#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### **FORM 10-K**

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

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For the fiscal year ended December 31, 2020

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)		61-1547851 (I.R.S. Employer Identification No.)					
12730 High Bluff Drive, Suite 400, San Diege (Address of principal executive offices)	,	92130 (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	Trading Symbol(s)	Name of each exchange on which regis	stered				
Common Stock, par value \$0.0001 per share	KURA	The Nasdaq Global Select Marl	ket				
Securities registered pursuant to 12(g) of the Act: None							
Indicate by check mark if the registrant is a well-known sea	asoned issuer, as defined in Rule 405 of the	Securities Act. YES 🗵 NO 🗆					
Indicate by check mark if the registrant is not required to fi	ile reports pursuant to Section 13 or 15(d) of	the Act. YES $\Box$ NO $\boxtimes$					
Indicate by check mark whether the registrant: (1) has filed 2 months (or for such shorter period that the registrant was require	1 1 5	0	0 1 0				
Indicate by check mark whether the registrant has submi §232.405 of this chapter) during the preceding 12 months (or for su			05 of Regulation S-T				
Indicate by check mark whether the registrant is a large a company. See the definition of "large accelerated filer," "accelerated							
Large accelerated filer 🛛	Sn	aller reporting company					
Accelerated filer	En	nerging growth company					
Non-accelerated filer							
If an emerging growth company, indicate by check mark if accounting standards provided pursuant to Section 13(a) of the Excl		nded transition period for complying with any new	w or revised financial				
Indicate by check mark whether the registrant has filed a re eporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.0							
Indicate by check mark whether the registrant is a shell cor	npany (as defined in Rule 12b-2 of the Exch	ange 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 \$877.9 million as of June 30, 2020 based on the closing price of \$16.30 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 February 19, 2021 was 66,211,215 shares.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2021 Annual Meeting of Stockholders, 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, 2020.

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#### PART I

#### **Risk Factor Summary**

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" under Part I, Item 1A of this Annual Report and should be carefully considered, together with other information in this Annual Report before making investment decisions regarding our common stock.

- Our ability to conduct our clinical trials has been and could continue to be adversely impacted by COVID-19.
- We are highly dependent on the success of our lead product candidates, tipifarnib and KO-539, which are still in clinical development, and we cannot give any assurance that they or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- 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.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.
- Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.
- Failure by us or our third-party collaborators to successfully develop and commercialize a diagnostic testing platform for use by oncologists could harm our ability to develop and commercialize our product candidates.
- 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.
- 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.
- We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and operating results will vary significantly from period to period.
- We 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 certain rights to our technologies or product candidates.
- 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.
- 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.
- Any product candidate for which we obtain marketing approval will be subject to extensive post-approval regulatory requirements and could be subject to post-approval restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

- If we are unable to obtain and maintain intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.
- We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We currently have no sales or market access personnel. If we are unable to establish effective sales or market access 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 face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- 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.
- Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock.
- The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

#### **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. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "may," "plan," "potential," "project," "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. These statements reflect our beliefs and opinions on the relevant subject and are based upon information available to us as of the date of this Annual Report. 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 information that may be limited or incomplete, 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. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements. 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 impact of the COVID-19 pandemic on our business and operations;
- 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, any clinical holds established by any relevant regulatory bodies 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;
- 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.

Unless the context requires otherwise, references in this Annual Report to "we," "us" and "our" refer to Kura Oncology, Inc.

#### 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 where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We presently have two clinical-stage product candidates for which we own global commercial rights, tipifarnib and KO-539, as well as additional programs that are at a discovery stage. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

Program	Preclinical	Phase 1	Phase 2	Registration-Directed		
Tipifarnib	HRAS mutant Head and Neck Squamous Cell Carcinoma (HNSCC)					
Farnesyl Transferase	Enrollment in AIM-HN registration-directed trial ongoing					
Inhibitor (FTI)	PI3Kα mutant and HRAS overexpressed HNSCC					
	Initiation of PI3K $\alpha$ inhibitor combination study expected in second half of 2021					
KO-539	Acute Myeloid Leukemia (AML)					
Menin Inhibitor	Enrollment in Phase 1 expansion cohorts expected to begin in mid-2021					
Next-	Solid tumors					
Generation FTI	Nomination of development candidate expected in mid-2021					

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

Our most advanced solid tumor indication for tipifarnib is in patients with head and neck squamous cell carcinoma, or HNSCC, that carry mutations in the HRAS gene. In September 2017, we reported that our ongoing proof-of-concept Phase 2 clinical trial of tipifarnib in patients with HRAS mutant relapsed or refractory HNSCC, or RUN-HN, achieved its primary efficacy endpoint. In October 2018, we reported updated data from RUN-HN showing a significant association between tumor HRAS mutant allele frequency and clinical benefit from tipifarnib. Based upon these observations, we introduced a minimum HRAS mutant variant allele frequency as an entry criterion in the RUN-HN trial. Following feedback from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities, we initiated a global, multi-center, open-label, non-comparative registration-directed clinical trial of tipifarnib in HRAS mutant HNSCC in November 2018. The clinical trial has two cohorts: a treatment cohort, which we call AIM-HN, and a noninterventional screening and outcomes cohort, which we call SEQ-HN. AIM-HN is designed to enroll at least 59 evaluable HNSCC patients with high HRAS mutant variant allele frequency who have received prior platinum-based therapy. In October 2019, we reported updated data from the ongoing RUN-HN trial that we believe confirms the association between HRAS mutant variant allele frequency and anti-tumor activity, and we believe further supports the design of our amended AIM-HN registration-directed trial in HRAS mutant HNSCC. On December 16, 2019, we reported that the FDA granted Fast Track Designation to tipifarnib for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy. On May 29, 2020, we announced updated clinical data for our RUN-HN study presented at the American Society of Clinical Oncology Virtual Scientific Program, including data collected as part of the trial showing a median overall survival of 15.4 months, a median progression free survival of 5.9 months and an objective response rate, or ORR, of 50% observed in patients with recurrent/metastatic HRAS mutant HNSCC among the 18 patients on the RUN-HN study who were evaluable for efficacy.

In July 2020, we amended the AIM-HN trial protocol to enable enrollment of patients with any HRAS mutation in order to assess the potential for clinical benefit in the overall HRAS mutant HNSCC population. We also introduced a number of modifications to the protocol that seek to enable us to enroll patients in the study more efficiently as well as modifications that we believe better reflected the evolving standards of care for recurrent/metastatic HNSCC. While these amendments do not change the primary outcome measure of ORR in patients with high HRAS mutant variant allele frequency, the modifications will require us to enroll an increased number of evaluable HNSCC patients. As a result of the pandemic caused by the coronavirus disease 2019, or COVID-19, and the additional patients required for the trial, we anticipate we will face delays in our timelines and milestones for the AIM-HN trial and, accordingly, are unable to reasonably forecast when our AIM-HN trial will become fully enrolled.

On February 24, 2021, we announced that tipifarnib has been granted Breakthrough Therapy Designation from the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma with variant allele frequency  $\geq$  20% after disease progression on platinum-based chemotherapy. The Breakthrough Therapy Designation is based upon data from our Phase 2 RUN-HN trial, which has been accepted for publication in an upcoming issue of the *Journal of Clinical Oncology*.

In addition to evaluating tipifarnib as a monotherapy in patients with recurrent or metastatic HRAS mutant HNSCC, we have also been evaluating the use of tipifarnib in combination with other oncology therapeutics to address larger patient populations and to pursue earlier lines of therapy. Among these potential combinations, we have prioritized the combination of tipifarnib and an inhibitor of the PI3 Kinase alpha enzyme for clinical evaluation in patients with HNSCC. In particular, we are planning to commence a Phase 1/2 open-label, biomarker-defined cohort study in the second half of 2021 to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of tipifarnib and a PI3 kinase alpha inhibitor for the treatment of adult participants who have HRAS-overexpressing, PIK3CA-mutated and/or PIK3CA-amplified HNSCC.

Our second product candidate, KO-539, is a potent, selective, reversible and oral small molecule inhibitor of the mixed-lineage leukemia 1, or MLL1, gene (now renamed Lysine K-specific Methyltransferase 2A, or KMT2A), or menin-KMT2A, protein-protein interaction. We have generated preclinical data that support the potential anti-tumor activity of KO-539 in genetically defined subsets of acute leukemia, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as nucleophosmin 1, or NPM1. The novel mechanism of action targets epigenetic dysregulation and removes a key block to cellular differentiation to drive anti-tumor activity. We believe KO-539 has the potential to address approximately 35% of acute myeloid leukemia, or AML, including NPM1-mutant AML and KMT2A-rearranged AML. In the pediatric population, KMT2A-rearranged leukemias make up approximately 10% of acute leukemias in all age groups and in the case of infant leukemias, the frequency of KMT2A rearrangements is 70–80%. These pediatric leukemia sub-types portend a poorer prognosis and five-year survival rate that is lower than other leukemia sub-types and therefore represent significant unmet medical needs given the lack of curative therapeutic options. In April 2020, a competitor reported that its menin-KMT2A inhibitor showed potential anti-tumor activity in KMT2A-rearranged AML.

We received orphan drug designation for KO-539 for the treatment of acute myeloid leukemia, or AML, from the FDA in July 2019. We initiated our Phase 1/2 clinical trial of KO-539 in relapsed or refractory AML in September 2019 and are actively recruiting at multiple sites in the United States and France with the anticipation of expanding to additional sites in the United States, France and other countries during the expansion phase of the study. Our menin-KMT2A Phase 1/2 clinical trial, which we call the Kura Oncology MEnin-KMT2A Trial, or KOMET-001, has an accelerated design and seeks to determine a recommended Phase 2 dose and schedule, or RP2D, using a modified toxicity probability interval, or MTPI, model.

On December 5, 2020, we announced preliminary results from our KOMET-001 Phase 1/2 clinical trial at an oral presentation at the 2020 American Society of Hematology, or ASH. As of the data cutoff date for the ASH presentation, November 2, 2020, the trial had enrolled 12 patients with relapsed or refractory AML, of whom ten were evaluable for safety and tolerability and eight were evaluable for efficacy. Clinical or biological activity was reported in six of the eight efficacy-evaluable patients, including two patients achieving a complete remission, one patient achieving a morphological leukemia-free state, and one patient experiencing a marked decrease in hydroxyurea requirements and having attained peripheral blood count stabilization. As presented at ASH, KO-539 has been well tolerated with a manageable safety profile to date. As of the data cutoff date, no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation were reported. Treatment related adverse effects (grade <sup>3</sup> 3) were reported to include pancreatitis, increased lipase, decreased neutrophil count, tumor lysis syndrome and deep venous thrombosis.

On February 24, 2021, we reported that we completed the 600 mg dose cohort of KOMET-001 without determining a RP2D and we are currently evaluating an 800 mg dose cohort. We also indicated that, based on guidance we received from the FDA, we may seek to determine a minimum safe and biologically effective dose for use in the Phase 2 portion of KOMET-001 by initiating Phase 1 expansion cohorts at lower doses in parallel to continuing the Phase 1 dose escalation portion of the study. Initiating Phase 1 expansion cohorts at lower doses requires a protocol amendment and additional patient recruitment.

#### **Our 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 of cancer;
- Identify molecular, genetic or other tumor-related characteristics 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 our clinical-stage programs, tipifarnib and KO-539, as well as our earlier discovery-stage programs in clinical indications of high unmet need where improved outcomes are associated with specific biomarkers;
- Advance our programs 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 through internal discovery and development efforts as well as through potential external sources including collaborations, in-licensings and acquisitions.

#### The COVID-19 Pandemic

The COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business interruptions and shutdowns. These precautions may continue to disrupt our business operations and prospects. Since early March 2020, we have taken temporary precautionary measures, including routine screening and remote working initiatives, intended to help minimize the risk of COVID-19 to our employees and their families. We also suspended non-essential travel worldwide for our employees. In addition, we have experienced, and expect to continue to experience, patient screening and enrollment at a slower pace at many of our clinical trial sites than what was projected when the trials began. Some of our clinical sites have experienced challenges in conducting trial activities while they focus critical resources on caring for COVID-19 patients and due to facility restrictions,

quarantines, travel restrictions, remote work requirements and other precautions. To manage the COVID-19 impact on our business, we developed a comprehensive COVID-19 contingency plan designed to work closely with our third-party contractors and investigators to ensure our ongoing clinical trials proceed safely and efficiently. As a result of these efforts, we continue to accrue patients for our clinical trials, but we expect the disruption caused by and the challenges associated with COVID-19 to continue for the foreseeable future. The long-term trends impacting our business from COVID-19 are uncertain and will depend on the continued world-wide progress toward managing this health crisis.

#### **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 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. Patients with EGFR mutations treated with EGFR inhibitors have a response rate in the 65% range, as opposed to a response rate of approximately 10% in unselected lung patients. Erlotinib (Tarceva®) was approved in the United States as a first-line treatment for patients with non-small cell lung cancer, or NSCLC, characterized by EGFR mutations. Other examples of approved agents developed using precision medicine approaches include ALK, BCR-ABL, BRAF, ROS1, RET and TRK inhibitors.

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 enrolled 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 using a number of tools, including 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 to identify and prioritize potential clinical indications.

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, such as next-generation sequencing, or NGS, or RNA expression profiling, 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 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 of 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, the ability to leverage clinical and pathology trends towards comprehensive tumor profiling and the potential for expedited clinical development.

#### **Clinical Programs and Pipeline**

#### Tipifarnib - An Oral Farnesyl Transferase Inhibitor

#### Overview

Tipifarnib is a member of a class of product candidates called farnesyl transferase inhibitors, or FTIs. We in-licensed tipifarnib from Janssen Pharmaceutica NV, or Janssen, an affiliate of Johnson & Johnson, in December 2014. Previously, tipifarnib was studied in more than 5,000 oncology patients in more than 70 clinical trials 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. We have worldwide rights to tipifarnib in all indications other than virology.

#### 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 inner cell membrane is farnesylation, which modifies the protein by attaching a farnesyl group. Another, related mechanism of attachment of proteins to the membrane 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 farnesyl transferase enzyme have been discovered, and several inhibitors including tipifarnib have been evaluated in human clinical trials. The small molecule inhibitors are commonly referred to as FTIs. 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 properly. Treatment of tumors with FTIs results in the reversal of several hallmarks of cancer, including mitotic arrest, induction of apoptosis, growth inhibition, tissue invasion, sustained angiogenesis and tumor growth, as well as induction of tumor regression in animal models.

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

#### Solid Tumors with HRAS Mutations

Retrovirus-associated DNA sequences, or RAS, are 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 the 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 in human cancers, they have a higher prevalence in cancers of the upper digestive tract, skin, thyroid and urinary bladder.

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 it 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.

HNSCC is one of a number of different types of cancer that arises from squamous cells. 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. HNSCC develops in the mucous membranes of the mouth, nose, and throat and is classified by its location. HNSCC 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 HNSCC.

HNSCC is a disease of high unmet need. Response rates for the three approved second-line agents, cetuximab (Erbitux<sup>®</sup>), nivolumab (Opdivo<sup>®</sup>) and pembrolizumab (Keytruda<sup>®</sup>), are in the range of 13-16% in unselected populations, with a median progression-free survival, or PFS, of approximately two months and a median overall survival of fewer than eight months. Data in the literature along with our own clinical data suggest response rates in patients with HRAS mutations may be even lower.

