liability therefor, nor shall such failure affect the validity of this Sublease or the obligations of Subtenant hereunder or extend the term hereof, provided that no rent shall be due hereunder with respect to the Subleased Premises until possession of the Subleased Premises has been delivered to Subtenant, and if for any reason Sublandlord cannot deliver possession of any of the Subleased Premises to Subtenant within thirty (30) days following the Sublease Commencement Date, Subtenant may terminate this Sublease by written notice to Sublandlord.

4. **Rent.**

(a) Commencing on the Sublease Commencement Date and continuing throughout the term of this Sublease, Subtenant shall pay monthly rent consisting of Base Rent and Additional Rent (as defined below) (collectively, "Rent") to Sublandlord in the following amounts:

(i) **Base Rent.** Subtenant shall pay to Sublandlord the Base Rent, on a per rentable square foot basis, then payable by Sublandlord under the Master Lease with respect to the Subleased Premises pursuant to Section 3(a), as adjusted by Section 4 of the Master Lease ("Base Rent").

(ii) **Additional Rent.** In addition to Base Rent, Subtenant shall also pay to Sublandlord, (A) all Subtenant's Proportionate Share (as defined below) of Operating Expenses (as that term is defined in Section 5 of the Master Lease), (B) all of all Subtenant's Proportionate Share of the Amenities Fee (as that term is defined in the Master Lease), which Amenities Fee shall be considered a Premises Expense for the purposes of calculating the Proportionate Share, and (C) all Subtenant's Proportionate Share of all other costs payable by Subtenant under the Master Lease (collectively with the Operating Expenses and Amenities Fee, "Additional Rent"). Additional Rent shall be payable to Sublandlord as and when payments are due from Sublandlord pursuant to the Master Lease, but at least five (5) business days prior to the date Sublandlord must pay such amounts to Master Landlord, provided Sublandlord has invoiced Subtenant at least ten (10) business days prior to the date

Sublandlord must pay such amounts to Master Landlord. Subtenant shall further pay to Sublandlord as Additional Rent any costs and expenses applicable to the Subleased Premises which are paid directly by Sublandlord, including, but limited to, utilities, personal property taxes and real property taxes. Notwithstanding the foregoing, in the event any amounts payable by Sublandlord to Master Landlord are (i) due to Sublandlord's breach of any provision of the Master Lease which is not the result of or attributable to any action or inaction by Subtenant or any of its employees, contractors or guests, (ii) due to Sublandlord's negligence or willful misconduct, or (iii) are for the sole benefit of Sublandlord, then such amounts shall not be pro-rated between Sublandlord and Subtenant and shall be the sole responsibility of Sublandlord. Notwithstanding the foregoing, in the event any amounts payable by Sublandlord to Master Landlord are (i) due to Subtenant's breach of any provision of the Master Lease (ii) due to Subtenant's negligence or willful misconduct, or (iii) are for the sole benefit of Subtenant, then such amounts shall not be pro-rated between Sublandlord and Subtenant and shall be the sole responsibility of Subtenant. For the purposes of this Sublease, "Subtenant's Proportionate Share" means the total rentable area of the Subleased Premises subleased by Subtenant hereunder divided by 165,607 (as to Subtenant's Proportionate Share of the Project expenses), 102,607 (as to Subtenant's Proportionate Share of the Building expenses) or 24,759 (as to Subtenant's Proportionate Share of the Premises expenses) expressed as a percentage, as of each date under which payment is due from Subtenant hereunder.

(iii) Payment of Rent. If the Sublease Commencement Date does not fall on the first day of a calendar month, Rent for the first month shall be prorated on a daily basis based upon a calendar month. Rent shall be payable to Sublandlord in lawful money of the United States, in advance, without prior notice, demand, or offset, on or before the first day of each calendar month during the term hereof. All Rent shall be paid to Sublandlord at the address specified for notices to Sublandlord in Section 14, below.

(b) In the event of any casualty or condemnation affecting the Subleased Premises, Rent payable by Subtenant shall be abated hereunder, but only to the extent that Rent under the Master Lease is abated, and Subtenant waives any right to terminate this Sublease in connection with such casualty or condemnation except to the extent the Master Lease is also terminated as to the Premises or any portion thereof.

5. Security Deposit. Upon execution of this Sublease, Subtenant shall deposit with the Sublandlord the sum of fifteen thousand nine hundred and eight Dollars (\$15,908) as a security deposit ("Security Deposit"). If Subtenant fails to pay Rent or other charges when due under this Sublease, or fails to perform any of its other obligations hereunder, and such failure is not cured within the applicable cure period under this Sublease, Sublandlord may use or apply all or any portion of the Security Deposit for the payment of any Rent or other amount then due hereunder and unpaid, for the payment of any other sum for which Sublandlord may become obligated by reason of Subtenant's default or breach, or for any loss or damage sustained by Sublandlord as a result of Subtenant's default or breach. If Sublandlord so uses any portion of the Security Deposit, Subtenant shall restore the Security Deposit to the full amount originally deposited within ten (10) days after Sublandlord's written demand. Sublandlord shall not be required to keep the Security Deposit separate from its general accounts, and shall have no obligation or liability for payment of

interest on the Security Deposit. The Security Deposit, or so much thereof as had not theretofore been applied by Sublandlord, shall be returned to Subtenant within thirty (30) days of the expiration or earlier termination of this Sublease, provided Subtenant has vacated the Subleased Premises.

6. Assignment and Subletting. Subtenant may not assign, sublet, transfer, pledge, hypothecate or otherwise encumber the Subleased Premises, in whole or in part, or permit the use or occupancy of the Subleased Premises by anyone other than Subtenant, unless Subtenant has obtained Sublandlord's consent thereto (which consent Sublandlord may withhold in its sole discretion) and the consent of Master Landlord.

7. Master Lease. This Sublease shall be subject and subordinate to all of the terms and provisions of the Master Lease, and Master Landlord shall have all rights in respect of the Master Lease and the Premises as set forth therein. Except for payments of Rent and Operating Expenses under Sections 3 and 5 of the Master Lease (which payments shall be made by Sublandlord), and, except as otherwise provided herein, Subtenant hereby agrees to perform for Sublandlord's benefit, during the term of this Sublease, all of Sublandlord's obligations under the Master Lease but only to the extent they relate to the Subleased Premises which accrue during the term of this Sublease. In the event of a conflict between the provisions of this Sublease and the Master Lease, as between the Sublandlord and the Subtenant, the provisions of this Sublease shall control.

8. Condition of Subleased Premises. Subtenant has used due diligence in inspecting the Subleased Premises and agrees to accept the Subleased Premises in "as-is" condition and with all faults without any representation or warranty of any kind or nature whatsoever, or any obligation on the part of Sublandlord to modify, improve or otherwise prepare the Subleased Premises for Subtenant's occupancy.

9. Use. Subtenant may use the Subleased Premises only for the purposes as allowed in the Master Lease, and for no other purpose. Subtenant shall promptly comply with all applicable statutes, ordinances, rules, regulations, orders, restrictions of record, and requirements in effect during the term of this Sublease governing, affecting and regulating the Subleased Premises, including but not limited to the use thereof, to the extent such compliance is required of the Sublandlord as tenant under the Master Lease. Subtenant shall not use or permit the use of the Subleased Premises in a manner that will create waste or a nuisance, interfere with or disturb other tenants in the Building or violate the provisions of the Master Lease. Additionally, Subtenant shall be responsible, at its sole cost and expense, to reimburse Sublandlord for any legal compliance costs incurred by Sublandlord as a result of Subtenant's (a) particular use of the Subleased Premises (as opposed to general office and lab use), or (b) Subtenant's obtaining any permit or license with respect to the Subleased Premises (regarding hazardous materials or otherwise).

10. Furniture. During the term of this Sublease, Subtenant shall have the right to use the modular work stations and furniture identified on **Exhibit C** hereto ("**Furniture**"). Subtenant shall accept such Furniture in its "as-is" condition without any representation or warranty by Sublandlord. Subtenant's insurance as required under this Sublease shall include an all risk property insurance policy for the Furniture for its full replacement value, and Subtenant shall maintain the Furniture

during the term hereof. At the expiration or earlier termination of this Sublease, Subtenant shall return the Furniture to Sublandlord in the same condition received, ordinary wear and tear excepted.

11. Incorporation of Sublease.

(a)

All of the terms and provisions of the Master Lease, except as provided in subsection (b) below, are incorporated into and made a part of this Sublease, and the rights and obligations of the parties under the Master Lease are hereby imposed upon the parties hereto with respect to the Subleased Premises, the Subleased Premises being substituted for the Premises, the Term being substituted for the Term, the Sublandlord being substituted for the Landlord in the Master Lease, the Subtenant being substituted for the Tenant in the Master Lease with respect to the Subleased Premises, provided, however, that under no circumstance shall Sublandlord be obligated to, or be responsible or liable in any way, for Sublandlord's or Master Landlord's failure to, (i) perform any acts required to be completed by Master Landlord under the Master Lease, (ii) supply any item, including, but not limited to, any utility or service to the Subleased Premises required to be supplied by Master Landlord under the Master Lease, or (iii) complete any work and/or maintenance in the Subleased Premises required to be completed by Master Landlord under the Master Lease; and no such failure will in any way excuse Subtenant's performance under this Sublease or entitle Subtenant to any abatement of rent or other charge. In all provisions of the Master Lease requiring the approval or consent of Master Landlord, Subtenant shall be required to obtain the approval or consent of both Sublandlord and Master Landlord. In all provisions of the Master Lease requiring that the tenant thereunder deliver notice to Master Landlord, Subtenant shall be required to deliver notice concurrently to Sublandlord and Master Landlord. In all provisions of the Master Lease requiring tenant to submit, exhibit to, supply or provide Master Landlord with evidence, certificates, or any other matter or thing, Subtenant shall be required to submit, exhibit to, supply or provide, as the case may be, the same to both Master Landlord and Sublandlord. In any such instance, Sublandlord shall determine if such evidence, certificate or other matter or thing shall be satisfactory. In addition, (A) with respect to work, services, repairs, restoration, insurance, indemnities, representations, warranties or the performance of any other obligation of Master Landlord under the Master Lease, the sole obligation of Sublandlord shall be to request the same in writing from Master Landlord as and when requested to do so by Subtenant, and to use Sublandlord's reasonable efforts (without requiring Sublandlord to spend more than a nominal sum) to obtain Master Landlord's performance; (B) with respect to any obligation of Subtenant to be performed under this Sublease, wherever the Master Landlord grants to Sublandlord a specified number of days to perform its obligation under the Master Lease, except as otherwise provided herein, Subtenant shall have three (3) fewer days to perform the obligation, including, without limitations, curing any defaults; (C) in any case where the "Landlord" reserves or is granted the right to manage, supervise, control, repair, alter, regulate the use of, enter or use the Premises or any areas beneath, above or adjacent thereto, such reservation or grant of right of entry shall be deemed to be benefit of both Master Landlord and Sublandlord; (D) in any case where "Tenant" is to indemnify, release or waive claims against "Landlord", such indemnity, release or waiver shall be deemed to run from Subtenant to both Master Landlord and Sublandlord; and (E) in any case where "Tenant" is to execute and deliver certain documents or notices to "Landlord" such obligation shall be deemed to run from Subtenant to both Master Landlord and Sublandlord. In the event any casualty or condemnation

gives either Master Landlord or Sublandlord the right to terminate the Master Lease and such right is exercised, this Sublease shall be terminated as of the date the Master Lease is so terminated, and neither Master Landlord nor Sublandlord shall have any liability to Subtenant by reason of such termination.

(b) The following Sections of the Master Lease are not incorporated herein: the introductory paragraphs, Sections 1, 2, 3, 4, 5, 6, 10, 11, 13, 14 17, 22 (except the second sentence of Section 22(a)), 35, 38, 39, 40, 42, 43 and 44(k) and Exhibits A, C and G.

(c) Subtenant hereby assumes and agrees to perform for Sublandlord's benefit, during the term of this Sublease, all of Sublandlord's obligations with respect to the Subleased Premises under the Master Lease, except as otherwise provided herein. Subtenant shall not commit or permit to be committed any act or omission which violates any term or condition of the Master Lease. This Sublease shall be subject and subordinate to all of the terms of the Master Lease. If the Master Lease is terminated for any reason whatsoever, this Sublease shall automatically terminate and in such event Sublandlord shall have no liability whatsoever to Subtenant.

12. **Insurance.** Subtenant shall be responsible for compliance with the insurance provisions of the Master Lease to the extent applicable to the Sublease Premises. Such insurance shall insure the performance by Subtenant of its indemnification obligations hereunder and shall name Master Landlord and Sublandlord as additional insureds. All insurance required under this Sublease shall contain an endorsement requiring thirty (30) days written notice from the insurance company to Subtenant and Sublandlord before cancellation or change in the coverage, insureds or amount of any policy. Subtenant shall provide Sublandlord with certificates of insurance evidencing such coverage prior to the commencement of this Sublease.

13. **Default.** In addition to defaults contained in the Master Lease and incorporated by reference above, failure of Subtenant to make any payment of Rent within three days of notice that it was not received when due hereunder shall constitute an event of default hereunder. If Subtenant's default causes Sublandlord to default under the Master Lease, Subtenant shall defend, indemnify and hold Sublandlord harmless from all damages, costs (including reasonable attorneys' fees), liability, expenses or claims relating to such default.

14. **Notices.** The addresses specified in the Master Lease for receipt of notices to each of the parties are deleted and replaced with the following:

To Sublandlord at:

Before the Sublease Commencement Date:

Wellspring Biosciences LLC
11119 North Torrey Pines Road, Suite 125
La Jolla, CA 92037
Attn: Chief Financial Officer

After the Sublease Commencement Date:

Wellspring Biosciences LLC
3033 Science Park Drive
San Diego, CA 92121
Attn: Chief Financial Officer

To Subtenant at:

Before the Sublease Commencement Date:

Kura Oncology, Inc.
11119 North Torrey Pines Road, Suite 125
La Jolla, CA 92037
Attn: Chief Financial Officer

After the Sublease Commencement Date:

Kura Oncology, Inc.
3033 Science Park Drive
San Diego, CA 92121
Attn: Chief Financial Officer

15. Sublandlord's Obligations.

(a) To the extent that the provision of any services or the performance of any maintenance or any other act respecting the Subleased Premises, the Premises or Building is the responsibility of Master Landlord (collectively "Master Landlord Obligations"), upon Subtenant's request, Sublandlord shall make reasonable efforts to cause Master Landlord to perform such Master Landlord Obligations, provided, however, that in no event shall Sublandlord be liable to Subtenant for any liability, loss or damage whatsoever in the event that Master Landlord should fail to perform the same, nor shall Subtenant be entitled to withhold the payment of Rent or terminate this Sublease. It is expressly understood that the services and repairs which are incorporated herein by reference, including but not limited to the maintenance of exterior walls, structural portions of the roof, foundations, walls and floors, will in fact be furnished by Master Landlord and not by Sublandlord. In addition, Sublandlord shall not be liable for any maintenance, restoration (following casualty or destruction) or repairs in or to the Building or the Subleased Premises, other than its obligations under the Master Lease and other than its obligations under this Sublease to use reasonable efforts to cause Master Landlord to perform its obligations under the Master Lease.