Other types of cancer that can result from squamous cells include vulvar, penile, cutaneous and lung squamous cell carcinoma. Our preclinical and clinical data suggest that, among solid tumors with HRAS mutations, squamous cell tumors are sensitive tumors to treatment with tipifarnib, and treatment with tipifarnib can, in some patients, produce durable responses.

#### Clinical Development of Tipifarnib in HRAS Mutant Solid Tumors

*Proof-of-Concept Trial in HNSCC and other SCCs.* We initiated a proof-of-concept Phase 2 clinical trial in May 2015 to test the hypothesis whether tipifarnib could be used as a treatment for advanced tumors with HRAS mutations. The initiation of this clinical trial was based on our preclinical data, which demonstrated that tipifarnib inhibits HRAS mutant cell proliferation and HRAS tumor growth in mouse models. The clinical trial was originally designed to enroll two cohorts of 18 patients each, with a primary endpoint of ORR and tumor response assessments conducted according to Response Evaluation Criteria in Solid Tumors version 1.1, or RECIST 1.1, criteria with confirmation of response required.

Cohort 1 enrolled patients with malignant thyroid tumors with HRAS mutations, independently of thyroid histology. Ten evaluable patients were enrolled in Stage 1 of Cohort 1. Although evidence of prolonged disease stabilization was observed in several patients, we saw no objective responses within the first stage of the thyroid cohort and the cohort was closed to further enrollment. Cohort 2 was initially designed to enroll any patient with a non-hematological HRAS mutant tumor other than thyroid cancer who met the eligibility criteria. In March 2017, we presented preliminary data from this trial at the 15th International Congress on Targeted Anticancer Therapies, including data from a cohort of three patients with HRAS mutant HNSCC treated with tipifarnib, two of whom achieved confirmed partial responses, or PRs. Based upon these data, we amended the clinical trial protocol to focus enrollment in Cohort 2 entirely on patients with HRAS mutant HNSCC. In addition, a number of patients with HRAS mutant salivary gland cancer were treated with tipifarnib during the conduct of our Phase 2 clinical trial, several of whom experienced tumor shrinkage and prolonged disease stabilization.

In September 2017, we reported that our proof-of-concept clinical trial of tipifarnib in patients with HRAS mutant HNSCC achieved its primary efficacy endpoint with four confirmed, partial responses among the first six evaluable HNSCC patients enrolled in the trial. Following achievement of the primary efficacy endpoint in patients with HRAS mutant HNSCC, we further amended the clinical trial protocol to add a third cohort with patients having HRAS mutant SCCs other than HNSCC.

In October 2018, we reported updated data from our proof-of-concept clinical trial of tipifarnib in patients with HRAS mutant HNSCC and preliminary data in our cohort of other HRAS mutant SCCs at the European Society for Medical Oncology Congress. An analysis of available tumor biopsy samples showed a significant association between tumor HRAS mutant allele frequency, or the measurement of mutated HRAS encoding DNA in a patient's tumor compared to wild type HRAS DNA, and clinical benefit in patients treated with tipifarnib. Of the 14 HNSCC or other SCC patients with a tumor HRAS mutant allele frequency greater than 20%, seven achieved PRs, one achieved an unconfirmed PR and two experienced disease stabilization greater than six months. No meaningful clinical benefit was observed at that time in the seven patients with an allele frequency less than 20%. Data from The Cancer Genome Atlas indicate that approximately 5% of HNSCC patients have an HRAS mutant allele frequency greater than 20%.

Following the data update in October 2018, we modified our ongoing Phase 2 proof-of-concept clinical trial of tipifarnib in patients with HRAS mutant HNSCC whose disease had progressed after prior therapy to introduce a cohort of patients with a minimum tumor HRAS mutant allele frequency as an entry criterion and use 600 mg orally twice daily as the starting dose, the RUN-HN study. On May 29, 2020, updated clinical outcome data from the RUN-HN study was presented in an oral session at the American Society of Clinical Oncology Virtual Scientific Program. At data cutoff, 21 patients with HRAS mutant HNSCC were enrolled, of whom 18 were evaluable for efficacy. Nine of the 18 evaluable patients achieved a PR for an ORR of 50% (95% CI, 26.0 to 74.0), with a median duration of response of 14.7 months. Median progression-free survival, or PFS, was 5.9 months (95% CI, 3.5 to 19.2), compared to 2.8 months on the patients' last prior therapy. Median overall survival was 15.4 months (95% CI, 7.0 to 46.4). Patients had a median of two prior lines of therapy (range 0-6). Robust activity was seen despite resistance to chemotherapy, immunotherapy and/or cetuximab. Patients in the RUN-HN trial received tipifarnib at a starting dose of 600 or 900 mg orally twice daily on days 1-7 and 15-21 of 28-day cycles. Tipifarnib was generally well-tolerated. The most common grade 3 or 4 adverse events seen in at least 10% of patients were cytopenia and gastrointestinal disturbances.

*Registration-Directed Trial in HRAS Mutant HNSCC*. Based on the positive results observed in our proof-of-concept clinical trial, and following feedback from the FDA and other regulatory authorities, we initiated a global, multi-center, open-label, registration-directed clinical trial in recurrent or metastatic patients with HRAS mutant HNSCC in November 2018. The trial has two cohorts: A non-interventional screening and outcomes cohort, which we call SEQ-HN, and a treatment cohort, which we call AIM-HN.

SEQ-HN is designed as a case-control trial to determine the treatment outcomes of patients with recurrent or metastatic HNSCC with HRAS mutations. The primary objective of SEQ-HN is to determine the ORR of first-line therapy in patients with HNSCC that carry HRAS mutations compared to those without a known HRAS mutation. In addition, this screening and outcomes cohort is expected to enable the identification of patients with HRAS mutations for potential enrollment into AIM-HN.

In July 2020, we amended the AIM-HN trial protocol to enable enrollment of patients with any HRAS mutation in order to assess the potential for clinical benefit in the overall HRAS mutant HNSCC population. We also introduced a number of modifications to the protocol that seek to enable us to enroll patients in the study more efficiently and modifications that we believe better reflected the evolving standards of care for recurrent/metastatic HNSCC. Although these amendments do not change the primary outcome measure of ORR in patients with high HRAS mutant variant allele frequency, AIM-HN will require an increased number of evaluable HNSCC patients. As a result of the COVID-19 pandemic we anticipate we will face delays in our timelines and milestones for the AIM-HN trial and, accordingly, are unable to reasonably forecast at this time when our AIM-HN trial will become fully enrolled.

On February 24, 2021, we announced that tipifarnib has been granted Breakthrough Therapy Designation from FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma with variant allele frequency  $\geq$  20% after disease progression on platinum-based chemotherapy. The Breakthrough Therapy Designation is based upon data from our Phase 2 RUN-HN trial, which has been accepted for publication in an upcoming issue of the *Journal of Clinical Oncology*.

In addition to studying tipifarnib as a monotherapy in patients with recurrent or metastatic HRAS mutant HNSCC, we are also evaluating the potential use of tipifarnib in combination with other oncology therapeutics to address larger patient populations and pursue earlier lines of therapy. Among these potential combinations, we have prioritized the combination of tipifarnib and an inhibitor of the PI3 Kinase alpha enzyme for clinical evaluation in patients with HNSCC. In particular, we have developed preclinical data to support the potential for using tipifarnib in combination with a PI3 kinase alpha inhibitor to treat HNSCC patients whose tumors overexpress the HRAS protein and/or patients whose tumors have either mutations in or amplifications of the PIK3CA gene, and we are preparing to sponsor a study of tipifarnib in combination with a PI3 kinase alpha inhibitor which we hope to commence in the second half of 2021.

*Investigator-Sponsored Trials in HRAS Mutant Solid Tumors.* In addition to our company-sponsored clinical trials in HRAS mutant solid tumors, an investigator-sponsored clinical trial of tipifarnib for the treatment of HRAS mutant lung squamous cell carcinoma is ongoing. This proof-of-concept clinical trial is being conducted by Grupo Español de Cáncer de Pulmón, a Spanish lung cancer consortium, and is designed to enroll at least 18 patients. The primary endpoint of this clinical trial is ORR, and secondary endpoints include PFS, duration of response and safety.

An investigator-sponsored clinical trial of tipifarnib is also being conducted for the treatment of advanced, previously treated urothelial carcinomas that carry HRAS mutations. This proof-of-concept clinical trial is sponsored by the Samsung

Medical Center in Seoul, South Korea and is designed to enroll at least 18 patients. The primary endpoint of this clinical trial is PFS at six months, and secondary endpoints include ORR, duration of response and safety. In September 2019, we reported that this trial met its primary efficacy endpoint.

*Companion Diagnostics for Tipifarnib in HRAS Mutant Solid Tumors.* Patients are currently being enrolled in the ongoing Phase 2 proof-of-concept HRAS mutant tumor clinical trial and our AIM-HN clinical trial based either upon information on the patients' tumor HRAS mutation status obtained by the clinical sites from NGS panels used by the site, or upon information obtained from third-party laboratories who conduct genetic screening on patient samples for the clinical sites. Working with our collaborators, we have obtained an investigational device exemption, or IDE, for use of a qualitative polymerase chain reaction, or qPCR, -based assay as a companion diagnostic test for our AIM-HN clinical trial. 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. On January 4, 2021, we entered into a collaboration agreement, or the Illumina Agreement, with Illumina, Inc., or Illumina. Under the Illumina Agreement, Illumina has agreed to develop and commercialize an assay as a companion diagnostic test to identify head and neck squamous cell carcinoma patients with an HRAS mutation for use with tipifarnib. Illumina is also responsible for developing, and obtaining and maintaining regulatory approvals for, the companion diagnostic test in the United States, the United Kingdom and major European markets and such other countries as the parties may mutually agree.

Registration Strategy for Tipifarnib in HRAS Mutant Solid Tumors. Our immediate strategy for tipifarnib in HRAS mutant solid tumors is to generate a data package to support an application for marketing approval in HRAS mutant HNSCC. In mid-2021, we are also planning to commence a Phase 1/2 open-label, biomarker-defined cohort study to evaluate the safety and tolerability, determine the recommended combination dosing, and assess early antitumor activity of the combination of tipifarnib and a PI3 kinase inhibitor for the treatment of adult participants who have HRAS-overexpressing, PIK3CA-mutated and/or -amplified HNSCC. And we are also evaluating tipifarnib in combination with other agents, including chemotherapy, immune therapies and other targeted therapies, to advance to earlier lines of therapy. We may also seek to broaden tipifarnib's potential use in other HRAS mutant solid tumors, including HRAS mutant SCCs other than HNSCC, as we believe this may represent further opportunity to expand the use of tipifarnib into a broader set of HRAS mutant cancers. Longer term, our development strategy for tipifarnib is to advance toward earlier lines of therapy and, ultimately, to treat patients with HRAS mutant SCCs in the continuum of systemic treatment settings.

#### Clinical Development of Tipifarnib in CXCL12 Expressing Tumors

In addition to its activity against HRAS mutant solid tumors, we have data that supports that tipifarnib inhibits the production of CXCL12, a chemokine that binds to the receptors CXCR4 and CXCR7 and regulates a number of key cellular processes associated with cancer including proliferation, survival, migration, invasion, and metastasis. Targeting the CXCR4–CXCL12 axis has the potential of affecting CXCR4-expressing primary tumor cells, modulating the immune response, or synergizing with other anticancer therapies. As an example of using tipifarnib to affect CXCR4-expressing primary tumor cells, we have been evaluating the potential utility of tipifarnib in various lymphomas and leukemias.

CXCL12 has been reported to promote the progression of lymphomas and leukemias carrying the CXCR4 receptor. We had previously identified an association between CXCL12 expression levels and clinical benefit in patients with relapsed or refractory peripheral T-cell lymphomas, or PTCL, treated with tipifarnib. At the ASH Annual meeting in Orlando, Florida on December 8, 2019, we presented interim results from an ongoing trial of tipifarnib showing robust and durable activity as a monotherapy for: (1) patients with advanced AITL, an aggressive form of T-cell lymphoma often characterized by high levels of CXCL12 expression and, (2) patients with PTCL who lack a single nucleotide variation in the 3'-untranslated region of the CXCL12 gene.

Although we believe this data and other ancillary studies show tipifarnib's potential to modulate the CXCR4-expressing primary tumor cells in AITL, PTCL and other diseases such as relapsed or refractory acute myeloid leukemia, or AML, chronic myelomonocytic leukemia, or CMML, diffuse large B-cell lymphoma, cutaneous T-cell lymphoma and pancreatic cancer, we suspended the initiation of a planned registration directed study for tipifarnib in T-cell lymphoma and of a planned Phase 2 clinical trial for tipifarnib in pancreatic cancer as a result of a strategic review conducted in the Spring of 2020. We have continued preclinical work to validate tipifarnib in the CXCR4 receptor pathway and to assess the timing and strategy for further development.

#### KO-539 – A Selective Inhibitor of the Menin-KMT2A Interaction

We are developing an orally bioavailable small molecule inhibitor of the menin-KMT2A interaction for the treatment of genetically defined subsets of acute leukemias, including AML and acute lymphoblastic leukemia, or ALL. The menin-KMT2A program was licensed from the Regents of The University of Michigan, or the University of Michigan.

Acute leukemias, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as nucleophosmin, or KMT2A-r, are characterized by chromosomal translocations of the KMT2A gene that are primarily found in patients with AML and ALL and affect both children and adults. These translocations form oncogenes encoding KMT2A fusion proteins, which play a causative role in the onset, development and progression of KMT2A-r leukemias. KMT2A fusion proteins drive the upregulation of expression of a small set 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-KMT2A interaction represents a valuable target for molecular therapy and supports the development of inhibitors of the menin-KMT2A protein-protein interaction.

The target genes of the KMT2A fusion proteins are also found to be overexpressed in a broader subset of AMLs characterized by mutations in NPM1, DNMT3A, IDH1, IDH2 and a different mutation in the KMT2A gene, known as an KMT2A-partial tandem duplication, or KMT2A-PTD. These mutations also appear to be dependent on the interaction between menin and KMT2A, suggesting that the menin-KMT2A complex is a central node in epigenetic dysregulation driven by distinct oncogenic driver mutations known to be important in AML and other hematologic malignancies.

We have generated preclinical data that support the potential anti-tumor activity of KO-539 in genetically defined subsets of acute leukemia, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as nucleophosmin 1, or NPM1. In November 2017, we reported preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing robust and durable efficacy in multiple *in vivo* models of AML characterized by KMT2A-rearrangements or mutations in NPM1, DNMT3A, IDH1 and IDH2. We have further demonstrated that the inhibition of the menin-KMT2A interaction results in the down-regulation of KMT2A fusion target genes and an upregulation of markers of differentiation.

In September 2019, we initiated a Phase 1/2 clinical trial of KO-539 in patients with relapsed or refractory AML to investigate the safety and tolerability of KO-539 in humans, determine a recommended Phase 2 dose, characterize pharmacokinetics of KO-539 and assess any early evidence of antitumor activity.

On December 5, 2020, we announced preliminary results from our KOMET-001 Phase 1/2 clinical trial at an oral presentation at the 2020 ASH. As of the data cutoff date for the ASH presentation, November 2, 2020, the trial had enrolled 12 patients with relapsed or refractory AML, of whom ten were evaluable for safety and tolerability and eight were evaluable for efficacy. Clinical or biological activity was reported in six of the eight efficacy-evaluable patients, including two patients achieving a complete remission, one patient achieving a morphological leukemia-free state, and one patient experiencing a marked decrease in hydroxyurea requirements and having attained peripheral blood count stabilization. As presented at ASH, KO-539 has been well tolerated with a manageable safety profile to date. As of the data cutoff date, no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation or other clinically significant EKG changes were reported. Treatment related adverse effects (grade <sup>3</sup> 3) were reported to included pancreatitis, increased lipase, decreased neutrophil count, tumor lysis syndrome and deep venous thrombosis.

On February 24, 2021, we reported that we completed the 600 mg dose cohort of KOMET-001 without determining a RP2D and we are currently evaluating an 800 mg dose cohort. We also indicated that, based on guidance we received from the FDA, we may seek to determine a minimum safe and biologically effective dose for use in the Phase 2 portion of KOMET-001 by initiating Phase 1 expansion cohorts at lower doses in parallel to continuing the Phase 1 dose escalation portion of the study. Initiating Phase 1 expansion cohorts at lower doses requires a protocol amendment and additional patient recruitment.

#### Next Generation Farnesyl Transferase Inhibitor

On February 24, 2021 we also revealed that we have commenced a discovery-stage program to develop a next-generation farnesyl transferase inhibitor, or FTI, with comparable potency and selectivity as tipifarnib but improved pharmacokinetic and physicochemical properties. Based on our experience with tipifarnib over the past several years, through our internal efforts and a network of academic collaborations, we have uncovered what we believe are compelling



opportunities for farnesyl transferase inhibitors in combination with other targeted therapies. We have already identified multiple advanced lead compounds and expect to nominate a development candidate for IND-enabling studies in mid-2021. We intend to direct this next-generation FTI at new biology and larger disease indications, and we look forward to sharing our progress and our plans with you later this year.

#### 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 had a first right to negotiate for an exclusive license back from us to develop and commercialize tipifarnib on terms to be negotiated in good faith, which Janssen could exercise during the 60-day period following completion of a Phase 2 clinical trial of tipifarnib in HRAS mutant patients in oncology and delivery by us to Janssen of a complete data package from such clinical trial. In June 2018, Janssen declined to exercise this first right to negotiate.

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 teens 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 \$25.0 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 \$50.0 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 licensed rights to tipifarnib.

#### The University of Michigan

In December 2014, we entered into a license agreement with the University of Michigan, which was amended in March 2015, July 2015, September 2016, February 2017, May 2017 and August 2017, which grants us exclusive worldwide rights under certain patent rights to compounds in our menin-KMT2A program. Under this license agreement, we paid the University of Michigan an upfront nonrefundable license fee and are obligated to pay the University of Michigan annual license maintenance fees. We are also required to make development and regulatory milestone payments to the University of Michigan of up to \$3.4 million in the aggregate if specified development and regulatory events are achieved for the first indication and additional payments for each subsequent indication. If we grant sublicenses under the license from the University of Michigan, we are required to pay the University of Michigan a percentage of certain amounts received from the sublicenses. When and if commercial sales of products covered by the licensed patent rights begin, we are obligated to pay the University of Michigan tiered royalties of low single digit percentages of our net sales depending on the amount of our net sales with standard provision for royalty offsets and sales-based milestones. All future development, regulatory and commercial work on the licensed compounds will be completed fully by us and at our sole expense. The University of Michigan 79,113 shares of our common stock at a fair value of \$0.5 million. The license agreement with the University of Michigan 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.



#### 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 we 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 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 Pharmaceuticals, 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 each targeted therapeutic indication. 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 HNSCC, including Eli Lilly's/Merck KGaA's cetuximab (Erbitux<sup>®</sup>), Bristol Myers Squibb's nivolumab (Opdivo<sup>®</sup>) and Merck's pembrolizumab (Keytruda<sup>®</sup>), and Sq-NSCLC, including Keytruda, Opdivo, Roche's atezolizumab (Tencentriq<sup>®</sup>) and Eli Lilly's ramucirumab (Cyramza<sup>®</sup>).

#### Menin-KMT2A Inhibitor Competition

Although there are currently no approved drugs targeting the menin-KMT2A interaction, we are aware of other companies engaged in discovery, preclinical or clinical development of menin-KMT2A inhibitors including Syndax and

Biomea. Although there are no targeted therapies approved specifically for the treatment of KMT2A-r leukemias, there are several products in clinical development, including Kronos' entospletinib, Epizyme's EPZ-5676 and Novartis' midostaurin.

#### Commercialization

We have not yet established a full-scale sales, marketing or product distribution infrastructure because our lead candidates are still in 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 commercial team (marketing, analytics, market access and sales) in North America to sell our products. We may also build a focused commercial team in Europe to sell our products. 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 commercial team to create and implement strategies for any products that we may in the future bring to market. We anticipate that our goals for any such commercial teams include developing initiatives with respect to market development or commercialization for any approved products.

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.

#### 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. All of our product candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

For all our product candidates, we aim to identify and qualify manufacturers to provide the active pharmaceutical ingredient, or API, and drug product 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 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. The U.S. Patent and Trademark Office, or U.S. PTO, issued us several patents directed to the method of treatment of HRAS mutant HNSCC with tipifarnib and corresponding patents have been issued in a number of foreign jurisdictions. In July and November 2019, the U.S. PTO issued us patents directed to the treatment of HRAS mutant HNSCC with any farnesyl transferase inhibitor. In addition, in July 2019 and January 2020, the European Patent Office, or EPO, granted us patents directed to the method of treatment of HRAS mutant HNSCC patients with tipifarnib. The U.S. PTO also issued us patents directed to the method of treatment of AITL with tipifarnib and the method of treatment of CXCL12-expressing peripheral T-cell lymphomas, or PTCL, or AML with tipifarnib. In October 2019, the U.S. PTO issued us a patent directed to the method of treatment of CXCL12-expressing PTCL or AML with any farnesyl transferase inhibitor. We are pursuing additional U.S. and foreign method of treatment patents using farnesyl transferase inhibitors, particularly using tipifarnib. We have also exclusively licensed from Memorial Sloan Kettering Cancer Center a patent family pertaining to a method of use of tipifarnib. In addition, the U.S. PTO and a number of foreign jurisdictions, including the EPO, have issued us patents covering the composition of matter of KO-947 and certain structurally related compounds, and methods of using the compounds for the treatment of cancers, and we are pursuing additional U.S. and foreign patents for KO-947. We have exclusively licensed from the University of Michigan or co-own multiple families of patent applications pertaining to our menin-KMT2A program. The U.S. PTO has issued the University of Michigan and us patents covering the composition of matter of KO-539 and certain structurally related compounds, and methods of using the compounds for the treatment of cancers, and we are pursuing additional U.S. and foreign patents for KO-539. 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 ANDA 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 investigational new drug, or 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. 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 the 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 the 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. Product development is also guided by The International Council for Harmonisation (ICH), a global initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. Regional and country-specific health authorities such as FDA, Europe's EMA and Japan's PMDA have adopted the ICH guidance as standards to be used in product development.

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 the 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 the FDA has not placed the IND on hold 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; and (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 the FDA as part of the IND.

The 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 trial 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 the 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, the 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 the 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.

The 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, the FDA begins an in-depth review. The 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 the 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 the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The 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 the 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 the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The 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, the 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 is 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 the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

#### Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or lifethreatening 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 the 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. The FDA must determine if the product candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with the FDA, and the FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the 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 the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the FDA's accelerated approval regulations, the 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-approval 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-approval studies, will allow the 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 the FDA.

#### Breakthrough Therapy Designation

A Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). The FDA may 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 the 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. A Breakthrough Therapy designation provides all Fast Track designation features, offers intensive guidance on an efficient drug development program and ensures organizational commitment involving senior management at FDA. The 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 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 basis of greater efficacy or safety or is shown to provide 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 designation also entitles a party to financial incentives such as reduction of fees or fee waivers and a grant of ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan 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 designation must be requested prior to submission of an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. An Orphan Drug designation does not obviate, in certain circumstances, the need to evaluate a product in pediatric patients.

#### Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the postapproval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industrysponsored 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. However, companies may share truthful and not misleading information that is otherwise consistent with the drug's FDA approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require postapproval testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product or the 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 the FDA



and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the 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. The 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 the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the 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, the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product in order to allow for its commercial use. This policy is described in an August 2014 FDA guidance document.

Laboratory Developed Tests which are regulated via the Department of Health and Human Services, specifically the Centers for Medicare & Medicaid Services' Clinical Laboratory Improvement Amendments regulations and the Food and Drug Administration under the Public Health Service Act have been accepted, to date. for the conduct of clinical trials. The 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. The FDA has indicated that it 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 the FDA's Center for Drug Evaluation and Research and by the 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 the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the 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, the 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 the 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 the FDA's evaluation of the PMA application is favorable, the 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 the FDA concludes that the applicable criteria have been met, the 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 the 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 the 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 the FDA. The 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 the 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 trial. 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 trial centers where the device will be used.

During the clinical 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 trial 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 trial and the clinical data supporting the PMA application for compliance with applicable requirements.

Although the QSR does not fully apply to investigational devices, the QSR 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 based on regulations enacted by regional entities such as the European Medicines

Agency as well as country-specific health authorities such as Japan's Pharmaceuticals and Medical Devices Agency, 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.

There are also foreign regulations governing the privacy and security of health information and the use of personal information to sell or market products, including the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect on May 25, 2018, and which imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union and/or sells or markets products in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance.

#### Additional Healthcare 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 include transparency laws, anti-kickback statutes, false claims, health information privacy and security 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.

Federal false claims laws, 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. 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, as well as their covered subcontractors. 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals. It also requires certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute 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 track and report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives. Our activities may also subject to be certain state laws regarding the privacy and security of health information that may not be preempted by HIPAA.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, 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, disgorgement, 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, including any drug or companion diagnostics we may develop, 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 payor 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 companion diagnostic that we or our collaborators develop will be subject to separate coverage and reimbursement determinations by third-party payors.

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 rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility

payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-ofsale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and

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 and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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, including the BBA, will stay in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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.

#### **Human Capital**

As of December 31, 2020, we employed 89 people of which 88 people are full-time employees. Our employees comprised 59 in research, development and supply chain and 30 in commercial and general and administrative capacities. As of such date, all our employees were based in the United States except one employee who works from an international location. We also engage temporary consultants and contractors. All of our employees are at will employees, which means that each employee can terminate his or her relationship with us and we can terminate our relationship with him or her at any time and none of our employees are represented by a labor union with respect to his or her employment with us.

We believe our employees are the driving force to achieving our business goals and growth strategy and we continuously monitor our demand for capable and talented people to support our mission. We invest in our employees through high-quality benefits and various health and wellness initiatives, competitive compensation packages and practicing fair compensation practices. For our talent pipeline development, we work closely with individual business functions to provide training and hands-on support for managers and leaders, to assess talent and identify development opportunities. Our human capital strategy is overseen at the highest levels of our organization, from the Board of Directors and across our senior management.

Our Code of Business Conduct and Ethics ensures that our core values of respect, integrity, collaboration, innovation, trust, and excellence are applied throughout our operations. Our Code of Business Conduct and Ethics serves as a critical tool to help all of us recognize and report unethical conduct, while preserving and nurturing our culture of honesty and accountability. We provide a comprehensive training program on our Code of Business Conduct and Ethics for our all of our staff and management employees annually.

We are an Equal Opportunity and Affirmative Action employer in compliance with the requirements of the Executive Order 11246 of the Rehabilitation Act of 1973 and the Vietnam Era Veterans' Readjustment Assistance Act. We pride ourselves on our commitment to fostering a diverse, inclusive, and empowered workforce. In 2020, we established the Company's Culture and Inclusion Leadership Committee, which seeks to obtain feedback from our employees and focuses on matters related to our corporate culture, specifically related to diversity, inclusion, and social justice.

#### **Corporate Information**

Our corporate headquarters are located at 12730 High Bluff Drive, Suite 400, San Diego, California 92130, and our telephone number is (858) 500-8800. We also occupy offices in Boston, 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. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on the Investors and Media portion of our website as soon as reasonably practical after we electronically file such material with, or furnish it to, the SEC.

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.

#### **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 the Discovery and Development of Our Product Candidates**

#### Our ability to conduct our clinical trials has been and could continue to be adversely impacted by COVID-19.

COVID-19 has and could continue to adversely impact our ability to conduct our clinical trials. The COVID-19 pandemic may negatively affect the operations of third-party suppliers and service providers that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates for our clinical trials. Furthermore, the COVID-19 pandemic may delay startup of new clinical trial sites and enrollment in our clinical trials due to prioritization of hospital resources toward the pandemic, requirements for working remotely and restrictions in travel. Some patients may be unwilling to enroll in our current and future clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. Increased demand at clinical trial sites and quarantined doctors and staff may reduce personnel and other available resources at clinical trial sites needed to conduct our clinical trials and may cause the screening of new patients or clinical trial operations to be delayed or paused. Trial sites may also limit or prohibit on site dosing and monitoring to decrease potential exposure of doctors, staff and patients to COVID-19, which may require us to adopt remote monitoring and other procedures to ensure verifiable trial execution. In alignment with recent FDA guidance on clinical trials, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards," we are taking steps to address potential trial protocol deviations due to COVID-19 pandemic or the pandemic control measures taken. Although we continue to enroll patients in our clinical studies, there is the potential that we may experience significant delays or other material adverse effects from the COVID-19 pandemic with regard to the conduct of our clinical trials and the COVID-19 pandemic could potentially decrease the implementation of protocol required trial activities and the quality of source data verification at clinical trial sites. Additionally, if a clinical trial site is not capable of new remote clinical trial capabilities, we may be required to find and engage new clinical trial investigative sites. Any negative impact of the COVID-19 pandemic on patient enrollment or treatment could delay our clinical trial timelines and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines. We remain in active dialog with our contract research organizations, or CROs, and clinical sites to minimize the impact of the COVID-19 pandemic to our clinical trials without adversely affecting the safety of patients, the quality of clinical data and overall integrity of our clinical trials. Despite our best efforts, it may prove difficult to continue to treat patients in a timely manner and activation of new sites could be delayed, particularly for our clinical trial sites in areas with high rates of community spread.

# We are highly dependent on the success of our lead product candidates, tipifarnib and KO-539, which are still in clinical development, and we cannot give any assurance that they or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize, our lead product candidates, tipifarnib and KO-539. Our business depends entirely on the successful development and commercialization of our product candidates. We have not completed the development of any product candidates; we currently generate no revenues from sales of any product, and we have not demonstrated that we can successfully develop a marketable product.



Tipifarnib and KO-539 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We presently anticipate that an approved companion diagnostic will be required in order to obtain approval for tipifarnib in HRAS mutant HNSCC and for KO-539 in NPM1-mutant AML and KMT2A-rearranged AML. Companion diagnostics are subject to regulation and must be separately approved for marketing by the FDA. We are not permitted to market or promote tipifarnib, KO-539 or any other product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals. Although the scope of regulatory approval is similar in other countries, in some countries there are additional regulatory requirements and potential regulatory risks and we cannot predict success in these jurisdictions.