(b) Except as otherwise provided herein, Sublandlord shall have no other obligations to Subtenant with respect to the Subleased Premises or the performance of the Master Landlord Obligations.

16. Early Termination of Sublease. If the Master Lease should terminate prior to the expiration of this Sublease (for any reason other than a breach of the Master Lease by Sublandlord which is not the result of or attributable to any action or inaction by Subtenant or any of its employees, contractors or guests), Sublandlord shall have no liability to Subtenant on account of such termination. To the extent that the Master Lease grants Sublandlord any discretionary right to

terminate the Master Lease, whether due to casualty, condemnation, or otherwise, Sublandlord shall be entitled to exercise or not exercise such right in its complete and absolute discretion.

17. Consent of Master Landlord and Sublandlord. If Subtenant desires to take any action which requires the consent or approval of Sublandlord pursuant to the terms of this Sublease, prior to taking such action, including, without limitation, making any alterations, then, notwithstanding anything to the contrary herein, (a) Sublandlord shall have the same rights of approval or disapproval as Master Landlord has under the Master Lease, and (b) Subtenant shall not take any such action until it obtains the consent of Sublandlord and Master Landlord, as may be required under this Sublease or the Master Lease. This Sublease shall not be effective unless and until any required written consent of the Master Landlord shall have been obtained.

18. Indemnity. Subtenant shall indemnify, defend, protect, and hold Sublandlord and Master Landlord harmless from and against all actions, claims, demands, costs liabilities, losses, reasonable attorneys' fees, damages, penalties, and expenses (collectively "Claims") which may be brought or made against Sublandlord or which Sublandlord may pay or incur to the extent caused by (i) a breach of this Sublease by Subtenant, (ii) any violation of law by Subtenant or its employees, agents, contractors or invitees (collectively, "Agents") relating to the use or occupancy of the Subleased Premises, (iii) any act or omission by Subtenant or its Agents resulting in contamination of any part or all of the Premises by Hazardous Materials, (iv) the negligence or willful misconduct of Subtenant or its Agents or (v) the use or occupancy of the Subleased Premises by Subtenant or its Agents.

Sublandlord shall indemnify, defend, protect, and hold Subtenant harmless from and against all Claims which may be brought or made against Subtenant or which Subtenant may pay or incur to the extent caused by a breach of this Sublease or Master Lease by Sublandlord, except to the extent due to any action or inaction by Subtenant or its agents.

19. Brokers. Each party hereto represents and warrants that it has dealt with no broker in connection with this Sublease and the transactions contemplated herein. Each party shall indemnify, protect, defend and hold the other party harmless from all costs and expenses (including reasonable attorneys' fees) arising from or relating to a breach of the foregoing representation and warranty.

20. Maintenance and Repair; Surrender of Subleased Premises. Subtenant shall, at Subtenant's sole cost and expense, keep the Subleased Premises, including all improvements, fixtures and furnishings therein, in good order, repair and condition at all times during the Sublease Term, and in any event at least in the same condition as that when the Subtenant first takes possession of the Subleased Premises less normal wear and tear and Subtenant shall otherwise perform all maintenance and repairs in the Subleased Premises which Sublandlord is required to perform under the Master Lease; provided however, that, if Subtenant fails to make such repairs, Sublandlord may upon reasonable prior written notice to Subtenant, but need not, make such repairs and replacements, and Subtenant shall pay Sublandlord's reasonable costs or expenses, arising from Sublandlord's involvement with such repairs and replacements upon being billed for same. Upon the expiration or earlier termination of this Sublease, Subtenant shall surrender the Subleased

Premises in the same condition as they were in on the Sublease Commencement Date, except for ordinary wear and tear.

21. No Third Party Rights. The benefit of the provisions of this Sublease is expressly limited to Sublandlord and Subtenant and their respective permitted successors and assigns. Under no circumstances will any third party be construed to have any rights as a third party beneficiary with respect to any of said provisions.

22. Counterparts. This Sublease may be signed in two or more counterparts, each of which shall be deemed an original and all of which shall constitute one agreement.

IN WITNESS WHEREOF, the parties have executed this Sublease as of the date first written above.

WELLSPRING BIOSCIENCES LLC

KURA ONCOLOGY, INC.

By: /s/ Heidi Henson

By: /s/ Troy E. Wilson, Ph.D., J.D.

Its: CFO

Its: President and CEO

EXHIBIT A

MASTER LEASE

EXHIBIT B

SUBLEASED PREMISES

EXHIBIT C

FURNITURE

Open Office Workstations	21
Private Office Workstations	5
Private Office Case Goods	5
Reception Desk	1
Conference Room Tables	1
Occasional Table (Lobby)	1
Occasional Table (Private Office)	5

Chairs:

Office Task Chairs	26
Conference Chairs	8
Lobby Chairs	2

THIRD AMENDMENT TO SUBLEASE

THIS THIRD AMENDMENT TO SUBLEASE (this "**Third Amendment**") is made as of December 20, 2016, by and between **WELLSPRING BIOSCIENCES LLC**, a Delaware limited liability company ("**Sublessor**"), and **KURA ONCOLOGY, INC.**, a Delaware corporation ("**Sublessee**").

RECITALS

A. ARE-SD Region No. 24, LLC ("**Landlord**"), as landlord, and Sublessor, as tenant, are parties to that certain Lease dated March 1, 2013, as amended (the "**Lease**"), whereby Sublessor leases certain premises in a building located at 11119 North Torrey Pines, La Jolla, California ("**Premises**"). Sublessor and Sublessee are parties to that certain Sublease dated as of August 29, 2014, as amended (the "**Sublease**"), whereby Sublessee subleases a portion of the Premises ("**Subleased Premises**"). The Subleased Premises are more particularly described in the Sublease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Sublease.

B. Concurrently with this Third Amendment, Sublessor is entering into a new lease with an affiliate of Landlord ("**New Lease**") pursuant to which Sublessor is leasing approximately 24,759 rentable square feet of space in that certain building located at 3033 Science Park Road, San Diego, California ("**New Premises**") and Sublessee is entering into a new sublease with Sublessor ("**New Sublease**") pursuant to which Sublessee is leasing a portion of the New Premises.

C. Sublessor and Sublessee desire, subject to the terms and conditions set forth below, to provide for the acceleration of the expiration date of the term of the Sublease in connection with the commencement of the New Sublease.

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublessor and Sublessee hereby agree as follows:

- 1. Term.** Notwithstanding anything to the contrary contained in the Sublease, the expiration date of the term of the Sublease shall be accelerated to the date that is the later of (i) June 8, 2017 or (ii) 7 days after the date that Landlord Delivers (as defined in the New Lease) the premises subject to the New Lease with Landlord's Work in such premises Substantially Completed (as such terms are defined in the New Lease) ("**Termination Date**"). Notwithstanding the foregoing, if the New Lease terminates prior to the Commencement Date (as defined in the New Lease) of the New Lease such that the Commencement Date (as defined in the New Lease) of the New Lease never occurs, this Third Amendment shall be null and void and of no further force or effect, the expiration date of the Sublease shall not be accelerated and the Sublease shall continue in full force and effect.
 - 2. Base Rent and Operating Expenses.** Sublessee shall continue to pay, through the date that is 7 days prior to the Termination Date, all amounts due and owing under the Sublease including, without limitation, Base Rent and Operating Expenses as provided under the Sublease. Notwithstanding the foregoing, if Sublessee does not surrender the Subleased Premises on or before the Termination Date, Sublessee shall be in holdover under the Sublease and the terms of the Sublease with respect thereto shall apply.
 - 3. Termination and Surrender.** Sublessee shall voluntarily surrender the Subleased Premises on or before the Termination Date. Sublessee agrees to cooperate reasonably with Landlord and Sublessor in all matters, as applicable, relating to (i) surrendering the Premises in accordance with the surrender requirements and in the condition required pursuant to the Lease, and (ii) all other matters related to restoring the Subleased Premises to the condition required under the Lease. Notwithstanding anything to the contrary contained in this Third Amendment or in the Sublease, Sublessee shall not be required to remove any Tenant Improvements or Alterations (as defined in
-

the Lease) existing in the Premises as of the date of this Third Amendment. After the Termination Date, Sublessee shall have no further rights of any kind with respect to the Premises. Nothing herein shall excuse Sublessee from its obligations under the Sublease prior to the Termination Date, except as expressly provided in Section 2 above with respect to the payment of Base Rent and Operating Expenses.

4. **Brokers.** Sublessor and Sublessee each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this Third Amendment and that no Broker brought about this transaction. Sublessor and Sublessee each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Sublessor or Sublessee, as applicable, with regard to this Third Amendment.

5. **OFAC.** Sublessee is currently (a) in compliance with and shall at all times during the term of the Sublease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of the Sublease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

6. **Miscellaneous.**

a. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Third Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective their respective successors and assigns.

c. This Third Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this Third Amendment attached thereto.

d. Except as amended and/or modified by this Third Amendment, the Sublease is hereby ratified and confirmed and all other terms of the Sublease shall remain in full force and effect, unaltered and unchanged by this Third Amendment. In the event of any conflict between the provisions of this Third Amendment and the provisions of the Sublease, the provisions of this Third Amendment shall prevail. Whether or not specifically amended by this Third Amendment, all of the terms and provisions of the Sublease are hereby amended to the extent necessary to give effect to the purpose and intent of this Third Amendment.

[Signatures are on the next page]

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment as of the day and year first above written.

SUBLESSOR:

WELLSPRING BIOSCIENCES LLC,
a Delaware limited liability company

By: /s/ Heidi Henson
Its: CFO

SUBLEESSEE:

KURA ONCOLOGY, INC.,
a Delaware corporation

By: /s/ Troy E. Wilson, Ph.D., J.D.
Its: President and CEO

PATENT LICENSE AGREEMENT

This Agreement is effective as of December 22, 2014 (the "EFFECTIVE DATE"), between Kura Oncology, Inc. ("LICENSEE") having the address in Article 12 below, and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan ("MICHIGAN"). LICENSEE and MICHIGAN hereby agree as follows:

BACKGROUND

MICHIGAN and FOUNDATION (as defined below) are the sole assignees of the rights with respect to the applications and patents within the JOINTLY OWNED PATENT RIGHTS (as defined below).

MICHIGAN and FOUNDATION have signed an inter-institutional agreement dated September 10, 2009 (the "INSTITUTIONAL AGREEMENT") giving MICHIGAN the right to negotiate license terms, maintain patent protection, and grant, maintain and administer licenses for the JOINTLY OWNED PATENT RIGHTS.

The Leukemia and Lymphoma Society ("LLS") provided funding to MICHIGAN which contributed to the inventions claimed in the PATENT RIGHTS. MICHIGAN and the LLS have signed an agreement for collaboration dated July 9, 2010 (the "LLS Agreement") giving MICHIGAN the responsibility for negotiating license terms, maintaining patent protection and granting, maintaining and administering licenses for the PATENT RIGHTS.

ARTICLE 1 – DEFINITIONS

1.1 "AFFILIATE" means any entity or corporation which, directly or indirectly, controls, is controlled by or is under common control with LICENSEE, where "control" means (i) owning or controlling more than fifty percent (50%) of the voting stock or other ownership interest of the other entity; (ii) the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the other entity or in any country where the local law will not permit foreign equity participation of a majority, ownership or control, directly or indirectly, of the maximum percentage of such outstanding stock or voting rights permitted by local law.

1.2 "FIELD OF USE" means all fields.

1.3 "FIRST COMMERCIAL SALE" means the first SALE through a bona fide arms length transaction of any LICENSED PRODUCT by LICENSEE or a SUBLICENSEE or first commercial use of any LICENSED PROCESS by LICENSEE or a SUBLICENSEE, excluding the SALE of a LICENSED PRODUCT or use of a LICENSED PROCESS for use in trials, for compassionate use, as a sample or that is of temporary availability.

1.4 "FOUNDATION" means [...***...].

***** Confidential Treatment Requested**

1.5 “JOINTLY OWNED PATENT RIGHTS” means MICHIGAN and FOUNDATION’s legal rights under the patent laws of the United States or relevant foreign countries for all of the following in:

(a) the following United States and foreign patent(s) and/or patent application(s), and foreign counterparts of the same:

US Provisional Patent Application [...***...], filed [...***...] ([...***...])

US Patent Application [...***...] filed [...***...] ([...***...])

[...***...] (nationalized) filed [...***...]; and ([...***...])

(b) United States and foreign counterpart patents or patent applications claiming and entitled to the priority date of the respective patent application(s) referenced in subparagraph 1.5(a) above or patents issuing from such applications;

(c) United States and foreign divisionals, substitutions, continued prosecution applications, including requests for continued examination, and continuations and continuations-in-part (but only those claims in the continuation-in-part applications that are entitled to the priority date of the parent patent or application in the PATENT RIGHTS) of any patent applications referenced in subparagraphs 1.5(a) and (b) above or patents issuing from such applications;

(d) United States and foreign patents issued from the applications listed in subparagraphs 1.5(a), (b), (c) and (d) above, including any reviewed, reissued, renewed or reexamined patents and patent term extensions based upon the same.

1.6 “LICENSED PROCESS(ES)” means any process or method the practice or use of which in the relevant country would, but for the license granted herein under the PATENT RIGHTS, comprise an infringement of (including contributory or inducement a Valid Claim contained in the PATENT RIGHTS.

1.7 “LICENSED PRODUCT(S)” means any product (a) the manufacture, use, SALE, offer for SALE or import of which in the relevant country would but for a license granted under the PATENT RIGHTS, comprise an infringement of (including contributory or inducement) Valid Claim contained in the PATENT RIGHTS in the country in which any such product is made, used, imported, offered for SALE or SOLD or (b) that is manufactured by using a LICENSED PROCESS or is employed to practice a LICENSED PROCESS .

1.8 “MICHIGAN” has the meaning given the first paragraph of this Agreement and, as used in Articles 9 and 10, shall include its Regents, officers, employees, students, and agents.

1.9 “MICHIGAN PATENT RIGHTS” means MICHIGAN’s legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

(a) the following United States and foreign patent(s) and/or patent application(s), and foreign counterparts of the same:

US Provisional Patent Application [...***...] filed [...***...] ([...***...])

***** Confidential Treatment Requested**

US Patent Application [...***...] filed [...***...] ([...***...])

[...***...] filed [...***...]

US Provisional Patent Application [...***...] filed [...***...] ([...***...])

(b) United States and foreign counterpart patents or patent applications claiming and entitled to the priority date of the respective patent application(s) referenced in subparagraph 1.9(a) above or patents issuing from such applications;

(c) United States and foreign divisionals, substitutions, continued prosecution applications, including requests for continued examination, and continuations and continuations-in-part (but only those claims in the continuation-in-part applications that are entitled to the priority date of the parent patent or application in the PATENT RIGHTS) referenced in subparagraphs 1.9(a) and (b) above or patents issuing from such applications;

(d) United States and foreign patents issued from the applications listed in subparagraph 1.9(a), (b), (c) and (d) above, including any reviewed, reissued, renewed or reexamined patents and patent term extensions based upon the same.