There is no guarantee that our current clinical trials for tipifarnib or KO-539 will be completed on time or at all. Prior to receiving approval to commercialize tipifarnib or KO-539, if any, in the United States or internationally, we must demonstrate to the satisfaction of the FDA and other regulatory authorities, that such product candidates are safe and effective for their intended uses. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of a product candidate may not be replicated in subsequent clinical trials. Even if we believe the preclinical or clinical data are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. We maintain frequent, ongoing dialogue with the FDA and other regulatory bodies regarding our clinical trial designs, including the patient selection criteria, dosing plan and statistical analysis plans. There is a risk that the FDA or other regulatory agencies could at any time raise objections to the design or conduct of our clinical trials. Any such objections could delay the initiation or completion of our registration-directed clinical trial.

Although we believe from our discussions with the FDA and the minutes from our end-of-Phase 2 meeting with the FDA that, if AIM-HN is positive, there is the potential for accelerated approval of tipifarnib for the treatment of patients with relapsed or refractory HNSCC who harbor the HRAS mutation, the FDA has substantial discretion in the approval process and may not grant approval based on data from AIM-HN and RUN-HN. Even if the trial results are positive, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do. There is also no guarantee that data from SEQ-HN will support any potential marketing application for tipifarnib in HRAS mutant HNSCC.

Although we believe there may be potential to pursue a path to accelerated approval for KO-539 for the treatment of patients with particular subtypes of relapsed or refractory AML, we cannot guarantee that KO-539 will demonstrate sufficient safety and tolerability and clinical activity in that subtype to support an application for accelerated approval. Even if KO-539 demonstrates sufficient activity in one patient subtype, such as patients with KMT2A-rearranged AML, to support an application in that subset, there can be no assurance it will demonstrate sufficient activity to support an application for accelerated approval in other patient subsets. Even if the trial results from KO-539 demonstrate a compelling clinical benefit, the FDA has substantial discretion in the approval process and may not grant approval based on data generated by us.

If the results of our trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant additional resources to conduct additional trials in support of potential approval of tipifarnib, KO-539 or our other product candidates.

We have not previously submitted a new drug application, or NDA, to the FDA, or similar product approval filings to comparable foreign authorities, or received marketing approval for any product candidate, and we cannot be certain that tipifarnib or KO-539 will be successful in clinical trials or receive regulatory approval for any indication. We cannot anticipate whether or when we will seek regulatory review of tipifarnib or KO-539 for any other indications. If we do not receive regulatory approvals for and successfully commercialize tipifarnib on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market tipifarnib or KO-539, our revenues will be dependent, in part, on our third-party collaborator's ability to commercialize the companion diagnostic as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the market opportunities for the treatment of HRAS mutant HNSCC, NPM1-mutant AML and KMT2Arearranged AML and other diseases are not as significant as we estimate, our business and prospects may be harmed.

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

The discovery and development of targeted therapeutics for patients with genetically defined cancers, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates, are a relatively new and rapidly



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

In order to execute on our strategy of advancing the clinical development of tipifarnib and KO-539, we have designed our clinical trials, and expect to design future clinical trials of our product candidates, to include patients who harbor a particular attribute such as a particular genetic alteration, tumor histology or expression level that we believe contribute to or are associated with particular cancer subsets. Our goal in doing this is to enroll patients who have the highest probability of responding to our product candidate and in our proof-of-concept Phase 2 clinical trials, to show early and statistically significant evidence of clinical efficacy. Potential molecular biomarkers we have identified in retrospective analyses of data from clinical trials of tipifarnib in certain cancer indications may not be prospectively validated as biomarkers of tipifarnib activity in our ongoing Phase 2 clinical trials or in future clinical trials that we may conduct in these indications. If we are unable to identify molecular or genetic alterations, or biomarkers, that are predictive of response to our product candidates fail to work as we expect, our ability to assess the therapeutic effect, seek participation in FDA expedited review and approval programs, including Breakthrough Therapy, Fast Track Designation, Priority Review and Accelerated Approval, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised, resulting in longer development times, larger clinical trials and a reduced likelihood of obtaining regulatory approval.

### We may find it difficult to enroll patients in our clinical trials for tipifarnib and KO-539. Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates.

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, the eligibility criteria of our clinical trials will further limit the pool of available trial participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a trial. Additionally, the process of finding and diagnosing patients may prove costly. For example, many physicians who treat HNSCC patients do not routinely screen their patients for genetic mutations, such as oncogenic mutations present in the HRAS gene. To seek to address these limitations, we have contracted with third-party laboratories to facilitate the genetic screening of patients for our clinical sites. However, there is no guarantee that these efforts will be effective.

We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under trial including the number and frequency of trial required procedures and tests, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. For example, with the approvals of immune therapy agents nivolumab and pembrolizumab, many HNSCC patients are now being treated with one of these agents in the first line in combination with chemotherapy and after failure of first-line treatments such as chemotherapy and/or cetuximab. If patients receiving immune therapy, or the physicians treating them are unwilling or unable to participate in our studies for any reason, or if such patients experience positive results from such agents resulting in longer times to disease progression than originally anticipated, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed or we may not be able to successfully complete our studies. Further, if patients do not comply with clinical trial process and procedure and, for example, drop out, miss scheduled doses or follow-up visits, or fail to follow trial protocols, then the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities. Lastly, if our trials are otherwise disputed due to delays resultant from staff re-directed to take actions to slow the spread of COVID-19, collectively all of these possibilities, which would represent a significant setback for the applicable clinical program.

Additionally, in estimating the frequency of biomarkers, such as the frequency of HRAS mutations in patients with HNSCC, we rely on data published in the scientific literature as well as our experience and that of our collaborators. Initial studies on the frequency of HRAS mutation in HNSCC were conducted retrospectively and may not reflect the current incident HRAS mutational rates that can be affected by changes in environmental exposures, access to early treatment, viral infections with HPV and other variables that influence oncogenesis. The technologies used to identify mutations in published datasets may be different from the technologies we are using currently, which may make it more difficult to compare results across clinical trials or we may experience lower rates of HRAS mutation frequency in our clinical trial than provided in the current scientific literature. Moreover, sample quality in academic studies of molecular biomarkers may not reflect standard clinical practice that is focused on pathological diagnosis. Even if patients carrying HRAS mutations are identified, potential clinical benefit of tipifarnib may be delayed or reduced due to increased durations in time to disease progression in patients treated with immune therapy and the number of patients who could benefit from tipifarnib may be reduced. Potential trial subjects may also be located at too great a distance to participate at our clinical trial sites. Any delay or failure by us or third-party collaborators to screen patients or identify patients with HRAS mutations for enrollment in our AIM-HN clinical trial and other ongoing trials could delay or prevent us from completing our clinical trials which could prevent us from obtaining regulatory approval or commercializing tipifarnib on a timely or profitable basis, or at all.

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

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

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

The risk of failure for our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive preclinical and clinical testing to demonstrate the safety and efficacy of our product candidates in humans. This testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, the preliminary data we have presented from our positive Phase 2 clinical trial of tipifarnib in HRAS mutant HNSCC, may not predict the results of AIM-HN or any other later-stage clinical trials we may conduct. The primary endpoint of AIM-HN is ORR as determined using RECIST 1.1 criteria and as determined by independent radiological review. Independent radiological review refers to a formal process whereby third-party radiologists who are not affiliated with the drug development program are engaged to provide an independent assessment of the primary radiological images. All of our patient responses disclosed to date in our ongoing Phase 2 proof-of-concept clinical trial in HRAS mutant HNSCC have been assessed by the trial investigators. In contrast to independent radiology review, investigator assessed response is performed by investigators or their affiliated radiology colleagues who may be aware of the trial treatment, patient history or other information that could impact their choices in applying the rules and conventions of RECIST 1.1. Conversely, independent radiology reviewers have limited access to non-radiographic clinical information or other ancillary information, which could have informed their application of RECIST 1.1 response rules. The published literature demonstrates a consistent decrease in response rate when investigator assessed response rates are verified by independent radiology review. Furthermore, HNSCC lesions are difficult to assess due to the complexity of the anatomic locations. For AIM-HN we will be identifying trial subjects with measurable disease that meets criteria for RECIST 1.1 target lesions by local radiology review. This may further reduce the number of subjects eligible to join AIM-HN within the small pool of HRAS mutant HNSCC patients.

Results from clinical trials conducted at a single clinical site or a small number of clinical sites, may not be predictive of results from additional clinical sites or from subsequent clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, the FDA previously issued a non-approval letter to Janssen for tipifarnib as a treatment for elderly, untreated AML in June 2005. It is impossible to predict with certainty if or when any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

We may experience delays in our clinical trials and we do not know whether ongoing or planned clinical trials will begin or enroll patients on time, need to be redesigned or be completed on schedule, if at all. If the FDA or comparable foreign regulatory authorities, or IRBs have comments on our study plans for our clinical trials of tipifarnib or any of our other product candidates, that we are required to address, such studies may be delayed, or may not start at all. Clinical trials may be delayed, suspended or prematurely terminated at any time by us or by the FDA or other similar regulatory agency if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including risk of death, or if compounds are not manufactured in compliance with current good manufacturing practice, or cGMP, regulations or with acceptable quality. There can be no assurance that the FDA or other similar regulatory agency will not put any of our product candidates on clinical hold in the future. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

- failure to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a clinical trial;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow-up;
- delay or failure in determining an acceptable dose and schedule for a product candidate in a clinical trial;
- clinical sites and investigators deviating from clinical trial protocol, failing to conduct the clinical trial in accordance with regulatory requirements or dropping out of a clinical trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to
  conduct additional clinical studies and increased expenses associated with the services of our CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to redesign or modify our clinical trial protocols, conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients whose tumors harbor the specific genetic alterations that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;

- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

In addition, our clinical trials have been and may continue to be affected by COVID-19. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward COVID-19. Current or potential patients in our ongoing or planned clinical trials may also choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting COVID-19. Further, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Some clinical sites in the United States have started to slow or stop further enrollment of new patients in clinical trials, denied access to site monitors or otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials. On May 4, 2020, we announced the suspension and termination of certain development activities due to a strategic review of our portfolio, including the suspension of the initiation of a planned registration directed study for tipifarnib in T-cell lymphoma, the suspension of a planned Phase 2 clinical trial for tipifarnib in pancreatic cancer and the termination of our KO-947 ERK inhibitor program.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that could reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-approval restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

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

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



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

Our current product candidates and any future product candidates have the potential to be administered in combination with one or more cancer therapies, such as PI3 kinase alpha inhibitor in the case of tipifarnib, VENCLEXTA (venetoclax) in the case of KO-539, or other drugs, both approved and unapproved. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with another drug or biologic will depend on our ability to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing PI3 kinase alpha inhibitor or other drugs, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are currently developing tipifarnib and may develop other future product candidates for use in combination with PI3 kinase alpha inhibitor or other therapies. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

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

#### 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, or low white blood cell count, anemia and thrombocytopenia, or low platelet count. The most common non-hematologic adverse events of any grade were gastrointestinal system disorders such as 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%. The side effects observed so far in our ongoing Phase 2 clinical trials of tipifarnib have been generally consistent with the prior observations; however, there is no guarantee that additional or more severe side effects will not be identified through further clinical studies, including our AIM-HN clinical trial. Rights to develop tipifarnib in virology indications have been granted by Janssen to EB Pharma LLC, or EB Pharma, a subsidiary of Eiger BioPharmaceuticals. Undesirable side effects may be identified in clinical trials that EB Pharma may conduct in virology indications, which may negatively impact the development, commercialization or potential value of tipifarnib.

We are currently conducting a Phase 1/2 clinical trial to evaluate KO-539 in relapsed or refractory AML. Any observed, drug-related side effects could affect the ability of patients to tolerate potentially therapeutically effective doses of the drug, which in turn could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Additionally, if results of our ongoing or planned clinical trials for tipifarnib or KO-539 reveal an unacceptable frequency and severity of serious adverse events or side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory agencies could require us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of those compounds. Any of these occurrences may significantly harm our business, financial condition and prospects.

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

### 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 by us or our third-party collaborators to successfully develop and commercialize a diagnostic testing platform for use by oncologists could harm our ability to develop and commercialize our product candidates.

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

As we do not have in-house diagnostic testing capabilities, we rely extensively on third-party collaborators for the development and commercialization of these diagnostic tests. Our goal is to provide a sensitive, accurate and cost-effective diagnostic testing solution for oncologists, whereby they can obtain molecular testing data that will help them to identify whether their patients are eligible as candidates for enrollment in our clinical trials. Moreover, we anticipate that, if and when tipifarnib and/or KO-539 receives marketing approval, a significant percentage of patients will be identified using diagnostic testing platforms such as NGS testing.

We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these diagnostic tests. We may also experience difficulties in having these diagnostic tests adopted and used at clinical sites, both during the clinical development phase and if and when approved for commercial sale. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of these diagnostic tests or any failure in having a sufficient number of clinical sites adopt and use these diagnostic tests could delay or prevent approval of our product candidates, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.



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

As one of the central elements of our business strategy and clinical development approach, we seek to screen and identify subsets of patients with molecular or genetic alterations who may derive meaningful clinical benefit from our product candidates. To achieve this, certain of our programs may require the *de novo* development and commercialization of a companion diagnostic for marketing approval. We rely on third-party collaborators for development of companion diagnostics for use in clinical trials and, if successful, will rely on third-party collaborators for development of companion diagnostics for use in clinical trials and, if successful, will rely on third-party collaborators for the associated product and are subject to regulation as medical devices. For example, for tipifarnib for the treatment of HRAS mutant HNSCC, we and our third-party collaborators have obtained an IDE for use of a qPCR-based assay to identify patients with HRAS mutant tumors as the companion diagnostic in AIM-HN in this indication. Patients can also be enrolled based on information on the patients' tumor HRAS mutant allele frequency is an important measure of an end point in AIM-HN. The results of NGS panels used by our clinical sites may not be accurate or consistent across sites and may not be consistent with results obtained from our companion diagnostic, and our development of tipifarnib or a companion diagnostic may be delayed or complicated as a result.

If the results of AIM-HN, KOMET-001 or other 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 any subsequent clinical trials we decide to pursue for those product candidates and to prepare and submit an application for IDE for use of the companion diagnostic in the clinical trials, when necessary. Any delay or failure by us or our third-party collaborators to develop or obtain IDE approval for use of companion diagnostics in our clinical trials could delay or prevent us from commencing or completing our clinical trials. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has frequently required a premarket approval application of companion diagnostics for cancer therapies. We presently anticipate that an approved companion diagnostic will be required in order to obtain approval for tipifarnib in HRAS mutant HNSCC and for KO-539 in NPM1-mutant AML and KMT2Arearranged AML. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. The approval of a companion diagnostic as part of the product label will limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a tim

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

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

- may not perform their obligations as expected;
- may not pursue commercialization of companion diagnostics for our therapeutic product candidates that achieve regulatory approval;
- may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of such product or products; and
- may terminate their relationship with us.

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

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

#### Risks Related to Our Financial Position and Need for Additional Capital

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

To date, we have financed our operations primarily through equity and debt financings. 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:

- manage the risks associated with the COVID-19 pandemic or any other similar health emergencies;
- continue research and development of our product candidates;
- initiate new clinical trials for our product candidates;
- seek marketing approvals for our product candidates;
- enter into collaboration arrangements for companion diagnostics for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur increased costs as a result of continued operations as a public company.

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

The COVID-19 pandemic has caused volatility in the global financial markets and threatened a slowdown in the global economy, which may have a material adverse effect on our ability to raise additional capital on attractive terms or at all.

### 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, including COVID-19. Factors relating to our business that may contribute to these fluctuations include:

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

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

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

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

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

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

Until such time, if ever, as we can generate sufficient product revenues to fund our operations, we will need to raise additional capital in connection with our continuing operations. We expect to finance our cash needs through a combination of equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of our stockholders as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive.

In March 2019, we entered into the ATM facility with SVB Leerink LLC and Stifel, Nicolaus & Company, Incorporated, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$75.0 million. We have not yet sold any shares of our common stock under the ATM facility.

In November 2018, we entered into the loan agreement with Silicon Valley Bank, providing for up to \$20.0 million in a series of term loans, which was subsequently amended in April 2020 to extend the second draw period. Under the terms of the loan agreement, we have borrowed \$7.5 million. The draw period for the additional loan expired without us drawing down the additional loan. We do not have any committed external source of funds. 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 lender may accelerate our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lender 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 lender 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 lender. 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 Our Dependence on Third Parties**

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

We rely, and expect to continue to rely, on third-party contractors, clinical data management organizations, independent contractors, medical institutions and clinical investigators to support our preclinical development activities and conduct our clinical trials, including our registration-directed clinical trial of tipifarnib in HRAS mutant HNSCC, our Phase 1/2 clinical trial of KO-539 in AML and any other subsequent clinical trials of tipifarnib and KO-539. These agreements may terminate for a variety of reasons, including a failure to perform by the third parties. If we are required to enter into alternative arrangements, our product development activities could be delayed.

We compete with many other companies, some of which may be our business competitors, for the resources of these third parties. Large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third-party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which could result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Our reliance on these third parties to conduct our clinical trials reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA and other regulatory authorities require us to comply with good clinical practice guidelines for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on 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.

In addition, the ability of these third parties to conduct certain of their operations, including monitoring of clinical sites, may be limited by the COVID-19 pandemic, and to the extent that such third parties are unable to fulfil their contractual obligations as a result of the COVID-19 pandemic or government orders in response to the pandemic, we may have limited or no recourse under the terms of our contractual agreements with such third parties. Further, if any of the third parties with whom we engage were to experience shutdowns or other substantial disruptions due to the COVID-19 pandemic, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

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

We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of clinical supplies of tipifarnib and KO-539 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 package and label the drug product as well as to store and distribute drug supplies for our clinical trials.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of drug formulation and manufacturing techniques and process controls. Manufacturers of active pharmaceutical ingredients, or APIs, and pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We have developed a modified drug product manufacturing process and a modified tablet formulation of tipifarnib we are using in our AIM-HN clinical trial. Although our Phase 1 relative bioavailability study indicated pharmacokinetic comparability between the original and the modified tablets, we cannot be certain that in our AIM-HN or other clinical trials we will not observe differences between the tablets which could impact clinical outcomes.

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

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

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

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

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.

We and our collaboration partners have been able to continue to supply our clinical products to our patients and currently do not anticipate any interruptions in supply. To the extent our third-party manufacturers and supply chain suppliers are negatively impacted by COVID-19, we may not be able to provide continuous drug supply to our clinical sites and our clinical trials may be delayed or may not be completed which would have a material adverse effect on our business operations and performance.

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

### If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, 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. In addition, the COVID-19 pandemic could also potentially affect the business of the FDA, the EMA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing

approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our product candidates may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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

As the composition of matter patents covering tipifarnib expired in the United States and in countries in Europe in 2016 and we have only a limited number of issued U.S. and foreign patents directed to our potential tipifarnib indications, our commercial strategy for tipifarnib relies on obtaining method of use and method of treatment patents, including those directed to specific indications and biomarkers, other patents related to tipifarnib, method of treatment patents related to farnesyl transferase inhibitors including 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 new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any 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 could be harmed as a result.

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

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

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

In July 2019, the FDA granted orphan drug designation to KO-539 for the treatment of AML. If KO-539 receives marketing approval for an indication broader than AML, KO-539 may no longer be eligible for marketing exclusivity. In addition, we intend to pursue an orphan designation for some of our other product candidates, including tipifarnib. However, obtaining an orphan designation can be difficult, and we may not be successful in doing so for our other product candidates. The EMA does not generally recognize for orphan designation, molecular defined subsets of non-orphan disease indications, and as an example, EMA previously rejected orphan designation for a drug product for anaplastic lymphoma kinase, or ALK-positive NSCLC. As such, we do not expect to be able to obtain orphan drug designation in Europe for tipifarnib in the subset of HRAS mutant HNSCC at the current time. Even if we were to obtain orphan exclusivity for a product candidate, such as that received for KO-539, that exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same condition if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. The failure to obtain an orphan designation for any product candidates we may develop for the treatment of rare cancers, and/or the inability to maintain that designation for the duration of the applicable exclusivity period, could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

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

# A Fast Track Designation by the FDA, such as granted to tipifarnib for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy and for the treatment of adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma, follicular T-cell lymphoma and nodal peripheral T-cell lymphoma with T follicular helper phenotype, 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.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and 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. We have been granted Fast Track Designation by the FDA for our tipifarnib product candidate for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy and for the treatment of adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma, follicular T-cell lymphoma and nodal peripheral T-cell lymphoma with T follicular helper phenotype, but this is no assurance we will receive this designation for any future product candidates. Further, even though we have received this designation for tipifarnib, 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 have received Breakthrough Therapy Designation from the FDA on tipifarnib for the treatment of patients with recurrent or metastatic HRAS mutant HNSCC with variant allele frequency  $\geq 20\%$  after disease progression on platinum-based chemotherapy. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. However, the reduced timelines may introduce significant chemistry, manufacturing

and controls challenges for product development. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

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

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

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-approval studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;



- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

- the federal Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims, including the civil False Claims Act, which can be enforced by private citizens, on behalf of the government, through whistleblower actions, and civil monetary penalties laws which prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the HITECH Act, and their implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information on covered entities which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;



- the federal Physician Payments Sunshine Act which requires applicable manufacturers of certain drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
  - state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, thus complicating compliance efforts, including GDPR which went into effect on May 25, 2018, and imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

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

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

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

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

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, improve quality, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% 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.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. Certain changes to the ACA, such as the removal of the ACA's individual health insurance mandate by federal tax legislation, a delay in the implementation of certain ACA-mandated fees, and other changes to the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," were recently enacted or implemented, and the effect of these changes is unknown. On December 14, 2018, a U.S. District Court Judge in Texas ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through whe Supreme Court ruling, other such litigation, and the healthcare reform legislation or regulation or the impact of potential legislation or regulation or us, particularly in light of the new presidential administration.

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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 and other potential legislation may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. As a result, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform



government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Future legislation could potentially change drug pricing dynamics. We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

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

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new private right of action for data breaches. The CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data.

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

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

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

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

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

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

#### **Risks Related to Our Intellectual Property**

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

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

Our patent rights may not protect our patent protected products and product candidates if competitors devise ways of making products that compete with us without legally infringing our patent rights. For example, our patent rights in tipifarnib are limited in ways that affect our ability to exclude third parties from competing against us. In particular, the patent term for the composition of matter patents covering the API of tipifarnib expired in the United States and countries in Europe in 2016. Composition of matter patents on APIs are generally considered to be the strongest form of intellectual property protection because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. The U.S. PTO issued us several patents directed to the method of treatment of HRAS mutant HNSCC with tipifarnib and corresponding patents have been issued in a number of foreign jurisdictions. In July and November 2019, the U.S. PTO issued us patents directed to the treatment of HRAS mutant HNSCC with any farnesyl transferase inhibitor. In addition, in July 2019 and January 2020, the European Patent Office granted us patents directed to the method of treatment of HRAS mutant HNSCC patients with tipifarnib. The U.S. PTO also issued us patents directed to the method of treatment of angioimmunoblastic T-cell lymphoma with tipifarnib and the method of treatment of CXCL12-expressing PTCL or AML with tipifarnib. In October 2019, the U.S. PTO issued us a patent directed to the method of treatment of CXCL12-expressing PTCL or AML with any farnesyl transferase inhibitor.

Although these patents are currently in force, there is no guarantee that a court would agree that any of the patents are valid or enforceable. Further, if a competitor were to develop tipifarnib for use in an indication other than that claimed by the patents, we would not be able to prevent them from marketing tipifarnib in the United States or other jurisdictions based on our currently issued patents. A limited number of patents directed to the use of tipifarnib in certain patients with HRAS mutant HNSCC have been granted in foreign jurisdictions. We are pursuing additional United States and foreign method of treatment patents for tipifarnib and farnesyl transferase inhibitors, however there is no guarantee that any such patents will be granted.

We have issued patents in the United States covering the composition of matter of KO-539 and certain structurally related compounds and methods of using the compounds for treating cancers. Although these patents are currently in force, there is no guarantee that a court would agree that any of the patents are valid or enforceable.

We are pursuing additional U.S. and foreign patents for KO-539; however, there is no guarantee that any such patents will be granted. Patent term extension may be available in the United States to account for regulatory delays in obtaining human marketing approval for a product candidate; however, only one patent may be extended per marketed compound. Under our license agreement with Janssen for tipifarnib, we and Janssen agree to cooperate in obtaining available patent term extensions. We and Janssen may not reach agreement and no patent term extension may be obtained. Additionally, the applicable authorities, including the U.S. PTO and the FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, our competitors who obtain the requisite regulatory approval can offer products with the same API as tipifarnib so long as the competitors do not infringe any method of use patents that we may hold. Competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

We have licensed patent rights from third parties for some of our development programs, including tipifarnib from Janssen and compounds in our menin-KMT2A 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 KO-539 and other compounds in our menin-KMT2A program from the University of Michigan. Additionally, we have an exclusive worldwide license from Memorial Sloan Kettering Cancer Center to a patent family pertaining to a method of use of tipifarnib. 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 and the University of Michigan license agreement each provide that we are subject to diligence obligations relating to the commercialization and development of the respective product candidates, milestone payments, royalty payments and other obligations. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of our license agreement with Janssen,



University of Michigan or any of our other license agreements or license agreements we may enter into on which our business or product candidates are dependent, Janssen, University of Michigan or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. The loss of the rights licensed to us under our license agreement with Janssen, University of Michigan or our other license agreements or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

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

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

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

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

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file

provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO, or become involved in patent office post-grant proceedings, such as 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.

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

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

#### Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to 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 derivation, reexamination, inter partes review, post-grant review or interference proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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

### 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, an exclusive worldwide license from the University of Michigan for all therapeutic indications for KO-539 and other compounds in our menin-KMT2A program and an exclusive worldwide license from Memorial Sloan



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

For example, we may collaborate with U.S. and foreign academic 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 nondisclosure 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.

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

Although we do not currently own issued patents or pending patent applications covering tipifarnib or KO-539 that have been generated through the use of U.S. government funding, our license agreement with the University of Michigan includes intellectual property rights unrelated to KO-539 that have been generated through the use of U.S. government funding or grants, and we may acquire or license additional intellectual property rights from one or more entities that have been generated through the use of U.S. government funding. These U.S. government rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our intellectual property rights generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S.

government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

### **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, thirdparty 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 sales or market access personnel. If we are unable to establish effective sales or market access 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 sales or market access teams 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 sales, marketing, 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 continue to progress toward regulatory approval, we intend to establish sales and market access teams with expertise to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Capable managers with commercial experience may need to be identified and successfully recruited to our company. Any failure or delay in the development of our sales and market access 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. 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 we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies, which may directly compete with tipifarnib, KO-539 and any other future product candidates. In the case of KO-539, one of our competitors recently published preliminary clinical data demonstrating that their inhibitor of the menin-KMT2A interaction was able to drive clinical benefit, including objective responses, in relapsed or refractory patients with KMT2A-rearranged AML. If that competitor is able to advance their clinical program more quickly than ours, our commercial opportunity for KO-539 could be reduced.

Our commercial opportunity also 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 alone or in combination with other drugs or biologics. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or slow our regulatory approval. 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.

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 are uncertain. Failure to obtain or maintain coverage and adequate reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of coverage and reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under

Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. We or our collaborators may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective.

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

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

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and 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.

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face 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 Employee Matters, Managing Growth and Macroeconomic Conditions

### Our ability to manage our business operations, to execute our strategic plan and to recruit talented employees may be adversely impacted by COVID-19.

Since early March 2020, we have taken temporary precautionary measures, including increased screening and working remotely, intended to help minimize the risk of COVID-19 to our employees and their families. We have suspended non-essential travel worldwide for our employees. Further measures may be taken as the COVID-19 outbreak continues. These measures could negatively affect our business. For instance, remote work may disrupt our operations, limit our ability to interact with and effectively manage our third-party manufacturers, CROs or current and planned clinical trial sites. The measures taken now or in the future to contain the COVID-19 pandemic could negatively affect our ability to recruit and engage new employees and contractors necessary to the successful operation of our business.

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

We are a clinical-stage company with a limited operating history, and, as of December 31, 2020, we had 88 full-time employees and one part-time employee. We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and market access personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees 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 market access 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 development, regulatory affairs, operations, sales, marketing and market access. 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. From time to time, including recently as a result of the COVID-19 pandemic and actions taken to slow its spread, global financial markets have experienced volatility and uncertainty. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

In the ordinary course of our business, we use our data centers and our networks to store and access our proprietary business information. We are dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies. We face various cyber security threats, including cyber security attacks to our information technology infrastructure and attempts by others to gain access to our proprietary or sensitive information. Our dependence on technology systems in conducting our business has been underscored as a result of the COVID-19 pandemic and the precautions to control the pandemic. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that our office-based employees in the United States and in most of our other key markets work from home. Changes in how our employees work and access our systems during the current COVID-19 pandemic could lead to additional opportunities for bad actors to launch cyberattacks or for employees to cause inadvertent security risks or incidents. We have implemented procedures and controls, including the use of several information technology tools, to identify, monitor and prevent cyber security threats on our networks and will continue to assess for cybersecurity threats and protective tools. These procedures and controls may not be sufficient to prevent or mitigate cyber security incidents. The result of these incidents, which could be further amplified during the current COVID-19 pandemic, could include disrupted operations, lost opportunities, misstated financial data, liability for stolen assets or information, increased costs arising from the implementation of additional security protective measures, litigation and reputational damage. Any remedial costs or other liabilities related to cyber security incidents may not be fully insured or indemnified by other me

#### 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. As a result of the COVID-19 pandemic and the precautions to control the pandemic, we are increasingly dependent upon technology systems and data to operate our business. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that our office-based employees in the United States and in most of our other key markets work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies.