1.10 “NET SALES” means the amount billed or invoiced, and if any amount is not billed or invoiced, the amounts received, on SALES by LICENSEE and/or SUBLICENSEES of LICENSED PRODUCTS and uses of LICENSED PROCESSES by LICENSEE and/or SUBLICENSEES, less the following deductions (but only to the extent such deductions are otherwise included in NET SALES and are not obtained in view of other consideration received by LICENSEE):

(a) trade, quantity and/or cash discounts actually granted or allowed to or paid by customers in such invoices for SALE of LICENSED PRODUCTS or use of LICENSED PROCESSES, but only in amounts customary in the trade;

(b) SALES taxes, excise taxes, tariffs, duties, use taxes and/or other governmental charge (including without limitation custom surcharges) excise taxes, use taxes, tariffs, sales taxes and customs duties, and/or other governmental charge (including without limitation custom surcharges) separately stated in such bills or invoices with reference to particular SALES and actually paid by LICENSEE or SUBLICENSEE;

(c) actual freight expenses between LICENSEE or SUBLICENSEE and customers and any packing, handling, insurance, transportation and duty expenses, to the extent such expenses are not charged to or reimbursed by customers;

(d) rebates (whether or not government-mandated) actually allowed or taken, including without limitation chargebacks, retroactive price reductions, and discounts in the form of wholesaler inventory management fees; or

(e) amounts actually refunded or credited on rejections or returns.

***** Confidential Treatment Requested**

Where LICENSEE or SUBLICENSEE receives any consideration other than cash for such transactions, the fair market cash value for such consideration, equal to the established average price charged in cash transactions in such country or as otherwise agreed upon by the parties hereto, shall be included in NET SALES.

For purposes of calculating NET SALES, SALES of LICENSED PRODUCTS by LICENSEE to any SUBLICENSEE intended for resale shall be excluded from the calculation of NET SALES, but rather the SALE of such LICENSED PRODUCTS by SUBLICENSEES to third parties shall be included in the calculation of NET SALES. NET SALES shall exclude the distribution of LICENSED PRODUCTS, at cost or at no cost for use, (i) by a clinical or research organization for the research or development of LICENSED PRODUCTS, or (ii) in a sampling program or compassionate use program.

For LICENSED PRODUCTS which are sold as COMBINATION PRODUCTS (as defined below), the NET SALES for such COMBINATION PRODUCTS shall be adjusted by multiplying the actual NET SALES by the fraction $A/(A+B)$ where A is the actual average of the invoice price (on a per unit basis) of the LICENSED PRODUCT that is part of the COMBINATION PRODUCT in the relevant country, if sold separately, and B is the sum of the actual average of the invoice prices (on a per unit basis) of the other active product or product component that is part of the COMBINATION PRODUCT in the relevant country, if such other active product or product component is sold separately. If the other product or product component is not sold separately, then the actual NET SALES shall be adjusted by multiplying the actual NET SALES by the fraction A/C where A is the actual average of the invoice price (on a per unit basis) of the LICENSED PRODUCT that is part of the COMBINATION PRODUCT in the relevant country, if sold separately, and C is the actual average of the invoice prices (on a per unit basis) of the COMBINATION PRODUCT in the relevant country. If neither of the foregoing applies, then LICENSEE shall determine the NET SALES of the COMBINATION PRODUCT in good faith based on the respective values of the components of such COMBINATION PRODUCT. "COMBINATION PRODUCT" means (x) any pharmaceutical product that consists of a LICENSED PRODUCT and at least one other clinically active ingredient that is not a LICENSED PRODUCT; or (y) any combination of a LICENSED PRODUCT and another pharmaceutical product that contains at least one other clinically active ingredient that is not a LICENSED PRODUCT where such products are not formulated together but are sold together and invoiced as one product.

1.11 "PATENT RIGHTS" means JOINTLY OWNED PATENT RIGHTS and MICHIGAN PATENT RIGHTS.

1.12 "QUALIFIED FINANCING" means the first sale of preferred stock of LICENSEE, whether in one transaction or a series of related transactions, which occurs after the EFFECTIVE DATE and in which LICENSEE receives gross proceeds totaling at least \$[...***...] (exclusive of conversion of indebtedness) to one or more third party venture capital funds or institutional investors.

1.13 "ROYALTY PERIOD(S)" means the six-month periods ending on the last days of June and December each year.

***** Confidential Treatment Requested**

- 1.14 “SALE” means sale, rental, or lease, however characterized, and “SOLD” means the past tense of SALE.
- 1.15 “SUBLICENSEE(S)” means any person or entity that LICENSEE grants a sublicense under the license rights granted to LICENSEE under this Agreement.
- 1.16 “TERRITORY” means all of the countries of the world.
- 1.17 “[...***...]” means [...***...].
- 1.18 “Valid Claim” means (a) a claim of an issued patent in any country that (i) [...***...]; (ii) has not [...***...]; (iii) has not [...***...], or if [...***...], has been [...***...]; and (iv) has not [...***...] or [...***...] in such country from which [...***...] or (b) a pending claim of a patent application that (i) is [...***...], (ii) has not [...***...] and (iii) has not [...***...].

ARTICLE 2 – GRANT OF LICENSE

- 2.1 MICHIGAN hereby grants to LICENSEE an exclusive license under the PATENT RIGHTS, with the right to grant sublicenses, both subject to the terms and conditions of this Agreement, in the FIELD OF USE and the TERRITORY to make, have made, import, use, market, offer for sale and sell LICENSED PRODUCTS and to practice LICENSED PROCESSES.
- 2.2 Without limiting any other rights it may have, (i) MICHIGAN, [...***...] and FOUNDATION specifically reserve the right for them and their affiliates to practice and have practiced the JOINTLY OWNED PATENT RIGHTS for non-commercial research, public service, internal and/or educational purposes, and the right to grant the same limited rights to other non-profit research institutions and (ii) MICHIGAN and FOUNDATION, specifically reserve the right for themselves and their affiliates to practice and have practiced the MICHIGAN OWNED PATENT RIGHTS for non-commercial research, internal and/or educational purposes, and the right to grant the same limited rights to other non-profit research institutions.
- 2.3 This Agreement shall extend until expiration of the last to expire of the PATENT RIGHTS, unless sooner terminated as provided in another specific provision of this Agreement.
- 2.4 LICENSEE agrees that LICENSED PRODUCTS used, leased or sold in the United States shall be manufactured substantially in the United States to the extent required by 35 U.S.C. § 204 and implementing regulations, unless a waiver from such requirement is obtained in accordance with law and implementing regulations.
- 2.5 The licenses granted in this Agreement are subject to any rights retained by the U.S. government, for example in accordance with Chapter 18 of Title 35 of U.S.C. 200-212 and the regulations thereunder (37 CFR Part 401), when applicable. LICENSEE shall provide MICHIGAN with all reasonably requested information and cooperation for MICHIGAN to comply with applicable provisions of the same and any requirements of any agreements between MICHIGAN and any agency of the U.S. government that provided funding for the subject matter covered by the PATENT RIGHTS.

***** Confidential Treatment Requested**

2.6 MICHIGAN confirms that FOUNDATION has approved this Agreement in accordance with the requirements of the INSTITUTIONAL AGREEMENT and that MICHIGAN has the right under the INSTITUTIONAL AGREEMENT to grant the license and other rights with respect to the JOINTLY OWNED PATENT RIGHTS to LICENSEE under this Agreement and to execute this Agreement on behalf of itself and FOUNDATION.

2.7 MICHIGAN confirms that LLS has approved this Agreement in accordance with the requirements of the LLS AGREEMENT and that MICHIGAN has the right under the LLS AGREEMENT to grant the license and other rights with respect to the PATENT RIGHTS.

2.8 MICHIGAN shall not terminate or amend the INSTITUTIONAL AGREEMENT in any manner that would adversely affect the rights granted to LICENSEE under this Agreement.

2.9 MICHIGAN shall not terminate or amend the LLS AGREEMENT in any manner that would adversely affect the rights granted to LICENSEE under this Agreement.

ARTICLE 3 - CONSIDERATION

3.1 LICENSEE shall pay the following royalties to MICHIGAN:

(a) A License Issue Fee equal to [...***...] Dollars (\$[...***...]), due [...***...] ([...***...]) days from the complete execution of this Agreement.

(b) Running Royalties according to the following schedule:

- (1) [...***...]% of annual NET SALES up to and including \$[...***...]; and
- (2) [...***...]% of annual NET SALES in excess of \$[...***...] up to and including \$[...***...]; and
- (3) [...***...]% of annual NET SALES in excess of \$[...***...].

If LICENSEE makes any SALES of LICENSED PRODUCTS intended for resale to any party that is an AFFILIATE, such SALES shall be excluded from the calculation of NET SALES, however, the subsequent SALE of such LICENSED PRODUCTS by such AFFILIATE to a third party shall be included in the calculation of NET SALES. If an AFFILIATE is the end user of LICENSED PRODUCTS SOLD by LICENSEE, such SALES shall be included in the calculation of NET SALES at a price computed on the basis of the established average price charged to third parties in the applicable country in which such SALES occur.

If LICENSEE is obligated or finds it reasonably necessary to pay consideration to any third party (other than an AFFILIATE) that holds a patent that is in the reasonable judgment of LICENSEE and its counsel would be infringed by [...***...] LICENSED PRODUCT or use of a LICENSED PROCESS, and if the combined royalty due to MICHIGAN and such third party(ies) exceeds [...***...] percent ([...***...]), then the royalty percentage to be paid to MICHIGAN by LICENSEE set forth above shall be reduced by the percentage calculated by the following formula: $(A - [...***...]) / B$, in which A is the total royalty consideration to be paid on a LICENSED PRODUCT or LICENSED PROCESS and B is the total number of royalty-bearing licenses, including this Agreement, for such consideration on the LICENSED PRODUCT or LICENSED

***** Confidential Treatment Requested**

PROCESS. For example, if the combined royalty consideration due to MICHIGAN and one non-AFFILIATE third party is [...] percent ([...]%), the reduction would be equal to ([...])/2, or [...] and, the royalty percentages owed to MICHIGAN as set forth above would be reduced to [...]%, [...] and [...]%, respectively. However, in no event shall the royalty amount payable to MICHIGAN for any ROYALTY PERIOD be reduced below [...] percent ([...]%) of the royalty amounts set forth in this Section 3.1(b). LICENSEE shall provide MICHIGAN with a confidential copy of any such agreement referred to in this Section.

(c) Sublicensing Fees on any SUBLICENSING REVENUE (as defined below) according to the following schedule:

		% of SUBLICENSING REVENUE	
[...***...]		(i)	[...***...]%
(ii)	[...***...]	(iii)	[...***...]%
(iv)	[...***...]	(v)	[...***...]%

“SUBLICENSE REVENUE” means (i) revenue not based on NET SALES (including, without limitation, any license issue fees, maintenance fees, milestone payments, other royalties) that LICENSEE or its AFFILIATE actually receives from any non-AFFILIATE SUBLICENSEES in consideration for a sublicense under the PATENT RIGHTS, and (ii) amounts actually received by the LICENSEE from any non-AFFILIATE third party in consideration of the grant to such third party of an option to obtain a sublicense of the LICENSEE’s rights under this Agreement, provided that, for the sake of clarity, SUBLICENSE REVENUE will not include amounts received by or payable to LICENSEE or its AFFILIATE that are reasonably and fairly attributable to any of the following to the extent that each is bona fide: (a) debt financing of LICENSEE or its AFFILIATE, (b) amounts received by the LICENSEE as the purchase price, at fair market value, for equity securities (including stock of whatever class or series, and including the purchase price for warrants and the exercise price under such warrants, or as convertible debt, and the like) of LICENSEE or its AFFILIATE; (c) reimbursements to LICENSEE or its AFFILIATE of costs for filing, prosecuting and maintaining PATENT RIGHTS; (d) reimbursement to LICENSEE or its AFFILIATE for the cost of research and/or development activities performed or services or materials provided by LICENSEE or its AFFILIATE after the EFFECTIVE DATE on the basis of reimbursement of out-of-pocket expenses and/or payments for full-time equivalent (“FTE”) efforts of personnel at commercially reasonable and standard FTE rates for the location of LICENSEE or its AFFILIATE, and (e) royalty payments or revenue or profit sharing payments based on NET SALES.

(d) Patent Expenses pursuant to Article 7 hereof. LICENSEE shall pay [...] percent ([...]%) of current unreimbursed costs of \$[...] as of November 30, 2014 within [...] ([...] days) of the complete execution of this Agreement and the remaining [...] percent ([...]%) within [...] ([...] days) of closing of a QUALIFIED FINANCING.

***** Confidential Treatment Requested**

(e) Minimum Annual Royalties. Beginning [...***...], LICENSEE will pay to MICHIGAN a Minimum Annual Royalty of \$[...***...], increasing to \$[...***...] per year beginning with [...***...] in which the FIRST COMMERCIAL SALE of the first LICENSED PRODUCT occurs. Minimum Annual Royalties are due for each calendar year on each following [...***...]. Minimum Annual Royalties shall be credited against Running Royalties due on NET SALES made during the calendar year for which the Minimum Annual Royalties apply. Minimum Annual Royalties paid in excess of running royalties shall not be creditable to amounts due for future years

(f) Milestone payments as follows:

- (1) \$[...***...];
- (2) \$[...***...];
- (3) \$[...***...];
- (4) \$[...***...];
- (5) \$[...***...];
- (6) \$[...***...]; and
- (7) \$[...***...].

Milestone payments are non-refundable and non-creditable against future royalties. In the event a SUBLICENSEE pays LICENSEE a fee for achieving one of the milestone events listed above or a substantially similar milestone, LICENSEE shall pay the higher of: (i) the Milestone Payment in this Paragraph 3.1(f) or (ii) the fee due on such Milestone Payment pursuant to Paragraph 3.1(c), but not both.

(g) Royalties shall be payable on a LICENSED PRODUCT-by-LICENSED PRODUCT or LICENSED PROCESS-by-LICENSED PROCESS and country-by-county basis from the FIRST COMMERCIAL SALE of a LICENSED PRODUCT in a given country until [...***...].

3.2 Subject to the provisions of this Paragraph 3.2, the parties shall enter into a sponsored research agreement pursuant to which LICENSEE will sponsor not less than \$2,715,000, inclusive of any indirect or other expenses, of research at MICHIGAN over a three-year period upon commercially reasonable terms and conditions to be mutually agreed upon by the parties in good faith and subject to a workplan and budget no later than March 1, 2015 (the "SPONSORED RESEARCH").

3.3 LICENSEE is not obligated to pay multiple royalties if any LICENSED PRODUCT or LICENSED PROCESS is covered by more than one claim of PATENT RIGHTS or the same LICENSED PRODUCT is covered by claims in two or more countries.