While we have not experienced any system failures, accidents or security breaches to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

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

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

#### **Risks Related to Ownership of our Common Stock**

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

Our common stock has been listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol "KURA" since November 5, 2015. The high and low price per share of our common stock as reported by Nasdaq during the period from November 5, 2015 through December 31, 2020, were \$43.00 and \$2.50, respectively. We cannot predict the extent to which investor interest in our company will sustain an active trading market on Nasdaq or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if an active trading market is not sustained or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

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

The market for our common stock could fluctuate substantially due to a variety of factors, some of which may be beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual 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;
- the impact of the COVID-19 pandemic on our business and industry as well as the global economy;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- changes in the structure of healthcare payment systems;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;



- our dependence on third parties, including CROs as well as our 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, including recently as a result of the COVID-19 pandemic and actions taken to slow its spread. 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, interestbearing 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 brokerdealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

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

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We filed a shelf registration statement with the SEC, which has been declared effective, to register the resale of 13,947,599 shares of our common stock. The shelf registration statement permits the resale of these shares at any time, subject to restrictions under applicable law. The resale of a significant number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there are a large number of shares registered pursuant to the shelf registration 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 Nasdaq or any other stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years.

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

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

### Future sales and issuances of our common stock or rights to purchase 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 March 2019, we entered into the ATM facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$75.0 million. 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, 2020, we had 692,894 shares of common stock reserved for future issuance under the 2014 Plan and options to purchase up to an aggregate of 5,020,862 shares of common stock outstanding. The number of shares available for future grant under the 2014 Plan will automatically increase on January 1 of each year through January 1, 2025 by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2021, an automatic increase pursuant to the 2014 Plan occurred, resulting in 2,647,764 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, 2020, we had 163,051 shares of common stock reserved for future issuance under the ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year through January 1, 2025 by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2020, the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in 2021. In addition, a warrant to purchase up to 33,988 shares of our common stock at an exercise price of \$3.31 per share was outstanding as of December 31, 2020.

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

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

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

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- division of our board of directors into three classes;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 662/3% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 662/3% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation;
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

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

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act significantly revised the Internal Revenue Code of 1986, as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

Under the Tax Cuts and Jobs Act, as modified by the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

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

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

### **General Risk Factors**

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

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

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

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



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

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

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

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

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

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

#### Item 1B. Unresolved Staff Comments.

None.

### Item 2. Properties.

We occupy 13,420 square feet of office space for our corporate headquarters in San Diego, California under a lease that expires in November 2025. We also occupy approximately 16,541 square feet of office space in Boston, Massachusetts under a lease that expires in July 2024. 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**

Since November 5, 2015, our common stock has been listed on the Nasdaq Global Select Market under the symbol "KURA".

#### **Holders of Record**

As of February 19, 2021, there were approximately 107 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.

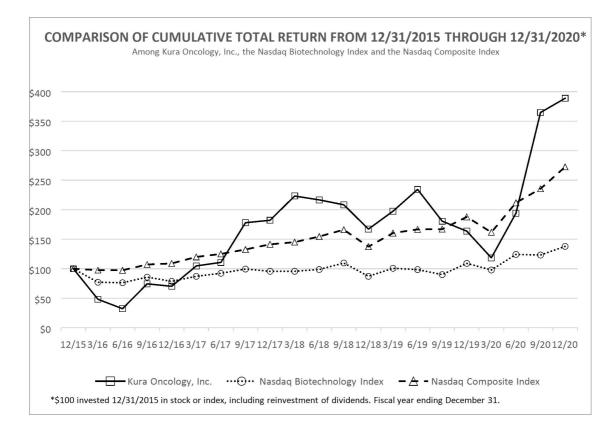
### Securities Authorized for Issuance Under Equity Compensation Plans

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.



#### Stock Performance Graph and Cumulative Total Return

The graph below shows the cumulative total stockholder return assuming the investment of \$100 on December 31, 2015, (and the reinvestment of dividends thereafter) in each of (i) Kura Oncology, Inc.'s common stock, (ii) the Nasdaq Biotechnology Index and (iii) the Nasdaq Composite Index. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or Indexes.



The foregoing graph is furnished solely with this Annual Report, and is not filed with this Annual Report, and shall not be deemed incorporated by reference into any other filing under the Securities Act or the Exchange Act, whether made by us before or after the date hereof, regardless of any general incorporation language in any such filing, except to the extent we specifically incorporate this material by reference into any such filing.

### Item 6. Selected Financial Data.

We have elected to comply with Item 301 of Regulation S-K, as amended February 10, 2021, and are omitting this disclosure in reliance thereon.



### 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. 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. For the comparison of the financial results for the fiscal years ended December 31, 2019 and 2018, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our <u>Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 25, 2020</u>.

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

#### Overview

We are a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We presently have two clinical-stage product candidates for which we own global commercial rights, tipifarnib and KO-539, as well as additional programs that are at a discovery stage. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

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

Our most advanced solid tumor indication for tipifarnib is in patients with head and neck squamous cell carcinoma, or HNSCC, that carry mutations in the HRAS gene. In September 2017, we reported that our ongoing proof-of-concept Phase 2 clinical trial of tipifarnib in patients with HRAS mutant relapsed or refractory HNSCC, or RUN-HN, achieved its primary efficacy endpoint. In October 2018, we reported updated data from RUN-HN showing a significant association between tumor HRAS mutant allele frequency and clinical benefit from tipifarnib. Based upon these observations, we introduced a minimum HRAS mutant variant allele frequency as an entry criterion in the RUN-HN trial. Following feedback from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities, we initiated a global, multi-center, open-label, non-comparative registration-directed clinical trial of tipifarnib in HRAS mutant HNSCC in November 2018. The clinical trial has two cohorts: a treatment cohort, which we call AIM-HN, and a noninterventional screening and outcomes cohort, which we call SEQ-HN. AIM-HN is designed to enroll at least 59 evaluable HNSCC patients with high HRAS mutant variant allele frequency who have received prior platinum-based therapy. In October 2019, we reported updated data from the ongoing RUN-HN trial that we believe confirms the association between HRAS mutant variant allele frequency and anti-tumor activity, and we believe further supports the design of our amended AIM-HN registration-directed trial in HRAS mutant HNSCC. On December 16, 2019, we reported that the FDA granted Fast Track Designation to tipifarnib for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy. On May 29, 2020, we announced updated clinical data for our RUN-HN study presented at the American Society of Clinical Oncology Virtual Scientific Program, including data collected as part of the trial showing a median overall survival of 15.4 months, a median progression free survival of 5.9 months and an objective response rate, or ORR, of 50% observed in patients with recurrent/metastatic HRAS mutant HNSCC among the 18 patients on the RUN-HN study who were evaluable for efficacy.

In July 2020, we amended the AIM-HN trial protocol to enable enrollment of patients with any HRAS mutation in order to assess the potential for clinical benefit in the overall HRAS mutant HNSCC population. We also introduced a number of modifications to the protocol that seek to enable us to enroll patients in the study more efficiently as well as modifications that we believe better reflected the evolving standards of care for recurrent/metastatic HNSCC. While these amendments do not change the primary outcome measure of ORR in patients with high HRAS mutant variant allele frequency, the modifications will require us to enroll an increased number of evaluable HNSCC patients. As a result of the pandemic caused by the coronavirus disease 2019, or COVID-19, and the additional patients required for the trial, we

anticipate we will face delays in our timelines and milestones for the AIM-HN trial and, accordingly, are unable to reasonably forecast when our AIM-HN trial will become fully enrolled.

On February 24, 2021, we announced that tipifarnib has been granted Breakthrough Therapy Designation from the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma with variant allele frequency  $\geq$  20% after disease progression on platinum-based chemotherapy. The Breakthrough Therapy Designation is based upon data from our Phase 2 RUN-HN trial, which has been accepted for publication in an upcoming issue of the *Journal of Clinical Oncology*.

In addition to evaluating tipifarnib as a monotherapy in patients with recurrent or metastatic HRAS mutant HNSCC, we have also been evaluating the use of tipifarnib in combination with other oncology therapeutics to address larger patient populations and to pursue earlier lines of therapy. Among these potential combinations, we have prioritized the combination of tipifarnib and an inhibitor of the PI3 Kinase alpha enzyme for clinical evaluation in patients with HNSCC. In particular, we are planning to commence a Phase 1/2 open-label, biomarker-defined cohort study in the second half of 2021 to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of tipifarnib and a PI3 kinase alpha inhibitor for the treatment of adult participants who have HRAS-overexpressing, PIK3CA-mutated and/or PIK3CA-amplified HNSCC.

While we believe tipifarnib has potential to modulate the CXCR4-expressing primary tumor cells in AITL, PTCL and other diseases such as relapsed or refractory acute myeloid leukemia, or AML, chronic myelomonocytic leukemia, or CMML, diffuse large B-cell lymphoma, cutaneous T-cell lymphoma and pancreatic cancer, we suspended the initiation of a planned registration directed study for tipifarnib in T-cell lymphoma and of a planned Phase 2 clinical trial for tipifarnib in pancreatic cancer as a result of a strategic review conducted in the Spring of 2020. We have continued preclinical work to validate tipifarnib in the CXCR4 receptor pathway and to assess the timing and strategy for further development.

Our second product candidate, KO-539, is a potent, selective, reversible and oral small molecule inhibitor of the mixed-lineage leukemia 1, or MLL1, gene (now renamed Lysine K-specific Methyltransferase 2A, or KMT2A), or menin-KMT2A, protein-protein interaction. We have generated preclinical data that support the potential anti-tumor activity of KO-539 in genetically defined subsets of acute leukemia, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as nucleophosmin 1, or NPM1. The novel mechanism of action targets epigenetic dysregulation and removes a key block to cellular differentiation to drive anti-tumor activity. We believe KO-539 has the potential to address approximately 35% of acute myeloid leukemia, or AML, including NPM1-mutant AML and KMT2A-rearranged AML. In the pediatric population, KMT2A-rearranged leukemias make up approximately 10% of acute leukemias in all age groups and in the case of infant leukemias, the frequency of KMT2A rearrangements is 70–80%. These pediatric leukemia sub-types portend a poorer prognosis and five-year survival rate that is lower than other leukemia sub-types and therefore represent significant unmet medical needs given the lack of curative therapeutic options. In April 2020, a competitor reported that its menin-KMT2A inhibitor showed potential anti-tumor activity in KMT2A-rearranged AML.

We received orphan drug designation for KO-539 for the treatment of acute myeloid leukemia, or AML, from the FDA in July 2019. We initiated our Phase 1/2 clinical trial of KO-539 in relapsed or refractory AML in September 2019 and are actively recruiting at multiple sites in the United States and France with the anticipation of expanding to additional sites in the United States, France and other countries during the expansion phase of the study. Our menin-KMT2A Phase 1/2 clinical trial, which we call the <u>Kura Oncology MEnin-KMT2A Trial</u>, or KOMET-001, has an accelerated design and seeks to determine a recommended Phase 2 dose and schedule, or RP2D, using a modified toxicity probability interval, or MTPI, model.

On December 5, 2020, we announced preliminary results from our KOMET-001 Phase 1/2 clinical trial at an oral presentation at the 2020 American Society of Hematology, or ASH. As of the data cutoff date for the ASH presentation, November 2, 2020, the trial had enrolled 12 patients with relapsed or refractory AML, of whom ten were evaluable for safety and tolerability and eight were evaluable for efficacy. Clinical or biological activity was reported in six of the eight efficacy-evaluable patients, including two patients achieving a complete remission, one patient achieving a morphological leukemia-free state, and one patient experiencing a marked decrease in hydroxyurea requirements and having attained peripheral blood count stabilization. As presented at ASH, KO-539 has been well tolerated with a manageable safety profile to date. As of the data cutoff date, no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation were reported. Treatment related adverse effects (grade  $\geq$  3) were reported to include pancreatitis, increased lipase, decreased neutrophil count, tumor lysis syndrome and deep venous thrombosis.

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On February 24, 2021, we reported that we completed the 600 mg dose cohort of KOMET-001 without determining a RP2D and we are currently evaluating an 800 mg dose cohort. We also indicated that, based on guidance we received from the FDA, we may seek to determine a minimum safe and biologically effective dose for use in the Phase 2 portion of KOMET-001 by initiating Phase 1 expansion cohorts at lower doses in parallel to continuing the Phase 1 dose escalation portion of the study. Initiating Phase 1 expansion cohorts at lower doses requires a protocol amendment and additional patient recruitment.

# Liquidity Overview

As of December 31, 2020, we had cash, cash equivalents and short-term investments of \$633.3 million. In December 2020 and May 2020, we completed public offerings that resulted in net proceeds to us, after deducting underwriting discounts, commissions and offering expenses, of approximately \$324.1 million and \$134.9 million, respectively. We have an at-the-market issuance sales agreement with SVB Leerink LLC and Stifel, Nicolaus & Company, Incorporated, or ATM facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$75.0 million. We have not yet sold any shares of our common stock under the ATM facility. To date, we have not generated any revenues from product sales, and we do not have any approved products. Since our inception, we have funded our operations primarily through equity and debt financings. We anticipate that we will require significant additional financing in the future to continue to fund our operations as discussed more fully below under the heading "Liquidity and Capital Resources."

### **Financial Operations Overview**

### **Research and Development Expenses**

We focus on the research and development of our product programs. Our research and development expenses consist of costs associated with our research and development activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of December 31, 2020, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

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

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

- managing the impact of COVID-19 pandemic and related precautions on the operation of our clinical trials;
- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of doses that patients receive;
- the number of patients that participate in the clinical trials;

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

# General and Administrative Expenses

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

### Other Income (Expense)

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

### **Income Taxes**

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

#### **Results of Operations**

## Comparison of Fiscal Years Ended December 31, 2020 and 2019

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

	 Years Ended December 31,				
	2020		2019		Change
Research and development expenses	\$ 60,397	\$	47,826	\$	12,571
General and administrative expenses	31,502		19,653		11,849
Other income, net	2,274		4,339		(2,065)

*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,				
		2020		2019	Change
Tipifarnib-related costs	\$	26,025	\$	26,517	\$ (492)
KO-539-related costs		6,629		2,496	4,133
KO-947-related costs		2,301		3,416	(1,115)
Discovery stage programs		2,255		318	1,937
Personnel costs and other expenses		19,227		11,652	7,575
Share-based compensation expense		3,960		3,427	533
Total research and development expenses	\$	60,397	\$	47,826	\$ 12,571



The increase in KO-539-related research and development expenses for the year ended December 31, 2020 compared to 2019 was primarily due to increases in costs related to our Phase 1/2 clinical trial of KO-539 which was initiated in September 2019 and manufacturing development activities. The increase in discovery stage programs for the year ended December 31, 2020 compared to 2019 was primarily due to increased research activities for new programs. The increase in personnel costs and other expenses for the year ended December 31, 2020 compared to 2019 was to support our registration-directed clinical trial of tipifarnib and the Phase 1/2 clinical trial of KO-539. Personnel costs and other expenses include employee salaries and related expenses, facilities expense and overhead expenses. We expect our research and development expenses to increase in future periods as we continue clinical development activities for tipifarnib and KO-539.

*General and Administrative Expenses.* The increase in general and administrative expenses for the year ended December 31, 2020 compared to 2019 was primarily due to increases of \$2.9 million in each of non-cash share-based compensation expense, pre-commercial planning expenses and personnel expenses and an increase of \$2.3 million in professional and legal services. 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, 2020 compared to 2019 was primarily due to a decrease in interest income.

# 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.

In December 2020, we completed a public offering in which we sold an aggregate of 9,326,500 shares of common stock at a price of \$37.00 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$324.1 million.

In May 2020, we completed a public offering in which we sold an aggregate of 10,465,000 shares of common stock at a price of \$13.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$134.9 million.

In March 2019, we entered into the ATM facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$75.0 million. We have not yet sold any shares of our common stock under the ATM facility.