***** Confidential Treatment Requested**

3.4 Royalty payments shall be made to "The Regents of the University of Michigan" in United States dollars. Payments drawn directly on a U.S. bank may be made by either check to the address in Article 12 or by wire transfer. Any payment drawn on a foreign bank or foreign branch of a U.S. bank shall be made only by wire transfer. Wire transfers shall be made in accordance with the following or any other instructions as may be specified by MICHIGAN: ABA/Routing No. [...***...]; Account No. [...***...]; SWIFT Bank Identifier Code [...***...]; Account Name: [...***...]. In computing royalties on NET SALES in an currency other than United States dollars, LICENSEE shall first determine the royalties due and payable in such currency and then convert such amount into its equivalent in United States dollars using the average exchange rate published in the Wall Street Journal during the ROYALTY PERIOD with respect to which such payment is due, or at such other exchange rate as the parties may agree to in writing.

3.5 Royalty payments shall be made on a semi-annual basis with submission of the reports required by Article 4. All amounts due under this Agreement, including amounts due for the payment of patent expenses, shall, if overdue, be subject to a charge of interest compounded monthly until payment, at a per annum rate of [...***...] percent ([...***...])% [...***...] in effect at the JP Morgan Chase Bank, N.A. or its successor bank on the due date (or at the highest allowed rate if a lower rate is required by law). The payment of such interest shall not foreclose MICHIGAN from exercising any other rights it may have resulting from any late payment. LICENSEE shall reimburse MICHIGAN for the costs, including reasonable attorney fees, for expenses paid in order to collect any amounts overdue more than [...***...] days.

3.6 All payments made under this Agreement are and shall be non-refundable. MICHIGAN shall have no obligation whatsoever to pay, return, credit, or refund any amounts paid hereunder, except as may be specifically provided herein. By way of example only, notwithstanding the deductions permitted to NET SALES, MICHIGAN shall have no obligation to pay any amounts to LICENSEE even if such deductions should result in a negative amount for NET SALES in any given ROYALTY PERIOD.

3.7 LICENSEE shall be responsible for the payment of all taxes, duties, levies, and other charges imposed by any taxing authority with respect to the royalties payable to MICHIGAN under this Agreement. Should LICENSEE be required under any law or regulation of any government entity or authority to withhold or deduct any portion of the payments on royalties due to MICHIGAN, then the sum payable to MICHIGAN shall be increased by the amount necessary to yield to MICHIGAN an amount equal to the sum it would have received had no withholdings or deductions been made. MICHIGAN shall cooperate reasonably with LICENSEE in the event LICENSEE elects to assert, at its own expense, any exemption from any such tax or deduction. If MICHIGAN is able to obtain credit for any taxes for which an additional payment is made by LICENSEE under this Section ("Creditable Taxes") against any tax liability otherwise payable by LICENSEE, MICHIGAN shall reimburse to LICENSEE an amount equivalent to the Creditable Taxes. MICHIGAN shall provide LICENSEE with evidence as LICENSEE may reasonably request to review the amount of any Creditable Taxes.

3.8.1 Upon the closing of the QUALIFIED FINANCING, LICENSEE shall separately issue to MICHIGAN and LLS those numbers of shares of the series of preferred stock of LICENSEE that is issued to the investors in such QUALIFIED FINANCING (such applicable series of

***** Confidential Treatment Requested**

preferred stock, the “PREFERRED STOCK”) equal to \$[...***...] with respect to MICHIGAN and \$[...***...] with respect to LLS, divided by the price per share paid by the investors for the new money invested in such QUALIFIED FINANCING (the “SHARES”). For example, if the price per share of PREFERRED STOCK issued in the QUALIFIED FINANCING is \$[...***...], then LICENSEE shall (a) issue [...***...] SHARES to MICHIGAN and (b) issue [...***...] SHARES to LLS. LICENSEE shall issue the SHARES to MICHIGAN and LLS pursuant to, and subject to the terms of, forms of stock issuance agreements attached hereto as Exhibits A-1 and A-2, respectively (each a “STOCK ISSUANCE AGREEMENT”).

3.8.2 Notwithstanding the foregoing, in the event that, prior to the issuance of SHARES to MICHIGAN and LLS pursuant to Section 3.8.1, LICENSEE shall have entered into any agreement that will result in a CHANGE OF CONTROL, LICENSEE shall promptly notify each of MICHIGAN and LLS in writing (the “TRANSACTION NOTICE”) and LICENSEE shall issue to MICHIGAN or LLS, as applicable, that number of shares of common stock of LICENSEE equal to \$[...***...] with respect to MICHIGAN or \$[...***...] with respect to LLS divided by the per share consideration to be received by holders of common stock of LICENSEE in the initial closing of the CHANGE OF CONTROL (or the fair market value of any non-monetary consideration, as reasonably agreed between MICHIGAN and LICENSEE), effective immediately prior to the closing of the CHANGE OF CONTROL. If shares of common stock of LICENSEE are issued to either MICHIGAN or LLS pursuant to this Section 3.8.2, the provisions of Section 3.8.1 with respect to MICHIGAN or LLS, respectively, shall immediately terminate upon such issuance. Any shares of common stock of LICENSEE issued to MICHIGAN or LLS pursuant to this Section 3.8.2 shall be issued pursuant to, and subject to the terms of, the applicable STOCK ISSUANCE AGREEMENT. For purposes of this Section 3.8, a “CHANGE OF CONTROL” means (i) any consolidation or merger of LICENSEE with any other entity or similar transaction, following which the stockholders of LICENSEE immediately prior thereto own, directly or indirectly, less than fifty percent (50%) of the voting power of the securities of the surviving entity in such transaction (or its parent), other than pursuant to a bona fide financing transaction, or (ii) a sale of all or substantially all of the assets of LICENSEE to a third party.

3.8.3 Within [...***...] ([...***...]) days after the final closing of any round of equity financing of LICENSEE that is consummated for bona fide fundraising purposes and in which LICENSEE issues shares of PREFERRED STOCK (a “TRIGGERING FINANCING”), LICENSEE shall give MICHIGAN written notice of the consummation of such TRIGGERING FINANCING that includes a report setting forth the basic terms of such TRIGGERING FINANCING, including, without limitation, the amount of new money raised, the nature of the PREFERRED STOCK issued and a summary of the post-financing capitalization of LICENSEE. The obligation of LICENSEE to give such notice shall terminate upon the first to occur of (a) the initial sale of LICENSEE’S capital stock to the public in a firmly underwritten offering registered under the Securities Act of 1933, as amended (an “IPO”), and (b) a CHANGE OF CONTROL.

3.8.4 Prior to the closing of any TRIGGERING FINANCING, LICENSEE shall deliver to MICHIGAN a written notice with respect thereto, specifying in reasonable detail the total number of shares of PREFERRED STOCK expected to be sold or issued, the applicable rights and preferences associated therewith, the purchase price, and the number of shares of

***** Confidential Treatment Requested**

PREFERRED STOCK eligible for purchase by MICHIGAN under this provision. For [...***...] days after receipt of the written notice, MICHIGAN or its designee shall have the right to agree to purchase up to [...***...] % of the total number of shares of PREFERRED STOCK sold or issued in such financing on the same terms and conditions as are offered to the other purchasers in each such financing. MICHIGAN shall be entitled to apportion this right among itself and its INVESTMENT AFFILIATES in such proportions as it deems appropriate. The term "INVESTMENT AFFILIATES" for this purpose shall mean (a) any entity controlled by MICHIGAN, or (b) any affiliate of MICHIGAN or any other entity in which MICHIGAN has a financial interest or investment, provided that such affiliate or entity is an "accredited investor" within the meaning of Regulation D under the Securities Act of 1933, as amended. In the event MICHIGAN fails to exercise its right within such [...***...] day period, LICENSEE may thereafter sell or enter into an agreement to sell shares of PREFERRED STOCK at a price and upon terms no more favorable to the other purchasers than specified in LICENSEE's notice to MICHIGAN under this Section, without further obligation to MICHIGAN. Notwithstanding anything in this Agreement to the contrary, the participation rights set forth in this Section 3.8.4 shall expire immediately prior to the first to occur of an IPO or a CHANGE OF CONTROL, and shall not be applicable to securities of LICENSEE (a) that are issued to employees, officers or directors of, or consultants or advisors to, LICENSEE pursuant to equity compensation plans or arrangements approved by the Board of Directors of LICENSEE, (b) that are issued upon the conversion, exercise or exchange of other securities outstanding on the date of this Agreement, or (c) that are issued in a stock split or stock split in the nature of dividend by LICENSEE that is paid on a proportionate non-cash basis to all holders of LICENSEE's capital stock.

3.8.5 Concurrent with the execution of this Agreement, MICHIGAN will make the representations and warranties to LICENSEE set forth on Exhibit B-1.

3.8.6 The entirety of this Section 3.8 shall survive termination of this Agreement.

ARTICLE 4 - REPORTS

4.1 Until the FIRST COMMERCIAL SALE, by [...***...] during the term of this Agreement, LICENSEE shall provide to MICHIGAN a [...***...] report that includes reports on progress since the prior [...***...] report and general future plans regarding: research and development, regulatory approvals, manufacturing, sublicensing, marketing and SALES. Further, LICENSEE shall specifically report to MICHIGAN the FIRST COMMERCIAL SALE within [...***...] days thereof, and provide a brief description of the LICENSED PRODUCT or LICENSED PROCESS subject of the SALE, and terms thereof.

4.2 After the FIRST COMMERCIAL SALE, LICENSEE shall provide [...***...] reports to MICHIGAN. Specifically, by [...***...], LICENSEE shall report to MICHIGAN for the applicable ROYALTY PERIOD:

(a) number of LICENSED PRODUCTS SOLD by LICENSEE and each SUBLICENSEE.

(b) NET SALES of LICENSED PRODUCTS SOLD by LICENSEE and all SUBLICENSEES.

***** Confidential Treatment Requested**

(c) a description and accounting for all LICENSED PROCESSES SOLD by LICENSEE and all SUBLICENSEES included in NET SALES.

(d) Sublicense Fees due on SUBLICENSE REVENUE under Paragraph 3.1(c) above, including supporting figures.

(e) foreign currency conversion rate and calculations (if applicable) and total royalties due.

(f) each milestone under Paragraph 3.1(f) or Article 5 having a deadline during the ROYALTY PERIOD, and a specific identification of whether or not it was achieved.

(g) for each sublicense or amendment thereto completed in the particular ROYALTY PERIOD: names, addresses, and U.S.P.T.O. Entity Status (as discussed in Paragraph 4.5) of such SUBLICENSEE; the date of each agreement and amendment; the territory of the sublicense; the scope of the sublicense; and the nature, timing and amounts of all fees, royalties to be paid thereunder.

(h) progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and SALES of LICENSED PRODUCTS and LICENSED PROCESSES.

(i) the date of first SALE of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country and the circumstances thereof.

LICENSEE shall include the amount of all payments due, and the various calculations used to arrive at those amounts, including the quantity, description (nomenclature and type designation as described in Paragraph 4.3 below), country of manufacture and country of SALE or use of LICENSED PRODUCTS and LICENSED PROCESSES.

If no payment is due, LICENSEE shall so report to MICHIGAN that no payment is due. Failure to provide reports as required under this Article 4 shall be a material breach of this Agreement. LICENSEE agrees to reasonably cooperate with MICHIGAN regarding any questions it may have relating to compliance with this Agreement, for example to discuss the information in reports.

4.3 LICENSEE shall promptly establish and consistently employ a system of specific nomenclature and type designations for LICENSED PRODUCTS and LICENSED PROCESSES to permit identification and segregation of various types where necessary, and shall require the same of SUBLICENSEES.

4.4 LICENSEE shall keep, and shall require SUBLICENSEES to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. LICENSEE shall and it shall require all SUBLICENSEES to: (a) open such records for inspection upon reasonable notice during business hours, and no more than [...***...] per year, by an independent certified accountant selected by MICHIGAN, for the purpose of verifying the amount of payments due, and shall provide information to MICHIGAN to facilitate such inspection; and (b) retain such records for [...***...] ([...***...]) years from date of the payment to which they pertain.

***** Confidential Treatment Requested**

The terms of this Article shall survive any termination of this Agreement for [...***...] ([...***...]) years. MICHIGAN is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than [...***...] percent of royalties due MICHIGAN, then LICENSEE shall pay all expenses of that inspection and the amount of the underpayment and interest to MICHIGAN within [...***...] days of written notice thereof. LICENSEE shall also reimburse MICHIGAN for reasonable expenses required to collect the amount underpaid.

4.5 So that MICHIGAN may pay the proper U.S. Patent and Trademark Office fees relating to the PATENT RIGHTS, if LICENSEE, any company related to LICENSEE, or any SUBLICENSEE (or optionees) does not qualify as a “Small Entity” under U.S. patent laws, LICENSEE shall notify MICHIGAN immediately. The parties understand that the changes to LICENSEE’s, SUBLICENSEE’s, or optionees’ businesses that might affect entity status include: acquisitions, mergers, hiring of a total of more than 500 total employees, sublicense agreements, and sublicense options.

ARTICLE 5 - DILIGENCE

5.1 During the term of this Agreement, LICENSEE shall (itself or through its AFFILIATES or SUBLICENSEES) use commercially reasonable efforts to [...***...] one or more LICENSED PRODUCTS and/or LICENSED PROCESSES, as applicable. LICENSEE and/or SUBLICENSEE has the responsibility to do all that is legally required and commercially reasonable to [...***...] LICENSED PRODUCTS and/or use LICENSED PROCESSES for all relevant activities of LICENSEE and SUBLICENSEES. If the commercialization of multiple LICENSED PRODUCTS or LICENSED PROCESSES is commercially reasonable, then the requirement so of this paragraph shall apply to all such LICENSED PRODUCTS and/or LICENSED PROCESSES.

5.2 As part of the diligence required by Paragraph 5.1 and subject to the provisions of Paragraph 5.3 and 5.4, LICENSEE (itself or through its AFFILIATES or SUBLICENSEES) agrees to reach the following commercialization and research and development milestones for a LICENSED PRODUCT and/or LICENSED PROCESS (together the “MILESTONES”) by the following dates:

- (a) [...***...].
- (b) [...***...].
- (c) [...***...].
- (d) [...***...];
- (e) [...***...];
- (f) [...***...].

For the purposes of this Agreement, [...***...] shall mean that date upon which [...***...]

***** Confidential Treatment Requested**

[...***...].

5.3 LICENSEE shall notify MICHIGAN within [...***...] days after each MILESTONE deadline date above, as to whether or not such MILESTONE was met. MICHIGAN recognizes that there are uncertainties associated with the development of therapeutic products and the regulatory process required by the FDA (and foreign regulatory authorities that are equivalent to the FDA), and that the parties may wish to amend the MILESTONES under Subparagraphs 5.2(b) through (f). Accordingly, if LICENSEE believes in good faith that it will be unable to timely achieve any MILESTONE in Paragraph 5.2 (b), (c), (d), (e) or (f) because the LICENSEE believes in good faith, after consultation with its clinical advisors, regulatory advisors and/or with regulatory agencies, that there is the possibility of the existence of a safety or efficacy reason not to perform one or more of the steps necessary to allow the achievement of such MILESTONE, then LICENSEE will promptly consult with MICHIGAN with respect to such determination, and the parties hereto will in good faith determine whether changes to the MILESTONES and related deadlines are appropriate, and if MICHIGAN agrees, at its sole discretion, that such changes are appropriate, the parties will execute and deliver a written confirmation of such changes to the MILESTONES and related deadlines within [...***...] ([...***...]) days of the original notification by LICENSEE to MICHIGAN. In addition, (i) LICENSEE will have the right to elect [...***...] extensions to the MILESTONES under Subparagraphs 5.2 (b) through (f), at [...***...] if such extensions are a result of causes beyond LICENSEE's direct control or any inaction of the FDA or foreign equivalent and (ii) LICENSEE will have the right to extend the deadline of any MILESTONE for a period of [...***...] after the scheduled deadline for such MILESTONE without MICHIGAN's approval ("MILESTONE EXTENSION") upon the [...***...] by LICENSEE to MICHIGAN, within [...***...] ([...***...]) days after the date of the scheduled deadline for such MILESTONE [...***...], accompanied by written notice from LICENSEE to MICHIGAN specifying the MILESTONE for which LICENSEE is [...***...], and setting forth in such notice the [...***...] extended due date for such MILESTONE. Upon the timely delivery to MICHIGAN from LICENSEE of the [...***...] notice, the due date for the MILESTONE as specified in such notice from LICENSEE and [...***...] by LICENSEE to MICHIGAN as provided herein, will be extended to a date which is [...***...] after the relevant original due date therefor. LICENSEE shall not be entitled to more than [...***...] MILESTONE EXTENSIONS under Subparagraph 5.3(ii) and no more than [...***...] extensions if [...***...]. For clarity, any election to extend a MILESTONE under this Paragraph 5.3 will extend all remaining milestones in subparagraphs 5.2(b) through (f) by the applicable time period. The [...***...] by LICENSEE to MICHIGAN in this Agreement.

5.4 If LICENSEE (itself or through its AFFILIATES or SUBLICENSEES) [...***...], MICHIGAN may terminate the Agreement solely as to the PATENT RIGHTS covering the LICENSED PRODUCT for which [...***...], effective on [...***...] days' notice, unless LICENSEE [...***...] within this [...***...] day period.

ARTICLE 6 - SUBLICENSING

6.1 LICENSEE shall notify MICHIGAN in writing of every sublicense agreement and each amendment thereto with any SUBLICENSEE (other than an AFFILIATE) within [...***...] days after their execution, and indicate the name of the SUBLICENSEE, the territory of the

***** Confidential Treatment Requested**

sublicense, the scope of the sublicense, and the nature, timing and amounts of all fees and royalties to be paid thereunder, and whether or not such SUBLICENSEE has greater or fewer than 500 employees. Upon request, LICENSEE shall provide MICHIGAN with a copy of sublicense agreements with any SUBLICENSEE (other than an AFFILIATE). LICENSEE may permit SUBLICENSEES to further sublicense any of the rights granted to LICENSEE hereunder provided that all of the terms and conditions required by a SUBLICENSEE under this Agreement are included in such sublicense agreements.

6.2 If LICENSEE receives from SUBLICENSEES any consideration that would be included in SUBLICENSE REVENUE in a form other than cash payments, LICENSEE shall include in SUBLICENSE REVENUE the fair market cash value for such consideration.

6.3 MICHIGAN agrees that in the event that MICHIGAN terminates this Agreement under Paragraph 5.3, 11.1, 11.2 or 11.3, and subject to the conditions set forth below, MICHIGAN shall assume the rights and obligations of LICENSEE under SUBLICENSES granted by LICENSEE under this Agreement after the EFFECTIVE DATE that are compliant with Article 6 hereof.

The following shall be conditions precedent to any obligation of MICHIGAN to assume such rights and obligations: (a) SUBLICENSEE shall have provided a written request to MICHIGAN within [...***...] ([...***...]) business days after MICHIGAN or LICENSEE (whichever is earlier) has provided SUBLICENSEE with written notice of termination of this Agreement; (b) SUBLICENSEE shall not be, or have been at any time during the term of this Agreement, an AFFILIATE of LICENSEE; (c) SUBLICENSEE shall not be in material breach of its sublicense with LICENSEE at the time of termination of this Agreement; (d) LICENSEE shall have provided MICHIGAN with a copy of such SUBLICENSE agreement between LICENSEE and SUBLICENSEE within [...***...] days after execution of such SUBLICENSE; and (e) SUBLICENSEE shall pay MICHIGAN any financial obligations owed by LICENSEE to MICHIGAN under subparagraphs 3.1(d) and 7.3 (for those countries in which the SUBLICENSEE has a sublicense both owed to MICHIGAN upon said termination of this Agreement (subject to equal proration among such SUBLICENSEES, if any, of the PATENT RIGHTS) and during the term of such assumed SUBLICENSE. MICHIGAN shall have only have an obligation to assume such rights and obligations of LICENSEE if, within [...***...] ([...***...]) days after said written request of SUBLICENSEE, MICHIGAN and SUBLICENSEE reduce their agreement in writing as an agreement between MICHIGAN and SUBLICENSEE, and such agreement includes the following terms and any others agreed to by MICHIGAN and SUBLICENSEE:

(a) MICHIGAN, aside only from the provision of a license under the PATENT RIGHTS, shall not be responsible for the performance or payment of any obligations of LICENSEE arising from any such SUBLICENSE, (b) payment of financial obligation owed by LICENSEE to MICHIGAN under subparagraph 3.1(d) during the term of such assumed SUBLICENSE, (c) reimbursement of ongoing patent expenses under subparagraph 7.3 by SUBLICENSEE during the term of such assumed sublicense for those countries in which the SUBLICENSEE has a sublicense and (d) the scope of the field of use of such direct license shall not be broader than the rights sublicensed by LICENSEE to SUBLICENSEE.

***** Confidential Treatment Requested**

6.4 Any sublicense for which MICHIGAN does not assume the rights and obligations of LICENSEE as set forth in Paragraph 6.3 shall terminate upon termination of this Agreement.

6.5 LICENSEE shall require that all sublicenses of rights granted under this Agreement: (a) be consistent with the terms and conditions of this Agreement; (b) contain the disclaimer of warranty and limitation on MICHIGAN, [...***...], FOUNDATION and LLS's liability, as provided by Article 9 below; and (c) contain provisions under which the SUBLICENSEE accepts duties at least equivalent to those accepted by the LICENSEE in the following Paragraphs: 4.4 (duty to keep records), 10.1 (duty to defend, hold harmless, and indemnify MICHIGAN, [...***...], FOUNDATION and LLS), 10.3 (duty to maintain insurance), 13.4 (duty to properly mark LICENSED PRODUCTS with patent notices), and 13.6 (duty to restrict the use of MICHIGAN, [...***...], FOUNDATION and LLS's name).

ARTICLE 7 - PATENT APPLICATIONS AND MAINTENANCE

7.1 MICHIGAN shall have the right to control all aspects of filing, prosecuting, and maintaining all of the patents and patent applications that form the basis for the PATENT RIGHTS, including reexaminations, reviews, disputes (including litigation) regarding inventorship and derivation, and interferences. LICENSEE shall fully cooperate with MICHIGAN in activities relating to the PATENT RIGHTS, including said activities.

7.2 MICHIGAN shall notify LICENSEE of all information received by MICHIGAN relating to the filing, prosecution and maintenance of the PATENT RIGHTS, and shall make reasonable efforts to allow LICENSEE to review, comment, and advise upon such information. LICENSEE shall hold such information confidential and to use the information provided by MICHIGAN only for the purpose of advancing MICHIGAN's PATENT RIGHTS. Without limiting the foregoing, MICHIGAN agrees to use reasonable efforts to include claims covering the products contemplated to be sold by LICENSEE or its SUBLICENSEES under this Agreement in any patent applications within the PATENT RIGHTS and to file and prosecute patent applications within the PATENT RIGHTS in foreign countries as designated and paid for by LICENSEE. LICENSEE shall cooperate in any activities under this Section 7.2.

7.3 LICENSEE shall reimburse MICHIGAN for [...***...]. Such reimbursement shall be made within [...***...] days of receipt of MICHIGAN's invoice and shall be subject to the interest and other requirements specified in Article 4 above. LICENSEE agrees that unless it fully complies with all Paragraphs in this Agreement relating to entity status, LICENSEE shall be obligated to reimburse MICHIGAN for "Large Entity" patent fees. LICENSEE may, at its sole discretion, elect to not reimburse MICHIGAN for [...***...] with respect to a particular patent application or patent within the PATENT RIGHTS upon written notice of such election to MICHIGAN no less than [...***...] days prior to any deadline for taking action in any applicable patent office. In such event, MICHIGAN may continue prosecution and/or maintenance of such application(s) or patent(s) at its sole discretion and expense, provided, however, that such patent applications and issued patents shall be excluded from the definition of PATENT RIGHTS thereafter and LICENSEE will have no right or licenses thereunder.

7.4 MICHIGAN reserves the right to apply for patent term extension or to demand that LICENSEE apply for patent term extension for any and all patents included in the PATENT

***** Confidential Treatment Requested**

RIGHTS. If MICHIGAN elects to exercise this right, LICENSEE agrees to cooperate fully with MICHIGAN in the preparation, filing, and prosecution of any and all patent term extensions and to provide MICHIGAN with complete copies of any and all documents or other materials that MICHIGAN deems necessary or helpful to undertake such responsibilities.

ARTICLE 8 – ENFORCEMENT

8.1 Each party shall promptly advise the other in writing of any known acts of potential infringement of the PATENT RIGHTS by another party. LICENSEE has the first option to police the PATENT RIGHTS against infringement by other parties within the TERRITORY and the FIELD OF USE, including those prior to the EFFECTIVE DATE. LICENSEE shall not file any suit without (a) a thorough, diligent investigation of the merits of such suit by its counsel, including with respect to PATENT RIGHTS and (b) notifying MICHIGAN [...***...] days before any such filing. This right to police includes defending any action for declaratory judgment of non-infringement or invalidity; and prosecuting, defending or settling all infringement and declaratory judgment actions at its expense and through counsel of its selection, except that LICENSEE shall make any such settlement only with the advice and consent of MICHIGAN. LICENSEE may grant to third parties the right to enforce the PATENT RIGHTS, but only with the express written permission of MICHIGAN.

8.2 If LICENSEE has a reasonable basis for policing the patents, (a) MICHIGAN shall provide reasonable assistance to LICENSEE with respect to such actions, and (b) MICHIGAN agrees to join in any such action or proceeding by LICENSEE to the extent that MICHIGAN is a necessary party under the law. but only if LICENSEE promptly reimburses MICHIGAN for out-of-pocket expenses incurred in connection with any such assistance rendered at LICENSEE'S request or reasonably required by MICHIGAN and if LICENSEE notifies MICHIGAN in writing [...***...] days before filing any suit. LICENSEE shall reimburse MICHIGAN for any otherwise unreimbursed expenses incurred in complying with discovery in any lawsuit involving the PATENT RIGHTS. MICHIGAN retains the right to participate, with counsel of its own choosing and at its own expense, in any action under this Article. LICENSEE shall defend, indemnify and hold harmless MICHIGAN with respect to any counterclaims asserted by an alleged infringer reasonably related to the enforcement of the PATENT RIGHTS under this Article, including but not limited to antitrust counterclaims and claims for recovery of attorney fees. Pursuant to the INSTITUTIONAL AGREEMENT, FOUNDATION will, at LICENSEE's request, make a reasonable effort to cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, and the like. MICHIGAN will use reasonable efforts to have the FOUNDATION joined in any action brought by LICENSEE if FOUNDATION is a necessary party.

8.3 MICHIGAN and its inventors have a vital interest in proceedings relating to the validity and enforceability of its PATENT RIGHTS. If a claim or counterclaim, in either litigation or an administrative proceeding, is made by any third party that any of the PATENT RIGHTS is invalid or unenforceable, then the parties shall jointly control the defense of such claim. Each party shall consult with the other with respect to the defense of such claim, and shall reasonably consider the other party's input. In furtherance of such joint control, at the onset of such claim, the parties shall meet and confer in good faith to set a plan for handling the defense with respect to such claim. The parties expect that in general (a) LICENSEE will have the right to lead daily

***** Confidential Treatment Requested**

activities, including but not limited to discovery, relating to the defense and (b) the parties would make joint court and/or administrative filings, but in the event that the parties cannot agree on how to proceed with respect to such claim of invalidity or unenforceability, MICHIGAN shall have the right to control the defense of such claim.

Except as provided below, LICENSEE shall be responsible for the reasonable costs and fees associated with the activities under this Article. The parties shall consider reasonable controls on costs and fees as part of the aforementioned meet and confer with respect to the handling of the defense, which shall include reasonable consideration of use of a single law firm representing both parties in the defense of such claim. Notwithstanding, if a third party asserts jurisdiction for any such action solely as the result of acts of MICHIGAN, then MICHIGAN shall be responsible for such reasonable costs and fees, and MICHIGAN shall then control such defense.

8.4 If LICENSEE recovers damages in patent litigation or settlement thereof, the award shall be applied first to satisfy [...***...]. The remaining balance shall be divided as follows: MICHIGAN will receive [...***...]% of the remaining balance and LICENSEE will retain [...***...]. This provision shall control the division of revenues where a license, covenant not to sue, or assignment of rights is granted as part of a settlement of such lawsuit.

ARTICLE 9 - NO WARRANTIES; LIMITATION ON MICHIGAN, [...***...],
FOUNDATION AND LLS'S LIABILITY

9.1 MICHIGAN warrants to LICENSEE as of the EFFECTIVE DATE to the actual knowledge of its Office of Technology Transfer that (a) it has the authority to execute this Agreement and grant the licensed granted hereunder and (b) that the inventors named in the PATENT RIGHTS filed as of the EFFECTIVE DATE have assigned their entire right, title, and interest in such PATENT RIGHTS to MICHIGAN or the FOUNDATION, as applicable. Neither MICHIGAN, [...***...], FOUNDATION nor LLS make any representations or warranties that PATENT RIGHTS are or will be held valid or enforceable, or that the manufacture, importation, use, offer for SALE, SALE or other distribution of any LICENSED PRODUCTS or LICENSED PROCESSES will not infringe upon any patent or other rights.

9.2 EXCEPT AS EXPRESSLY SET FORTH HEREIN, **MICHIGAN, [...***...], FOUNDATION AND LLS MAKE NO REPRESENTATIONS, EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUME NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS OR LICENSED PROCESSES.**

9.3 **LICENSEE AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS AND LICENSED PROCESSES.** In no event shall MICHIGAN, [...***...], FOUNDATION, OR LLS be responsible or liable for any direct, indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to the manufacture, use or sale of LICENSED PRODUCTS, or LICENSED PROCESSES to LICENSEE, SUBLICENSEE or any other individual or entity ,

***** Confidential Treatment Requested**

regardless of legal or equitable theory. The above limitations on liability apply even though MICHIGAN, [...***...], FOUNDATION, may have been advised of the possibility of such damage.