In November 2018, we entered into the SVB Loan Agreement, providing for up to \$20.0 million in a series of term loans. Upon entering into the SVB Loan Agreement, we borrowed \$7.5 million, or the Term Loan, the proceeds of which, in part, were used to pay off the outstanding balance of the debt under the loan and security agreement with Oxford Finance LLC and Silicon Valley Bank dated April 27, 2016, as amended in May 2017 and October 2017, or the SVB-Oxford Term Loan. Net proceeds from the Term Loan, after payoff of the SVB-Oxford Term Loan, were approximately \$0.6 million. Under the terms of the SVB Loan Agreement, we could, at our sole discretion, borrow from the lender up to an additional \$12.5 million by a specified date. The draw period for the additional loan expired in November 2020 without us drawing down the additional loan. The Term Loan is due on the scheduled maturity date of May 1, 2023, or Maturity Date. Repayment of the Term Loan was interest only through November 30, 2020, followed by 30 equal monthly payments of principal plus accrued interest which commenced on December 1, 2020. The per annum interest rate for the Term Loan is the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25%. In addition, a final payment of 7.75% of the amount of the Term Loan drawn will be due on the earlier of the Maturity Date, acceleration or prepayment of the Term Loan. If we elect to prepay the Term Loan, a prepayment fee equal to 1% of the then outstanding principal balance also will be due. See Note 7, Long-Term Debt, in the Notes to Financial Statements for further details of the term loan facility.

Our obligations under the SVB 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.

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We have incurred operating losses and negative cash flows from operating activities since inception. As of December 31, 2020, we had an accumulated deficit of \$302.5 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of December 31, 2020, we had cash, cash equivalents and short-term investments of \$633.3 million. Based on our current plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2024. Our future capital requirements will depend on many factors, including:

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, collaborations, strategic partnerships or licensing arrangements. We do not have any committed external source of funds. Additional capital may not be available on reasonable terms, if at all. Subject to limited exceptions, our term loan facility also prohibits us from incurring indebtedness without the prior written consent of the Lender. 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 adve



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

	Years Ended December 31,					
		2020		2019		Change
Net cash used in operating activities	\$	(69,830)	\$	(54,760)	\$	(15,070)
Net cash used in investing activities		(99,936)		(46,325)		(53,611)
Net cash provided by financing activities		469,334		111,101		358,233

*Operating Activities.* The increase of \$15.1 million in net cash used in operating activities for the year ended December 31, 2020 compared to 2019 was primarily due to the increase of \$26.5 million in net loss, partially offset by increases of \$4.8 million in changes in accounts payable and accrued expenses, \$3.4 million in non-cash share-based compensation expense and \$1.5 million in amortization of premiums and accretion of discounts on marketable securities.

*Investing Activities*. The increase of \$53.6 million in net cash used in investing activities for the year ended December 31, 2020 as compared to 2019 was primarily due to an increase of \$93.4 million in purchases of marketable securities, partially offset by an increase of \$42.0 million in maturities of marketable securities.

*Financing Activities.* The increase of \$358.2 million in net cash provided by financing activities for the year ended December 31, 2020 compared to 2019 was primarily due to increases of \$351.2 million in proceeds from sale of common stock and \$7.3 million in proceeds from exercise of stock options and purchases under our employee stock purchase plan.

# **Contractual Obligations**

The following is a summary of our significant contractual obligations as of December 31, 2020, in thousands:

	Payments Due by Period								
		L	ess than		1-3		3-5	Μ	ore than
	Total		1 Year		Years		Years	5	Years
Long-term debt, including current portion <sup>(1)</sup>	\$ 7,250	\$	3,000	\$	4,250	\$		\$	_
Interest payments on long-term debt(2)	1,086		327		759		—		—
Operating leases <sup>(3)</sup>	8,599		2,141		4,178		2,280		_
Total	\$ 16,935	\$	5,468	\$	9,187	\$	2,280	\$	_

(1) Principal payments on our term loan facility with SVB.

- (2) Interest payments on our term loan facility with SVB. The per annum interest rate for the Term Loan is the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25%. The interest rate as of December 31, 2020 was 5.50%. In addition, a final payment of 7.75% of the amount of the Term Loan drawn will be due on the earlier of the maturity date, acceleration or prepayment of the Term Loan.
- (3) Future minimum lease payments under our operating leases in San Diego, California and Boston, Massachusetts.

We enter into agreements in the normal course of business with clinical sites and CROs for clinical research studies, professional consultants and various third parties for preclinical research studies, clinical supply manufacturing and other services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

Excluded from the table above are milestone or contractual payment obligations contingent upon the achievement of certain milestones or events if the amount and timing of such obligations are unknown or uncertain. Our license agreements are cancellable by us with written notice within 180 days or less. We may be required to pay up to approximately \$80.2 million in milestone payments, plus sales royalties, in the event that regulatory and commercial milestones under the in-license agreements are achieved.

# **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, or GAAP. 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 in the Notes 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. Non-refundable 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 expenses 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 nonemployee 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 straightline basis over the requisite service period of the award less actual forfeitures.

#### **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.

### **Interest Rate Risk**

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in money market funds, corporate debt securities, U.S. Treasury securities and commercial paper. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For our short-term investments, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the statements of operations and comprehensive loss. We believe that should a 10.0% change in interest rates were to have occurred on December 31, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We are also subject to interest expense fluctuations through our term loan facility with SVB, as discussed in Note 7, Long-Term Debt, in the Notes to Financial Statements of this Annual Report, which as of December 31, 2020 bears interest at a rate equal to the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25% and is therefore exposed to changes in interest rates through its maturity date of May 2023. If a 10% change in interest rates were to have occurred on December 31, 2020, this change would not have had a material effect on our interest expense as of that date.

### **Inflation Risk**

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended December 31, 2020, 2019 or 2018.

# Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data 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 Framework)* 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, 2020.

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.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

# **Change in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting identified in connection with management's evaluation of such internal control that occurred during our most recent quarter ended December 31, 2020 that have materially affected, or are reasonably likely to material affect, our internal control over financial reporting.

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### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and the Board of Directors of Kura Oncology, Inc.

### **Opinion on Internal Control over Financial Reporting**

We have audited Kura Oncology, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Kura Oncology, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of Kura Oncology, Inc. as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements") and our report dated February 24, 2021 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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 risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California February 24, 2021



# 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 2021 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, 2020, 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 and Media 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	Page F-1
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Stockholders' Equity	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	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

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.		8-K (Exhibit 3.1)	6/14/2017	001-37620
3.2	Amended and Restated Bylaws of the Registrant.		8-K (Exhibit 3.2)	6/14/2017	001-37620
4.1	Form of Common Stock certificate.		8-K (Exhibit 4.1)	3/12/2015	000-53058
4.2	Warrant to Purchase Stock by Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
4.3	Description of Registrant's Common Stock.		10-K (Exhibit 4.3)	2/25/2020	001-37620
10.1+	<u>Kura Oncology, Inc. Amended and Restated 2014 Equity</u> <u>Incentive Plan and Forms of Stock Option Agreement, Notice of</u> <u>Exercise and Stock Option Grant Notice thereunder.</u>		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*	<u>License Agreement, dated December 18, 2014, by and between</u> the Registrant and Janssen Pharmaceutica NV.	Х			



Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.6*	<u>Amended and Restated Asset Purchase Agreement, dated</u> <u>February 12, 2015, by and between the Registrant and Araxes</u> <u>Pharma LLC.</u>	Х			
10.7	Sublease, dated December 20, 2016, by and between the Registrant and Wellspring Biosciences, Inc.		10-K (Exhibit 10.11)	3/14/2017	001-37620
10.8*	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, February 1, 2017.	Х			
10.9*	Fifth Amendment to Patent License Agreement, effective as of May 24, 2017, by and between the Registrant and the Regents of the University of Michigan.	Х			
10.10+	Kura Oncology, Inc. Amended and Restated Non-Employee Director Compensation Policy.		10-K (Exhibit 10.10)	3/12/2018	001-37620
10.11*	<u>Services Agreement, effective as of October 1, 2014, by and</u> <u>between the Registrant and Wellspring Biosciences, Inc.</u>	Х			
10.12*	<u>Management Services Agreement, effective as of October 1, 2014,</u> <u>by and between the Registrant and Araxes Pharma LLC.</u>	Х			
10.13	<u>Office Lease Agreement, dated August 1, 2015, by and between</u> the Registrant and 55 Cambridge Parkway, LLC.		S-1 (Exhibit 10.16)	10/20/2015	333-207534
10.14+	<u>Amended and Restated Executive Employment Agreement,</u> <u>effective as of January 29, 2016, by and between the Registrant and</u> <u>Troy E. Wilson, Ph.D., J.D.</u>		10-K (Exhibit 10.15)	3/17/2016	001-37620
10.15	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
10.16	<u>Amendment No. 1 to License Agreement, dated June 6, 2016, by</u> and between the Registrant and Janssen Pharmaceutica NV.		10-Q (Exhibit 10.3)	8/10/2016	001-37620
10.17**	Sixth Amendment to Patent License Agreement, effective as of August 24, 2017, by and between the Registrant and the Regents of the University of Michigan.		10-K (Exhibit 10.23)	3/12/2018	001-37620
10.18	Second Amendment to Management Services Agreement, effective as of April 1, 2018, by and between the Registrant and Araxes Pharma LLC.		10-Q (Exhibit 10.1)	5/8/2018	001-37620
10.19+	Executive Employment Agreement, effective as of August 21, 2018, by and between the Registrant and Marc Grasso, M.D.		10-Q (Exhibit 10.2)	11/5/2018	001-37620

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.20	<u>Loan and Security Agreement, dated as of November 1, 2018, by</u> and between the Registrant and Silicon Valley Bank.		10-Q (Exhibit 10.3)	11/5/2018	001-37620
10.21	<u>First Amendment to Sublease, dated March 1, 2019, by and</u> <u>between the Registrant and Wellspring Biosciences, Inc.</u>		10-K (Exhibit 10.24)	3/5/2019	001-37620
10.22	<u>Sales Agreement, dated March 5, 2019, by and among the</u> <u>Registrant, SVB Leerink LLC and Stifel, Nicolaus &amp; Company,</u> <u>Incorporated.</u>		8-K (Exhibit 10.1)	3/5/2019	001-37620
10.23	<u>Assignment and Assumption of Sublease, dated August 2, 2019, by and among the Registrant, Wellspring Biosciences, Inc. and Araxes Pharma LLC.</u>		10-Q (Exhibit 10.1)	11/5/2019	001-37620
10.24+	<u>First Amendment to Executive Employment Agreement, effective</u> as of August 21, 2018, by and between the Registrant and Marc <u>Grasso, M.D.</u>		10-Q (Exhibit 10.2)	11/5/2019	001-37620
10.25+	Executive Employment Agreement, effective as of August 9, 2019, by and between the Registrant and Kathleen Ford.		10-Q (Exhibit 10.3)	11/5/2019	001-37620
10.26	<u>Office Lease Agreement, dated January 8, 2020, by and between</u> <u>the Registrant and BRE CA Office Owners LLC.</u>		10-Q (Exhibit 10.28)	2/25/2020	001-37620
10.27	<u>Office Lease Agreement, dated March 24, 2020, by and between</u> the Registrant and East Office Operating Limited Partnership.		10-Q (Exhibit 10.5)	5/4/2020	001-37620
10.28	<u>First Amendment to Loan and Security Agreement, dated April 3,</u> 2020, by and between the Registrant and Silicon Valley Bank.		8-K (Exhibit 10.1)	4/7/2020	001-37620
10.29+	Executive Employment Agreement, effective as of November 4, 2019, by and between the Registrant and James Basta.		10-Q (Exhibit 10.1)	5/4/2020	001-37620
10.30	<u>Second Amendment to Sublease, dated April 22, 2020 by and between the Registrant and Araxes Pharma LLC</u> .		10-Q (Exhibit 10.7)	5/4/2020	001-37620
10.31	<u>First Amendment to Office Lease Agreement, dated May 2, 2020</u> by and between the Registrant and BRE CA Office Owner LLC.		10-Q (Exhibit 10.8)	5/4/2020	001-37620
10.32+	Amended and Restated Nonemployee Director Compensation Policy.		10-Q (Exhibit 10.4)	8/6/2020	001-37620
10.33+	Form of International Stock Option Grant Notice, International Stock Option Agreement and International Notice of Exercise under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan.		10-Q (Exhibit 10.1)	11/5/2020	001-37620

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Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.34	Second Amendment to Office Lease Agreement, dated October 27, 2020 by and between the Registrant and BRE CA Office Owner LLC.		10-Q (Exhibit 10.2)	11/5/2020	001-37620
10.35*	<u>Master Collaboration Agreement, dated January 4, 2021 by and</u> between the Registrant and Illumina, Inc.	Х			
10.36+	<u>Second Amendment to Executive Employment Agreement,</u> <u>effective as of February 19, 2021, by and between the Registrant</u> <u>and Troy E. Wilson, Ph.D., J.D.</u>	Х			
10.37+	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan.	Х			
23.1	Consent of Independent Registered Public Accounting Firm.	Х			
24.1	Power of Attorney (see signature page).	Х			
31.1	<u>Certification of Principal Executive Officer pursuant to Section 302</u> of the Sarbanes-Oxley Act of 2002.	Х			
31.2	<u>Certification of Principal Financial Officer pursuant to Section</u> <u>302 of the Sarbanes-Oxley Act of 2002.</u>	Х			
32.1	<u>Certifications of Principal Executive Officer and Principal</u> <u>Financial Officer pursuant to Section 906 of the Sarbanes-Oxley</u> <u>Act of 2002, 18 U.S.C. 1350.</u>	Х			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	Х			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Х			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Х			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Х			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Х			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Х			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101.INS).	Х			

Indicates management contract or compensatory plan. +

Certain portions of this exhibit (indicated by "[\*\*\*]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC. \*\*

# 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.

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 Marc Grasso, M.D., 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 SEC, 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.

Name	Title	Date
/s/ Troy E. Wilson, Ph.D., J.D. Troy E. Wilson, Ph.D., J.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 24, 2021
/s/ Marc Grasso, M.D. Marc Grasso, M.D.	Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	February 24, 2021
/s/ Faheem Hasnain Faheem Hasnain	Director	February 24, 2021
/s/ Robert E. Hoffman Robert E. Hoffman	Director	February 24, 2021
/s/ Thomas Malley Thomas Malley	Director	February 24, 2021
/s/ Diane Parks Diane Parks	Director	February 24, 2021
/s/ Steven H. Stein, M.D. Steven H. Stein, M.D.	Director	February 24, 2021
/s/ Mary Szela Mary Szela	Director	February 24, 2021



Date: February 24, 2021

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Kura Oncology, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Kura Oncology, Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 24, 2021 expressed an unqualified opinion thereon.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

# Clinical Trial Research and Development Expenses and Accruals

Description of the Matter	During 2020, the Company incurred \$60.4 million for research and development expense and as of December 31, 2020, the Company accrued \$4.1 million for clinical trial research and development expenses. As described in Note 2 of the financial statements, the Company records accruals for estimated costs of research and development activities that include contract services for clinical trials. Clinical trial activities performed by third parties are accrued and expensed based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with contract research organizations ("CROs") and clinical trial sites. Estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.
	challenging as evaluating the progress or stage of completion of the activities under the Company's research and development agreements is dependent upon a high volume of data from third-party service providers and internal clinical personnel, which is tracked in spreadsheets and other end user computing programs.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for accrued clinical trial research and development expenses. This included management's assessment of the assumptions and data underlying the accrued clinical trial research and development expenses estimate.
	To test the completeness of the Company's accrued clinical trial research and development expenses, among other procedures, we obtained supporting evidence of the research and development activities performed for significant clinical trials. We inspected meeting summaries of clinical trial and project status meetings with internal accounting personnel, internal clinical project managers and third-party service providers to corroborate the status of significant research and development activities. To verify the appropriate measurement of accrued research and development costs, we compared the costs for a sample of transactions against the related invoices and contracts, confirmed amounts incurred to-date with third-party service providers, and performed lookback analyses. We also examined a sample of subsequent payments to evaluate the completeness of the accrued clinical trial research and development expenses.
/s/ Ernst & Young LLP	
We have served as the Company's aud	itor since 2015.