9.4 LICENSEE shall not make any statements, representations or warranties whatsoever to any person or entity, or accept any liabilities or responsibilities whatsoever from any person or entity, that are inconsistent with any disclaimer or limitation included in this Article 9.

ARTICLE 10 - INDEMNITY; INSURANCE

10.1 LICENSEE shall defend, indemnify and hold harmless and shall require SUBLICENSEES to defend, indemnify and hold harmless MICHIGAN, [...***...], FOUNDATION and LLS for and against any and all claims, demands, damages, losses, and expenses of any nature (including attorneys' fees and other litigation expenses), resulting from, but not limited to, death, personal injury, illness, property damage, economic loss or products liability, including errors and omissions, arising from or in connection with, any of the following: (1) Any manufacture, use, SALE or other disposition by LICENSEE, SUBLICENSEES or transferees of LICENSED PRODUCTS or LICENSED PROCESSES; (2) The use by any person of LICENSED PRODUCTS made, used, sold or otherwise distributed by LICENSEE or SUBLICENSEES; and (3) The use or practice by LICENSEE or SUBLICENSEES of any invention or computer software related to the PATENT RIGHTS. LICENSEE shall not be obligated to defend, indemnify or hold MICHIGAN, [...***...], FOUNDATION or LLS harmless under this Paragraph after any unappealed or unappealable order of a court of competent jurisdiction holds that the claims, demands, damages, losses or expenses were determined to be legally caused solely by the gross negligence or willful misconduct by MICHIGAN, [...***...], FOUNDATION or LLS, respectively.

10.2 MICHIGAN is entitled to participate at its option and expense through counsel of its own selection, and may join in any legal actions related to any such claims, demands, damages, losses and expenses under Paragraph 10.1 above. LICENSEE shall not settle any such legal action with an admission of liability of MICHIGAN without MICHIGAN's written approval.

10.3 Prior to any distribution or commercial use of any LICENSED PRODUCT or use of any LICENSED PROCESS by LICENSEE, LICENSEE shall purchase and maintain in effect commercial general liability insurance, product liability insurance, and errors and omissions insurance which shall protect LICENSEE, [...***...], FOUNDATION and MICHIGAN with respect to the events covered by Paragraph 10.1, and LICENSEE shall require the same of any SUBLICENSEE. Each such insurance policy must provide reasonable coverage for all claims with respect to any LICENSED PROCESS used and any LICENSED PRODUCTS manufactured, used, sold, licensed or otherwise distributed by LICENSEE -- or, in the case of a SUBLICENSEE's policy, by said SUBLICENSEE -- and must specify MICHIGAN, [...***...] and FOUNDATION as an additional insured. LICENSEE shall furnish certificate(s) of such insurance to MICHIGAN, upon request.

10.4 In no event shall either party hereunder be liable to the other for any special, indirect, or consequential damages of any kind whatsoever resulting from any breach or default of this Agreement.

***** Confidential Treatment Requested**

ARTICLE 11 - TERM AND TERMINATION

11.1 If LICENSEE ceases to operate its business, or if it files a petition in bankruptcy, has an involuntary petition in bankruptcy filed against LICENSEE that is not dismissed within sixty days after the filing thereof, make a general assignment for the benefit of creditors or liquidates or dissolves, this Agreement shall immediately terminate upon MICHIGAN's attempt to deliver a termination notice to the address for notices provided herein. If LICENSEE makes or attempts to make an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy or insolvency are instituted on behalf of or against LICENSEE, or if a receiver or trustee is appointed for the property of LICENSEE, this Agreement shall automatically terminate. LICENSEE shall notify MICHIGAN of any such event mentioned in this Paragraph as soon as reasonably practicable, and in any event within [...***...] days after any such event.

11.2 If LICENSEE fails to make any payment due to MICHIGAN, upon thirty (30) days' written notice by MICHIGAN, this Agreement shall automatically terminate unless LICENSEE makes such payment by the end of such period or MICHIGAN specifically extends such date in writing. Such termination shall not foreclose MICHIGAN from collection of any amounts remaining unpaid or seeking other legal relief.

11.3 Upon any material breach or default of this Agreement by LICENSEE (other than as specifically provided herein, the terms of which shall take precedence over the handling of any other material breach or default under this Paragraph), MICHIGAN has the right to terminate this Agreement effective on sixty (60) days' written notice to LICENSEE. Such termination shall become automatically effective upon expiration of the sixty (60) day period unless LICENSEE cures the material breach or default before the period expires.

11.4 LICENSEE has the right to terminate this Agreement at any time on ninety days' written notice to MICHIGAN if LICENSEE prior to the termination date:

- (a) pays all amounts due MICHIGAN through the effective date of the termination;
- (b) submits a final report of the type described in Paragraph 4.2;
- (c) returns any patent documentation (including that exchanged under Article 7) and any other confidential or trade-secret materials provided to LICENSEE by MICHIGAN in connection with this Agreement, or, with prior approval by MICHIGAN, destroys such materials, and certifies in writing that such materials have all been returned or destroyed; and
- (d) suspends its manufacture, use and SALE of the LICENSED PROCESS(ES) and LICENSED PRODUCT(S), subject to Paragraph 11.8.

Upon notice by LICENSEE of intent to terminate under this Paragraph 11.4, MICHIGAN may elect to immediately terminate this Agreement upon written notice.

***** Confidential Treatment Requested**

11.5 Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the parties hereunder shall cease, except any previously accrued rights and obligations and further as follows: (a) obligations to pay royalties and other sums, or to transfer equity or other consideration, accruing hereunder up to the day of such termination, whether or not this Agreement provides for a number of days before which actual payment is due and such date is after the day of termination; (b) MICHIGAN's rights to inspect books and records as described in Article 4, and LICENSEE's obligations to keep such records for the required time; (c) any cause of action or claim of LICENSEE or MICHIGAN accrued or to accrue because of any breach or default by the other party hereunder; (d) the provisions of Articles 1, 9, 10, and 13; and (e) all other terms, provisions, representations, rights and obligations contained in this Agreement that by their sense and context are intended to survive until performance thereof by either or both parties.

Termination by either party hereunder shall not alter or affect any other rights or relief that either party may be entitled to under law.

11.6 Upon termination of this Agreement, if LICENSEE has filed patent applications or obtained patents to any modification or improvement to LICENSED PRODUCTS or LICENSED PROCESSES within the scope of the PATENT RIGHTS, LICENSEE agrees upon request to enter into good faith negotiations with MICHIGAN or MICHIGAN's future licensee(s) for the purpose of granting licensing rights to said modifications or improvements in a timely fashion and under commercially reasonable terms.

11.7 If LICENSEE or a SUBLICENSEE, or any affiliate thereof, asserts the invalidity or unenforceability of any claim included in the PATENT RIGHTS, including by way of litigation or administrative proceedings, either directly or through any other party, then MICHIGAN shall have the right to immediately terminate this Agreement upon written notice to LICENSEE. However, MICHIGAN shall not terminate this Agreement if, after a SUBLICENSEE makes such assertions of invalidity or unenforceability, LICENSEE, within thirty (30) days of such action, terminates the sublicense with respect to such PATENT RIGHTS and provides MICHIGAN written notice of such termination.

11.8 Upon MICHIGAN's termination (but not expiration) of this Agreement, other than under Section 11.2, within a period of [...***...] ([...***...]) days after the date of termination, LICENSEE is entitled to dispose of all previously made or partially made LICENSED PRODUCTS, provided that the SALE or use of such LICENSED PRODUCTS are subject to the terms of this Agreement, including, but not limited to, rendering such reports and making such payments as required under this Agreement.

***** Confidential Treatment Requested**

ARTICLE 12 - NOTICES

12.1 Any notice, request, or report required or permitted to be given or made under this Agreement by either party is effective when mailed if sent by recognized overnight carrier, certified or registered mail, or electronic mail followed by confirmation by U.S. mail, to the address set forth below or such other address as such party specifies by written notice given in conformity herewith. Any notice, request, or report not so given is not effective until actually received by the other party.

To MICHIGAN:

Office of Technology Transfer
University of Michigan
1600 Huron Parkway, 2nd Floor
Ann Arbor, MI 48109-2590

Attn: [...***...]

To LICENSEE:

Kura Oncology, Inc.
11119 North Torrey Pines Road
Suite 125
La Jolla, CA 92037

Attn: Chief Executive Officer
Copy: General Counsel

ARTICLE 13 - MISCELLANEOUS PROVISIONS

13.1 This Agreement shall be governed by and construed under the laws of the state of Michigan without regard for principles of choice of law, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted. Any claims, demands, or actions asserted against MICHIGAN, its Regents, fellows, officers, employees or agents shall only be brought in the Michigan Court of Claims. LICENSEE, its successors, and assigns consent to the jurisdiction of a court with applicable subject matter jurisdiction sitting in the state of Michigan with respect to any claims arising under this agreement or the relationship between the parties.

13.2 MICHIGAN and LICENSEE agree that this Agreement sets forth their entire understanding concerning the subject matter of this Agreement. The parties may amend this Agreement from time to time, such as to add new rights, but no modification will be effective unless both MICHIGAN and LICENSEE agree to it in writing.

13.3 If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

13.4 LICENSEE agrees to mark the LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers as necessary to meet the requirements of 35 U.S.C. 287 so that the full benefits of patent enforcement may be realized. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked to comply with the patent laws and practices of the countries of manufacture, use and SALE.

***** Confidential Treatment Requested**

13.5 No waiver by either party of any breach of this Agreement, no matter how long continuing or how often repeated, is a waiver of any subsequent breach thereof, nor is any delay or omission on the part of either party to exercise or insist on any right, power, or privilege hereunder a waiver of such right, power or privilege. In no event shall any waiver be deemed valid unless it is in writing and signed by an authorized representative of each party.

13.6 LICENSEE shall, and shall require its affiliates to, refrain from using and to require SUBLICENSEES to refrain from using the name of MICHIGAN, [...***...], FOUNDATION, LLS or their employees in publicity or advertising without the prior written approval of MICHIGAN, [...***...], FOUNDATION or LLS, as the case may be. Reports in scientific literature and presentations of joint research and development work are not publicity. Notwithstanding this provision, without prior written approval of MICHIGAN, [...***...], FOUNDATION or LLS, LICENSEE and SUBLICENSEES may state publicly that LICENSED PRODUCTS and PROCESSES were developed by LICENSEE based upon an invention(s) developed at the University of Michigan or [...***...] and/or that the PATENT RIGHTS were licensed from the University of Michigan and [...***...].

13.7 LICENSEE agrees to comply with all applicable laws and regulations, including but not limited to all United States laws and regulations controlling the export of commodities and technical data, with respect to the PATENT RIGHTS, LICENSED PRODUCTS and LICENSED PROCESSES. LICENSEE shall be solely responsible for any violation of such laws and regulations involving LICENSEE or its SUBLICENSEES with respect to PATENT RIGHTS, LICENSED PRODUCTS and LICENSED PROCESSES, and to defend, indemnify and hold harmless MICHIGAN if any legal action of any nature results from any such violation.

13.8 The relationship between the parties is that of independent contractor and contractee. Neither party is an agent of the other in connection with the exercise of any rights hereunder, and neither has any right or authority to assume or create any obligation or responsibility on behalf of the other.

13.9 LICENSEE may not assign this Agreement without the prior written consent of MICHIGAN and shall not pledge any of the license rights granted in this Agreement as security for any creditor. Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement without the prior consent of MICHIGAN will be void from the beginning. If MICHIGAN consents to any assignment of this Agreement, such assignment by LICENSEE will not be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement, and such writing is provided to MICHIGAN. Notwithstanding, LICENSEE may, without MICHIGAN's consent, assign its rights under this Agreement to a purchaser of all or substantially all of LICENSEE's business relating to the subject matter of this Agreement, whether by sale, merger, operation of law or otherwise, so long as such assignee provides a statement in writing to MICHIGAN that LICENSEE (if LICENSEE survives in such transaction) or the successor to LICENSEE (if LICENSEE does not survive in such transaction) shall be bound by all the terms and conditions of this Agreement.

13.10 If the registration, recordation, or reporting to a national or supranational agency of this Agreement, its terms, or assignment thereof is or becomes required or advisable (e.g., as a prerequisite to enforceability of the Agreement in such nation), LICENSEE shall, at its expense,

***** Confidential Treatment Requested**

promptly undertake such action. LICENSEE shall provide prompt notice thereof to MICHIGAN along with copies of relevant documentation.

13.11 Except for LICENSEE’s obligation to make any payments to MICHIGAN hereunder, the parties shall not be responsible for failure to perform due to the occurrence of any events beyond their reasonable control which render their performance impossible or onerous, including, but not limited to: accidents (environmental, toxic spill, etc.); acts of God; biological or nuclear incidents; casualties; earthquakes; fires; floods; governmental acts; orders or restrictions; inability to obtain suitable and sufficient labor, transportation, fuel and materials; local, national or state emergency; power failure and power outages; acts of terrorism; strike; and war.

13.12 This Agreement may be executed in one or more counterparts, each of which together shall constitute one and the same Agreement. For purposes of executing this Agreement, a facsimile (including a PDF image delivered via email) copy of this Agreement, including the signature pages, will be deemed an original.

ARTICLE 14 - CONFLICT OF INTEREST MANAGEMENT

14.1 This Agreement and the licenses granted hereunder are subject to approval by a two-thirds majority vote of the Board of Regents of the University of Michigan.

14.2 Unless MICHIGAN provides appropriate formal approvals, continuing development of LICENSED PRODUCTS and LICENSED PROCESSES shall take place without the use of MICHIGAN funds, facilities, or other resources of or funds administered by MICHIGAN.

14.3 LICENSEE shall cooperate with MICHIGAN in developing and implementing appropriate plans for management of potential conflicts of interest and conflicts of commitment of MICHIGAN employees.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

FOR KURA ONCOLOGY, INC.

FOR THE REGENTS OF THE
UNIVERSITY OF MICHIGAN

By /s/ Troy Wilson
(authorized representative)

By /s/ Kenneth J. Nisbet
Kenneth J. Nisbet
Assoc. Vice President for Research
U-M Tech Transfer

Printed Name Troy Wilson

Title Pres. & CEO

Date Dec. 22, 2014

Date 22 December 2014

***** Confidential Treatment Requested**

MICHIGAN Representations and Warranties

Concurrent with the execution of the Patent License Agreement (MICHIGAN File No(s): 4471, 5643, and 6393), dated December 22, 2014 (the "LICENSE"), MICHIGAN represents and warrants to LICENSEE that:

1.1 Purchase Entirely for Own Account. MICHIGAN has no present intention of selling, granting any participation in, or otherwise distributing the SHARES to be issued to MICHIGAN pursuant to Sections 3.8.1 or 3.8.2 of the LICENSE (the "MICHIGAN EQUITY").

1.2 Disclosure of Information. MICHIGAN has had an opportunity to discuss LICENSEE's business, management and financial affairs with LICENSEE's management.

1.3 Restricted Securities. MICHIGAN understands that the MICHIGAN EQUITY, when issued, will not be registered under the Securities Act of 1933, as amended, and will be "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, MICHIGAN must hold such shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available.

1.4 Accredited Investor. MICHIGAN is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.

REGENTS OF THE UNIVERSITY OF MICHIGAN

By: /s/ Kenneth J. Nisbet

Name: Kenneth J. Nisbet

Title: Assoc. V.P. for Research U-M Tech Transfer

STOCK ISSUANCE AGREEMENT

THIS STOCK ISSUANCE AGREEMENT (the "Agreement") is made as of [DATE] between Kura Oncology, Inc., a Delaware corporation, having offices at 11119 North Torrey Pines Road, Suite 125, La Jolla, CA 92037 (the "LICENSEE"), and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan ("MICHIGAN").

RECITALS

Pursuant to that certain Patent License Agreement (MICHIGAN File No(s): _____), dated [DATE OF LICENSE] (the "License"), between LICENSEE and MICHIGAN, MICHIGAN licensed certain rights to LICENSEE.

Pursuant to Section 3.8 of the License and in consideration thereof, the LICENSEE agreed to issue to MICHIGAN a specified number and type of shares of capital stock of LICENSEE at the times and on the terms described in such Section.

The obligation of LICENSEE to issue such shares of capital stock of LICENSEE to MICHIGAN has matured.

NOW, THEREFORE, In consideration of the License and this Agreement, LICENSEE and MICHIGAN agree as follows:

1. Issuance of Shares. In partial consideration of the License LICENSEE shall, upon execution of this Agreement, issue MICHIGAN a duly endorsed certificate for _____ shares of [TYPE OF STOCK REQUIRED BY SECTION 3.8 OF THE LICENSE] of LICENSEE (the "Michigan Equity"). The Michigan Equity is subject to the designations, powers, preferences and rights, and qualifications, limitations and restrictions set forth in LICENSEE's charter. MICHIGAN will not unreasonably withhold its consent to enter into any other commercially-reasonable agreements relating to the Michigan Equity entered into by all other holders of the same type and class of shares as the Michigan Equity.

2. LICENSEE Representations and Warranties. LICENSEE represents and warrants to MICHIGAN that:

(a) LICENSEE is validly existing in good standing in its state of incorporation or organization and has the power and authority to enter into this Agreement and to issue the Michigan Equity as contemplated hereby;

(b) this Agreement is a valid and binding obligation of LICENSEE, enforceable in accordance with its terms, except as limited by laws relating to creditors' rights and general principals of equity;

(c) issuance of the Michigan Equity satisfies all of the requirements of Section 3.8 of the License, including with respect to the number of shares of capital stock of

LICENSEE that LICENSEE is obligated to issue to MICHIGAN pursuant to Section 3.8 of the License;

(d) upon issuance pursuant to this Agreement, the Michigan Equity will be free of any lien, charge or other encumbrance, and will be validly issued, fully-paid and non-assessable;

(e) issuance of the Michigan Equity does not and will not violate (i) the charter or bylaws of LICENSEE (ii) any rights of preemption, first offer, first refusal, co-sale, registration, dividends or similar rights (collectively, "Equity Rights"), (iii) any agreement by which LICENSEE, its owners, property or assets are bound, or (iv) any Federal or applicable state securities law, rule or regulation; and

(f) LICENSEE has achieved (i) the Qualified Financing (as defined in the License) to the extent the Michigan Equity is being issued pursuant to Section 3.8.1 of the License or (ii) the Change of Control (as defined in the License) to the extent the Michigan Equity is being issued pursuant to Section 3.8.2 of the License.

3. Michigan's Representations and Warranties. MICHIGAN represents and warrants to LICENSEE that the following representations and warranties set forth are true and correct as of the date hereof.

(a) **Purchase Entirely for Own Account.** The Michigan Equity to be acquired by MICHIGAN under Section 3.8.1 or Section 3.8.2 of the License will be acquired for investment for MICHIGAN's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and MICHIGAN has no present intention of selling, granting any participation in, or otherwise distributing the same;

(b) **Disclosure of Information.** MICHIGAN has had an opportunity to discuss LICENSEE's business, management, financial affairs and the terms and conditions of the offering of the applicable shares of LICENSEE with LICENSEE's management;

(c) **Restricted Securities.** MICHIGAN understands that the applicable shares of LICENSEE have not been, and will not be, registered under the Securities Act of 1933, as amended, by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of MICHIGAN's representations as expressed herein. MICHIGAN understands that the applicable shares of LICENSEE are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, MICHIGAN must hold such shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. MICHIGAN acknowledges that LICENSEE has no obligation to register or qualify the applicable shares of LICENSEE, or any shares into which such shares may be converted, for resale except as set forth in the financing documents related to the Qualified Financing. MICHIGAN further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the applicable shares of LICENSEE, and on requirements relating to LICENSEE which are outside of the

MICHIGAN's control, and which LICENSEE is under no obligation and may not be able to satisfy;

(d) **No Public Market.** MICHIGAN understands that no public market now exists for the applicable shares of LICENSEE, and that LICENSEE has made no assurances that a public market will ever exist for such shares;

(e) **Accredited Investor.** MICHIGAN is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act; and

(f) **Legends.** MICHIGAN understands that the stock certificates for the applicable shares of LICENSEE and any securities issued in respect of or exchange for such shares, may bear one or all of the following legends:

(i) "THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED";

(ii) Any legend set forth in, or required by, the financing documents related to the Qualified Financing; and

(iii) Any legend required by the securities laws of any state to the extent such laws are applicable to such shares represented by the certificate so legended.

4. **Market Stand-Off.** MICHIGAN hereby agrees that MICHIGAN shall not sell, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale of, the Michigan Equity during the 180-day period following the effective date of LICENSEE's IPO (as defined in the License) (or such longer period, not to exceed 34 days after the expiration of the 180-day period, as the underwriters or the Company shall request in order to facilitate compliance with NASD Rule 2711 or NYSE Member Rule 472 or any successor or similar rule or regulation); provided, that all officers and directors of LICENSEE and holders of at least 1% of LICENSEE's voting securities are bound by and have entered into similar agreements. The obligations described in this Section 4 shall not apply to a registration relating solely to employee benefit plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a transaction on Form S-4 or similar forms that may be promulgated in the future.

5. General.

(a) *Assignment.* This Agreement is not assignable by LICENSEE or MICHIGAN.

(b) *Binding Effect.* All of the covenants and provisions of this Agreement shall bind and inure to the benefit of successors and permitted assigns and transferees of LICENSEE and MICHIGAN.

(c) *Notices.* Any notice, request, claim or other communication hereunder must be in writing and will be deemed to have been duly given if delivered by hand or if sent by certified mail, postage and certification prepaid, to LICENSEE and MICHIGAN at the addresses for each set forth in the introductory paragraph of this Agreement. Either party may change such address by giving notice to the other in the manner required by this subsection.

(d) *Entire Agreement; Amendments.* This Agreement and the License constitute the entire agreement between LICENSEE and MICHIGAN with respect to the subject matter of this Agreement. LICENSEE and MICHIGAN may only amend this Agreement by a written instrument executed by LICENSEE and MICHIGAN.

(e) *Governing Law.* This Agreement will be construed and governed by the laws of the State of Delaware, without giving effect to principals of conflicts of laws.

(f) *Counterparts.* This Agreement may be executed in any number of counterparts and by facsimile, each of which will be an original, but all of which together shall constitute one and the same instrument.

[Remainder of this page intentionally left blank]

LICENSEE and MICHIGAN have executed this Stock Issuance Agreement as of the date first written above.

KURA ONCOLOGY, INC.

REGENTS OF THE UNIVERSITY OF MICHIGAN

By _____

By _____

Name: _____

Name: _____

Title: _____

Title: _____

EXHIBIT A-2

STOCK ISSUANCE AGREEMENT

THIS STOCK ISSUANCE AGREEMENT (the "Agreement") is made as of [DATE] between Kura Oncology, Inc., a Delaware corporation, having offices at 11119 North Torrey Pines Road, Suite 125, La Jolla, CA 92037 (the "LICENSEE"), and The Leukemia & Lymphoma Society, Inc., a [_____] ("LLS").

RECITALS

Pursuant to that certain Agreement for Collaboration, dated July 9, 2010, as amended by that certain First Amendment to Agreement for Collaboration dated December [___], 2014, between the Regents of the University of Michigan ("MICHIGAN") and LLS (the "Amended Collaboration Agreement"), MICHIGAN and LLS agreed, among other things, to provide for the issuance or transfer of third party equity to LLS under certain circumstances specified therein.

Pursuant to that certain Patent License Agreement, dated [DATE OF LICENSE] (the "License"), between LICENSEE and MICHIGAN, MICHIGAN licensed certain rights to LICENSEE.

Pursuant to Section 7.1 of the Amended Collaboration Agreement and Section 3.8 of the License, respectively, and in consideration thereof, MICHIGAN agreed to require in the License that the LICENSEE issue or transfer to LLS, and the LICENSEE has agreed to issue to LLS, a specified number and type of shares of capital stock of LICENSEE at the times and on the terms described in Section 3.8 of the License.

The obligation of LICENSEE to issue such shares of capital stock of LICENSEE to LLS has matured.

NOW, THEREFORE, In consideration of the License and this Agreement, LICENSEE and LLS agree as follows:

1. Issuance of Shares. In partial consideration of the License and in satisfaction of the requirements of Section 3.8 thereof, and in partial consideration of Section 7.1 of the Amended Collaboration Agreement, LICENSEE shall, upon execution of this Agreement, issue LLS a duly endorsed certificate for _____ shares of [TYPE OF STOCK REQUIRED BY SECTION 3.8 OF THE LICENSE] of LICENSEE (the "LLS Equity"). The LLS Equity is subject to the designations, powers, preferences and rights, and qualifications, limitations and restrictions set forth in LICENSEE's charter or other applicable agreements and instruments relating thereto, and LLS agrees to execute any such applicable agreements and instruments as may be reasonably requested by LICENSEE.

2. LICENSEE Representations and Warranties. LICENSEE represents and warrants to LLS that:

(a) LICENSEE is validly existing in good standing in its state of incorporation or organization and has the power and authority to enter into this Agreement and to issue the LLS Equity as contemplated hereby;

(b) this Agreement is a valid and binding obligation of LICENSEE, enforceable in accordance with its terms, except as limited by laws relating to creditors' rights and general principals of equity;

(c) issuance of the LLS Equity satisfies all of the requirements of Section 3.8 of the License, including with respect to the number of shares of capital stock of LICENSEE that LICENSEE is obligated to issue to LLS pursuant to Section 3.8 of the License;

(d) upon issuance pursuant to this Agreement, the LLS Equity will be free of any lien, charge or other encumbrance, and will be validly issued, fully-paid and non-assessable;

(e) issuance of the LLS Equity does not and will not violate (i) the charter or bylaws of LICENSEE (ii) any rights of preemption, first offer, first refusal, co-sale, registration, dividends or similar rights (collectively, "Equity Rights"), (iii) any agreement by which LICENSEE, its owners, property or assets are bound, or (iv) any Federal or applicable state securities law, rule or regulation; and

(f) LICENSEE has achieved (i) the Qualified Financing (as defined in the License) to the extent the LLS Equity is being issued pursuant to Section 3.8.1 of the License or (ii) the Change of Control (as defined in the License) to the extent the LLS Equity is being issued pursuant to Section 3.8.2 of the License.

3. LLS' Representations and Warranties. LLS represents and warrants to LICENSEE that the following representations and warranties set forth are true and correct as of the date hereof.

(a) **Purchase Entirely for Own Account.** The LLS Equity to be acquired by LLS under Section 3.8.1 or Section 3.8.2 of the License will be acquired for investment for LLS' own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and LLS has no present intention of selling, granting any participation in, or otherwise distributing the same;

(b) **Disclosure of Information.** LLS has had an opportunity to discuss LICENSEE's business, management, financial affairs and the terms and conditions of the offering of the applicable shares of LICENSEE with LICENSEE's management;

(c) **Restricted Securities.** LLS understands that the applicable shares of LICENSEE have not been, and will not be, registered under the Securities Act of 1933, as amended, by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of LLS' representations as expressed herein. LLS understands that the applicable shares of LICENSEE are "restricted securities" under applicable U.S. federal and state securities

laws and that, pursuant to these laws, LLS must hold such shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. LLS acknowledges that LICENSEE has no obligation to register or qualify the applicable shares of LICENSEE, or any shares into which such shares may be converted, for resale except as set forth in the financing documents related to the Qualified Financing. LLS further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the applicable shares of LICENSEE, and on requirements relating to LICENSEE which are outside of the LLS' control, and which LICENSEE is under no obligation and may not be able to satisfy;

(d) **No Public Market.** LLS understands that no public market now exists for the applicable shares of LICENSEE, and that LICENSEE has made no assurances that a public market will ever exist for such shares;

(e) **Accredited Investor.** LLS is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act; and

(f) **Legends.** LLS understands that the stock certificates for the applicable shares of LICENSEE and any securities issued in respect of or exchange for such shares, may bear one or all of the following legends:

(i) "THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED";

(ii) Any legend set forth in, or required by, the financing documents related to the Qualified Financing; and

(iii) Any legend required by the securities laws of any state to the extent such laws are applicable to such shares represented by the certificate so legended.

4. General.

(a) *Assignment.* This Agreement is not assignable by LICENSEE or LLS.

(b) *Binding Effect.* All of the covenants and provisions of this Agreement shall bind and inure to the benefit of successors and permitted assigns and transferees of LICENSEE and LLS.

(c) *Notices.* Any notice, request, claim or other communication hereunder must be in writing and will be deemed to have been duly given if delivered by hand or if sent by

certified mail, postage and certification prepaid, to LICENSEE and LLS at the addresses for each set forth in the introductory paragraph of this Agreement. Either party may change such address by giving notice to the other in the manner required by this subsection.

(d) *Entire Agreement; Amendments.* This Agreement and the License constitute the entire agreement between LICENSEE and LLS with respect to the subject matter of this Agreement. LICENSEE and LLS may only amend this Agreement by a written instrument executed by LICENSEE and LLS.

(e) *Governing Law.* This Agreement will be construed and governed by the laws of the State of Delaware, without giving effect to principals of conflicts of laws.

(f) *Counterparts.* This Agreement may be executed in any number of counterparts and by facsimile, each of which will be an original, but all of which together shall constitute one and the same instrument.

[Remainder of this page intentionally left blank]

LICENSEE and LLS have executed this Stock Issuance Agreement as of the date first written above.

KURA ONCOLOGY, INC.

THE LEUKEMIA & LYMPHOMA SOCIETY, INC.

By _____

By _____

Name: _____

Name: _____

Title: _____

Title: _____

FIRST AMENDMENT TO PATENT LICENSE AGREEMENT

This FIRST AMENDMENT TO PATENT LICENSE AGREEMENT (“Amendment”) is entered into as of March 3, 2015 (the “Amendment Effective Date”) by and between Kura Oncology, Inc. (“Licensee”) having the address set forth in Article 12 of the Agreement (as defined below), and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan (“Michigan”).

RECITALS

A. Licensee and Michigan are parties to that certain Patent License Agreement, dated December 22, 2014 (the “Agreement”).

B. The Parties have decided to amend the Agreement as set forth herein.

Now, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Licensee and Michigan hereby agree as follows:

1. **Defined Terms.** All capitalized terms not otherwise defined in this Amendment shall have the same meanings that are ascribed to them in the Agreement.

2. **Section 1.12.** Section 1.12 of the Agreement shall be amended and restated in its entirety to read as follows:

“1.12 “QUALIFIED FINANCING” means the first sale of capital stock of LICENSEE, whether in one transaction or a series of related transactions, which occurs after the EFFECTIVE DATE and in which LICENSEE receives gross proceeds totaling at least \$[...***...] (exclusive of conversion of indebtedness) to one or more third party venture capital funds or institutional investors.”

3. **Article 2.** *Article 2* of the Agreement shall be amended to insert the following new **Section 2.10** as follows:

“2.10 Upon payment by LICENSEE to MICHIGAN of \$[...***...] as reimbursement for patent expenses incurred by Michigan prior to the Amendment Effective Date, MICHIGAN hereby grants to LICENSEE, at LICENSEE’s sole election, an exclusive option to obtain an exclusive license (with the right to grant sublicenses) solely under MICHIGAN’s legal rights in [...***...] filed [...***...] and [...***...] filed [...***...] (the “Additional Patent Applications”). Such option shall expire March 1, 2016 (“OPTION PERIOD”). LICENSEE shall reimburse MICHIGAN for [...***...]. If LICENSEE fails to reimburse these costs within [...***...] ([...***...]) days of receipt of an invoice from MICHIGAN, the option shall automatically terminate. LICENSEE may not exercise its option at any time any litigation or administrative proceeding is pending in which LICENSEE has asserted the invalidity or unenforceability of any claim in the Additional Patent Applications, either directly or through any other party. After LICENSEE exercises its option by providing an acceptable business plan to MICHIGAN describing LICENSEE’s intention and ability to develop and make commercially available LICENSED PRODUCTS or LICENSED PROCESSES within the FIELD OF USE for public use as soon as practicable, consistent with sound and reasonable business practices and

***Confidential Treatment Requested

judgment, such acceptance to be approved by MICHIGAN, with such approval not be unreasonably withheld or delayed, and for a reasonable period of up to [...***...] ([...***...]) months after exercise, the parties agree to negotiate in good faith an amendment to the Agreement or a separate license agreement granting LICENSEE exclusive rights to MICHIGAN's legal rights in Additional Patent Applications to make, have made, import, use, market, offer for sale, and sell LICENSED PRODUCTS and LICENSED PROCESSES in the FIELD OF USE under terms customary in the trade. MICHIGAN further agrees that if and when MICHIGAN executes an inter-institutional agreement with [...***...], the other owner of the Additional Patent Applications, which grants MICHIGAN the right to grant exclusive licenses under such other owner's rights in the Additional Patent Applications, the rights of such other owner in the Additional Patent Applications will be included in the option granted in this Section 2.10 to the extent permitted under such inter-institutional agreement and only after [...***...] provides review and approval for such license agreement.

In the event that the parties enter into a license agreement with respect to the Additional Patent Applications (the "2nd LICENSE"), LICENSEE will not be obligated to pay multiple milestones or royalties to MICHIGAN or be subject to multiple diligence obligations to MICHIGAN if any LICENSED PRODUCT or LICENSED PROCESS is covered by a claim of PATENT RIGHTS under this Agreement and a claim under the Additional Patent Applications in the 2nd LICENSE. In the event that: (a) the parties enter into the 2nd LICENSE and (b) a LICENSED PRODUCT or LICENSED PROCESS is covered by claims of PATENT RIGHTS under the Agreement and claims under the Additional Patent Rights, if MICHIGAN and LICENSEE are the only parties to the 2nd LICENSE, the terms and conditions of the Agreement shall control. In all cases, MICHIGAN shall be responsible for all payments due to [...***...] under the 2nd LICENSE and any [...***...]."

4. **Section 3.8.1.** Section 3.8.1 of the Agreement shall be amended and restated in its entirety to read as follows:

"3.8.1 Upon the closing of the QUALIFIED FINANCING, LICENSEE shall separately issue to MICHIGAN and LLS those numbers of shares of the same class of capital stock of LICENSEE that is issued to the investors in such QUALIFIED FINANCING (such applicable class of capital stock, the "CAPITAL STOCK") equal to \$[...***...] with respect to MICHIGAN and \$[...***...] with respect to LLS, divided by the price per share paid by the investors for the new money invested in such QUALIFIED FINANCING (the "SHARES"). For example, if the price per share of CAPITAL STOCK issued in the QUALIFIED FINANCING is \$[...***...], then LICENSEE shall (a) issue [...***...] SHARES to MICHIGAN and (b) issue [...***...] SHARES to LLS. LICENSEE shall issue the SHARES to MICHIGAN and LLS pursuant to, and subject to the terms of, forms of stock issuance agreements attached hereto as Exhibits A-1 and A-2, respectively (each a "STOCK ISSUANCE AGREEMENT")."

5. **Section 3.8.2.** The last sentence of Section 3.8.2 of the Agreement shall be amended and restated in its entirety to read as follows:

"For purposes of this Section 3.8, a "CHANGE OF CONTROL" means (i) any consolidation or merger of LICENSEE (or a parent of LICENSEE) with any other

***Confidential Treatment Requested

unaffiliated entity or similar transaction, following which the stockholders of LICENSEE (or parent, as applicable) immediately prior thereto own, directly or indirectly, less than fifty percent (50%) of the voting power of the securities of the surviving entity in such transaction (or its parent), other than pursuant to a bona fide financing transaction, or (ii) a sale of all or substantially all of the assets of LICENSEE (or a parent of LICENSEE) to a third party.”

6. **Section 3.8.3.** Section 3.8.3 of the Agreement shall be amended and restated in its entirety to read as follows:

“3.8.3 Within [...***...] ([...***...]) days after the final closing of any round of equity financing of LICENSEE (or a parent of LICENSEE) in excess of \$[...***...] that is consummated on or after April 1, 2015 for bona fide fundraising purposes (a “TRIGGERING FINANCING”), LICENSEE shall give MICHIGAN written notice of the consummation of such TRIGGERING FINANCING that includes a report setting forth the basic terms of such TRIGGERING FINANCING, including, without limitation, the amount of new money raised, the nature of the capital stock issued and a summary of the post-financing capitalization of LICENSEE (or a parent of LICENSEE, as applicable). The obligation of LICENSEE to give such notice shall terminate upon the first to occur of (a) the initial sale of the capital stock of LICENSEE (or a parent of LICENSEE) to the public in a firmly underwritten offering registered under the Securities Act of 1933, as amended (an “IPO”), and (b) a CHANGE OF CONTROL.”

7. **Section 3.8.4.** Section 3.8.4 of the Agreement shall be amended and restated in its entirety to read as follows:

“3.8.4 Prior to the closing of any TRIGGERING FINANCING, LICENSEE shall deliver to MICHIGAN a written notice with respect thereto, specifying in reasonable detail the total number of shares of capital stock expected to be sold or issued, the applicable rights and preferences associated therewith, the purchase price, and the number of shares of stock eligible for purchase by MICHIGAN under this provision. For [...***...] days after receipt of the written notice, MICHIGAN or its designee shall have the right to agree to purchase up to [...***...]% of the total number of shares of capital stock sold or issued in such financing on the same terms and conditions as are offered to the other purchasers in each such financing. MICHIGAN shall be entitled to apportion this right among itself and its INVESTMENT AFFILIATES in such proportions as it deems appropriate. The term “INVESTMENT AFFILIATES” for this purpose shall mean (a) any entity controlled by MICHIGAN, or (b) any affiliate of MICHIGAN or any other entity in which MICHIGAN has a financial interest or investment, provided that such affiliate or entity is an “accredited investor” within the meaning of Regulation D under the Securities Act of 1933, as amended. In the event MICHIGAN fails to exercise its right within such [...***...] day period, LICENSEE (or a parent of LICENSEE, as applicable) may thereafter sell or enter into an agreement to sell shares of stock at a price and upon terms no more favorable to the other purchasers than specified in LICENSEE’s notice to MICHIGAN under this Section, without further obligation to MICHIGAN. Notwithstanding anything in this Agreement to the contrary, the participation rights set forth in this Section 3.8.4 shall expire immediately prior to the first to occur of an IPO or a CHANGE OF CONTROL, and shall not be applicable to securities of LICENSEE (or a parent of LICENSEE) (a) that are issued to employees, officers or directors of, or consultants or advisors to, LICENSEE (or a parent of LICENSEE) pursuant to equity compensation plans or arrangements

approved by the Board of Directors of LICENSEE (or a parent of LICENSEE), (b) that are issued upon the conversion, exercise or exchange of other securities outstanding on the date of this Agreement, or (c) that are issued in a stock split or stock split in the nature of dividend by LICENSEE (or a parent of LICENSEE) that is paid on a proportionate non-cash basis to all holders of capital stock of LICENSEE (or a parent of LICENSEE).

8. **Continuing Effect.** All references to the “Agreement” in the Agreement shall hereinafter refer to the Agreement as amended by this Amendment. Except as specifically amended by this Amendment, the Agreement shall remain in full force and effect in accordance with its terms. Sections or other headings contained in this Amendment are for reference purposes only and shall not affect in any way the meaning or interpretation of this Amendment; and no provision of this Amendment shall be interpreted for or against any party because that party or its legal representative drafted the provision.

9. **Counterparts.** This Amendment may be executed in counterparts with the same force and effect as if each of the signatories had executed the same instrument.

[Signature Page Follows]

***Confidential Treatment Requested

IN WITNESS WHEREOF, the parties have executed this Amendment as of the Amendment Effective Date.

KURA ONCOLOGY, INC.

REGENTS OF THE UNIVERSITY OF MICHIGAN

By: /s/ Troy Wilson

By: /s/ Kenneth J. Nisbet

Name: Troy Wilson

Name: Kenneth J. Nisbet

Title: President & CEO

Title: Assoc. V.P. for Research U-M Tech Transfer

VIA CERTIFIED MAIL

July 22, 2015

The Regents of the University of Michigan
Office of Research and Sponsored Projects
3003 S. State St. Room 1070
Ann Arbor, MI 48109-1274

Attn: Anthony L. Neilsen, J.D.

RE: Research Agreement between Kura Oncology, Inc. (“Kura”) and The Regents of the University of Michigan (the “University”) dated February 15, 2015 (the “Research Agreement”)

Dear Anthony:

Pursuant to Section 8/2 of the Research Agreement, we hereby give notice of the exercise by Kura of its option to obtain an exclusive royalty-bearing license to the University’s interest in the patent applications numbered [...***...]. Effective upon this notice, the Patent License Agreement between the University and Kura is deemed amended to add the above referenced patent applications to the definition of PATENT RIGHTS under such agreement.

Please let me know if you have any questions.

Sincerely,

/s/ Annette North
Annette North
SVP, General Counsel

cc: Robin Rasor

*****Confidential Treatment Requested**



VIA CERTIFIED MAIL

September 29, 2016

The Regents of the University of Michigan
Office of Research and Sponsored Projects
3003 S. State St. Room 1070
Ann Arbor, MI 48109-1274

Attn: Anthony L. Neilsen, J.D.

RE: Research Agreement between Kura Oncology, Inc. ("Kura") and The Regents of the University of Michigan (the "University") dated February 15, 2015 (the "Research Agreement")

Dear Anthony:

Pursuant to Section 8.2 of the Research Agreement, we hereby give notice of the exercise by Kura of its option to obtain an exclusive royalty-bearing license to the University's interest in the patent applications numbered [...***...]. Effective upon this notice, the Patent License Agreement between the University and Kura is deemed amended to add the above-referenced patent applications to the definition of PATENT RIGHTS under such agreement.

The parties acknowledge and agree that as amended, PATENT RIGHTS means:

- (i) the JOINTLY OWNED PATENT RIGHTS and MICHIGAN PATENT RIGHTS; and
- (ii) (a) patent applications numbered [...***...], (b) United States and foreign counterpart patents or patent applications claiming and entitled to the priority date of the respective patent application(s) referenced in subparagraph (a) above, or patents issuing from such applications; (c) United States and foreign divisionals, substitutions, continued prosecution applications, including requests for continued examination, and continuations and continuations-in-part (but only those claims in the continuation-in-part applications that are entitled to the priority date of the parent patent or application in the PATENT RIGHTS) patent applications referenced in subparagraphs (a) and (b) above or patents issuing from such applications; and (d) United States and foreign patents issued from the applications listed in subparagraphs (a), (b), and (c) above, including any reviewed, reissued, renewed or reexamined patents and patent term extensions based upon the same.

11119 North Torrey Pines Road, Suite 125
La Jolla, CA 92037

*****Confidential Treatment Requested**

To acknowledge your agreement to the above, please have this letter signed where indicated below and return a copy of to me at your earliest convenience.

Sincerely,

/s/ Annette North
Annette North
SVP, General Counsel

Acknowledged and Agreed this 30th day of Sept. 2016
The Regents of the University of Michigan

By: /s/ Kenneth J. Nisbet

Name: Kenneth J. Nisbet
Title: Assoc. V.P. for Research U-M Tech Transfer

11119 North Torrey Pines Road, Suite 125
La Jolla, CA 92037



VIA CERTIFIED MAIL

February 1, 2017

The Regents of the University of Michigan
Office of Research and Sponsored Projects
3003 S. State St. Room 1070
Ann Arbor, MI 48109-1274

Attn: Anthony L. Neilsen, J.D.

RE: Research Agreement between Kura Oncology, Inc. (“Kura”) and The Regents of the University of Michigan (the “University”) dated February 15, 2015 (the “Research Agreement”)

Dear Anthony:

Pursuant to Section 8.2 of the Research Agreement, we hereby give notice of the exercise by Kura of its option to obtain an exclusive royalty-bearing license to the University’s interest in the patent applications numbered [...***...]. Effective upon this notice, the Patent License Agreement between the University and Kura is deemed amended to add the above-referenced patent applications to subsection (ii)(a) of the definition of PATENT RIGHTS under such agreement.

Please let me know if you have any questions.

Sincerely,

/s/ Annette North
Annette North
SVP, General Counsel

11119 North Torrey Pines Road, Suite 125
La Jolla, CA 92037

*****Confidential Treatment Requested**

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-210614) of Kura Oncology, Inc., and
2. Registration Statement (Form S-8 No. 333-210260) pertaining to the Amended and Restated 2014 Equity Incentive Plan and the 2015 Employee Stock Purchase Plan of Kura Oncology, Inc.;

of our report dated March 14, 2017, with respect to the financial statements of Kura Oncology, Inc., included in this Annual Report (Form 10-K) of Kura Oncology, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young LLP

San Diego, California
March 14, 2017

**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 Annual Report of Kura Oncology, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, Ph.D., J.D., as President and Chief Executive Officer of the Company, and Heidi Henson, as Chief Financial Officer and Secretary of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (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 result of operations of the Company.

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

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

/s/ Heidi Henson

Heidi Henson
Chief Financial Officer and Secretary

Date: March 14, 2017

Date: March 14, 2017