San Diego, California February 24, 2021

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

	December 31,		
	 2020		2019
Assets		-	
Current assets:			
Cash and cash equivalents	\$ 325,493	\$	26,135
Short-term investments	307,827		210,756
Prepaid expenses and other current assets	3,972		2,712
Total current assets	 637,292		239,603
Property and equipment, net	2,021		44
Restricted cash	210		_
Operating lease right-of-use assets	6,334		234
Other long-term assets	1,355		2,091
Total assets	\$ 647,212	\$	241,972
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable and accrued expenses	\$ 23,024	\$	15,314
Current portion of long-term debt	 3,000		250
Total current liabilities	26,024		15,564
Long-term debt	4,250		7,250
Long-term operating lease liabilities	5,638		—
Other long-term liabilities	 395		377
Total liabilities	36,307		23,191
Commitments and contingencies (Note 9)			
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;			
66,194 and 45,384 shares issued and outstanding as of			
December 31, 2020 and 2019, respectively	7		5
Additional paid-in capital	913,354		431,322
Accumulated other comprehensive income	46		331
Accumulated deficit	 (302,502)		(212,877)
Total stockholders' equity	 610,905		218,781
Total liabilities and stockholders' equity	\$ 647,212	\$	241,972

See accompanying notes to financial statements.

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

			Years E	nded December 31	,	
		2020		2019		2018
Operating Expenses:						
Research and development (includes related party amounts of \$196, \$432 and \$1,021 for the years ended December 31, 2020, 2019 and 2018, respectively)	\$	60,397	\$	47,826	\$	46,787
General and administrative (includes related party amounts of \$188, \$325 and \$273 for the years ended December 31, 2020, 2019 and 2018, respectively)		31,502		19,653		16,096
Total operating expenses		91,899		67,479		62,883
Other Income (Expense):		,				<u> </u>
Management fee income, related party		51		245		735
Interest income, net		2,801		4,674		3,169
Interest expense		(578)		(580)		(970)
Loss from extinguishment of debt					_	(498)
Total other income		2,274		4,339		2,436
Net Loss	\$	(89,625)	\$	(63,140)	\$	(60,447)
Net loss per share, basic and diluted	\$	(1.69)	\$	(1.51)	\$	(1.72)
Weighted average number of shares used in computing net loss per share, basic and diluted		53,077		41,946		35,191
Comprehensive Loss:						
Net loss	\$	(89,625)	\$	(63,140)	\$	(60,447)
Other comprehensive income (loss):						
Unrealized gain (loss) on marketable securities						
and foreign currency	<u>.</u>	(285)		462	<u> </u>	(82)
Comprehensive loss	\$	(89,910)	\$	(62,678)	\$	(60,529)

See accompanying notes to financial statements.

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

	Commo	on Stock	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2017	29,424	\$ 3	\$ 169,201	\$ (49)	\$ (89,290)	\$ 79,865
Issuance of common stock, net of offering costs	7,737	1	131,900			131,901
Share-based compensation expense		—	8,654			8,654
Restricted stock awards vested	793	—	2			2
Issuance of common stock from exercise of options and employee stock purchase plan	194		1,092			1,092
Other comprehensive loss	154		1,052	(82)		(82)
Net loss				(02)	(60,447)	(60,447)
Balance at December 31, 2018	38,148	4	310,849	(131)	(149,737)	160,985
Issuance of common stock, net of offering costs	6,785	1	108,128		_	108,129
Share-based compensation expense	_		9,409			9,409
Issuance of common stock from exercise of options						
and employee stock purchase plan	451		2,936	_	_	2,936
Other comprehensive income	_	_	_	462	_	462
Net loss	—	—	—		(63,140)	(63,140)
Balance at December 31, 2019	45,384	5	431,322	331	(212,877)	218,781
Issuance of common stock, net of offering costs	19,792	2	458,976	_	_	458,978
Share-based compensation expense	_	_	12,807		_	12,807
Issuance of common stock from exercise of options						
and employee stock purchase plan	1,018	—	10,249	_		10,249
Other comprehensive loss	_	_	_	(285)		(285)
Net loss					(89,625)	(89,625)
Balance at December 31, 2020	66,194	\$ 7	\$ 913,354	\$ 46	\$ (302,502)	\$ 610,905

See accompanying notes to financial statements.

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

	Years Ended December 31,					
		2020		2019		2018
Operating Activities						
Net loss	\$	(89,625)	\$	(63,140)	\$	(60,447)
Adjustments to reconcile net loss to net cash used in operating activities:						
Share-based compensation expense		12,807		9,409		8,654
Depreciation expense		194				10
Amortization of premium and accretion of discounts on marketable securities, net		410		(1,103)		(1,935)
Non-cash interest expense		_		—		184
Loss from extinguishment of debt		_				498
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets		(711)		(875)		(465)
Other long-term assets		1,205		(117)		(504)
Accounts payable and accrued expenses		5,677		856		5,116
Other long-term liabilities		213		210		234
Net cash used in operating activities		(69,830)		(54,760)	_	(48,655)
Investing Activities						
Purchases of marketable securities		(320,963)		(227,571)		(237,443)
Maturities and sales of marketable securities		223,198		181,246		158,143
Purchases of property and equipment		(2,171)				—
Net cash used in investing activities		(99,936)		(46,325)		(79,300)
Financing Activities						
Proceeds from issuances of common stock, net		459,335		108,165		132,172
Proceeds from exercises of stock options and purchases under						
employee stock purchase plan		10,249		2,936		1,092
Repayment of long-term debt		(250)				(1,250)
Proceeds from issuance of long-term debt, net						627
Net cash provided by financing activities		469,334		111,101		132,641
Net increase in cash, cash equivalents and restricted cash		299,568		10,016		4,686
Cash, cash equivalents and restricted cash at beginning of period		26,135		16,119		11,433
Cash, cash equivalents and restricted cash at end of period	\$	325,703	\$	26,135	\$	16,119
Supplemental disclosure of cash flow information:						
Interest paid	\$	419	\$	430	\$	641

See accompanying notes to financial statements.

# KURA ONCOLOGY, INC. Notes to Financial Statements

# 1. Description of Business

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

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

### 2. Summary of Significant Accounting Policies

# Reclassifications

Certain prior period balances have been reclassified to conform to the current period presentation.

### 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 in the United States.

## 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 have an original maturity of three months or less from date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments.

# **Restricted Cash**

Under the terms of an office lease entered into in March 2020, we are required to maintain a standby letter of credit during the term of the lease. As of December 31, 2020, restricted cash of \$0.2 million was pledged as collateral for the letter of credit.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets that sum to the total of the amounts shown in the statements of cash flows, in thousands:

		December 31,	
	2020	2019	2018
Cash and cash equivalents	\$ 325,493	\$ 26,135	\$ 16,119
Restricted cash	210	—	_
Total	\$ 325,703	\$ 26,135	\$ 16,119

#### 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 non-credit related losses recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities are determined on a specific identification basis and included in interest income, net on the statements of operations and comprehensive loss.

#### Allowance for Credit Losses

For available-for-sale debt securities in an unrealized loss position, we first assess whether we intend to sell, or it is more likely than not that we will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale debt securities that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive income (loss) 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. We periodically review and modify these guidelines to maximize trends in yields and interest rates without compromising 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. Computer software and equipment are depreciated over their estimated useful lives of three years. Laboratory equipment is depreciated over its estimated useful life of five years. Furniture and fixtures are depreciated over their estimated useful lives of five years. Leasehold improvements are depreciated over the lesser of the term of the related lease or the useful life of the asset.

## 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. For the years ended December 31, 2020, 2019 and 2018, there were no impairments of the value of long-lived assets.

### Leases

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

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

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

Research and development expenses consist of costs associated with our research and development activities including salaries, benefits, sharebased compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred 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 inlicensed 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, 2020, we had 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 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.

Subsequent to the adoption of the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting (Topic 718)*, on January 1, 2019, we measured awards granted to non-employees on the adoption date of the standard and recognized the expense over the remaining vesting period of the award. Prior to the adoption of ASU 2018-07, awards granted to non-employees were subject to periodic revaluation over their vesting terms. The fair value of non-employee awards was remeasured at each reporting period as the underlying awards vested unless the instruments were fully vested, immediately exercisable and nonforfeitable on the date of grant. We recorded 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 was recorded on the earlier of the performance commitment date or the date the services required were completed and were remeasured at fair value during the service period. As non-employee restricted stock awards vested, they were remeasured at fair value and expensed based on the intrinsic value method which was 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 lapsed 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 Loss**

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

### Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents outstanding are comprised of stock options, a warrant and employee stock purchase plan rights and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. Because of our net loss for the years ended December 31, 2020, 2019 and 2018, outstanding common stock equivalents totaling approximately 5,059,000, 4,120,000 and 3,225,000, respectively, were excluded from the calculation of diluted net loss per common share because their effect was anti-dilutive.

# 3. Recent Accounting Pronouncements

In June 2016, the FASB, issued ASU 2016-13, *Financial Instruments–Credit Losses: Measurement of Credit Losses on Financial Instruments*, in order to improve financial reporting of expected credit losses on financial instruments and other commitments to extend credit. ASU 2016-13 requires that an entity measure and recognize expected credit losses for financial assets held at amortized cost and replaces the incurred loss impairment methodology in prior GAAP with a methodology that requires consideration of a broader range of information to estimate credit losses, and establishes additional disclosures related to credit risks. We adopted ASU 2016-13 on January 1, 2020. The adoption of the new standard did not have a material impact on our financial statements. We will continue to actively monitor the impact of the recent COVID-19 pandemic on expected credit losses.

### 4. Investments

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

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

		December 31, 2020							
	Maturities (years)	A	mortized Cost	τ	Inrealized Gains	τ	Inrealized Losses	Est	imated Fair Value
Cash equivalents:			<u> </u>						
Money market funds	1 or less	\$	311,239	\$		\$		\$	311,239
Commercial paper	1 or less		5,998						5,998
Total cash equivalents			317,237						317,237
						_			
Short-term investments:									
Corporate debt securities	2 or less		113,020		36		(36)		113,020
Commercial paper	1 or less		106,350						106,350
U.S. Treasury securities	1 or less		88,409		50		(2)		88,457
Total short-term investments			307,779		86		(38)		307,827
Total		\$	625,016	\$	86	\$	(38)	\$	625,064
		-		_		_		-	



		December 31, 2019							
	Maturities (years)	A	Amortized Cost	1	Unrealized Gains	U	Inrealized Losses	Est	imated Fair Value
Cash equivalents:									
Money market funds	1 or less	\$	18,445	\$		\$		\$	18,445
Short-term investments:									
Corporate debt securities	2 or less		113,466		182		—		113,648
Commercial paper	1 or less		20,851				—		20,851
U.S. Treasury securities	2 or less		76,108		149				76,257
Total short-term investments			210,425		331		_		210,756
Total		\$	228,870	\$	331	\$	_	\$	229,201

Short-term investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. As of December 31, 2020 and 2019, short-term investments of \$242.6 million and \$196.1 million, respectively, had maturities less than one year, and short-term investments of \$65.2 million and \$14.7 million, respectively, had maturities between one to two years. Realized gains and losses were de minimis for the years ended December 31, 2020, 2019 and 2018.

As of December 31, 2020, 10 available-for-sale debt securities with a fair market value of \$85.2 million were in gross unrealized loss positions, none of which were in such position for greater than 12 months. We do not intend to sell these available-for-sale debt securities, and it is not more likely than not that we will be required to sell these securities prior to recovery of their amortized cost basis. Based on our review of these available-for-sale debt securities, none of the unrealized losses is the result of a credit loss. As such, we have no allowance for credit losses as of December 31, 2020. There were no available-for-sale debt securities in gross unrealized loss positions as of December 31, 2019. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss).

# 5. Fair Value Measurements

As of December 31, 2020 and 2019, we had cash equivalents and short-term investments measured at fair value on a recurring basis.

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

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

	 December 31, 2020				
	Total		Level 1		Level 2
Cash equivalents:					
Money market funds	\$ 311,239	\$	311,239	\$	—
Commercial paper	 5,998		—		5,998
Total cash equivalents	317,237		311,239		5,998
Short-term investments:					
Corporate debt securities	113,020		—		113,020
Commercial paper	106,350		—		106,350
U.S. Treasury securities	88,457		88,457		—
Total short-term investments	 307,827		88,457		219,370
Total	\$ 625,064	\$	399,696	\$	225,368

		Decen	ıber 31, 2019		
	 Total	]	Level 1		Level 2
Cash equivalents:				-	
Money market funds	\$ 18,445	\$	18,445	\$	
Short-term investments:					
Corporate debt securities	113,648		_		113,648
Commercial paper	20,851		—		20,851
U.S. Treasury securities	76,257		76,257		_
Total short-term investments	 210,756		76,257		134,499
Total	\$ 229,201	\$	94,702	\$	134,499

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 7, Long-Term Debt, for further details of our term loan facility.

# 6. Balance Sheet Detail

Property and equipment consisted of the following, in thousands:

	December 31,				
		2020		2019	
Leasehold improvements	\$	1,169	\$		
Furniture and fixtures		862			_
Computer software and equipment and laboratory equipment		276			136
Property and equipment, gross		2,307			136
Less: accumulated depreciation		(286)			(92)
Property and equipment, net	\$	2,021	\$		44

Depreciation expense was \$0.2 million for the year ended December 31, 2020 and de minimis for each of the years ended December 31, 2019 and 2018.

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

	December 31,				
		2020		2019	
Accounts payable	\$	2,753	\$	3,526	
Accrued clinical trial research and development expenses		4,080		4,139	
Accrued other research and development expenses		5,581		2,831	
Accrued compensation and benefits		7,016		3,694	
Operating lease liability, current portion		2,089		252	
Other accrued expenses		1,505		872	
Total accounts payable and accrued expenses	\$	23,024	\$	15,314	

# 7. Long-Term Debt

In April 2016, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, or the SVB-Oxford Term Loan, which was amended in May 2017 and October 2017, pursuant to which we borrowed \$7.5 million. As discussed below, we extinguished the SVB-Oxford Term Loan in November 2018. In connection with the SVB-Oxford Term Loan, we issued warrants to purchase shares of our common stock. As of December 31, 2020, the warrant issued to Oxford to purchase up to 33,988 shares of our common stock at an exercise price of \$3.31 per share remained outstanding.

On November 1, 2018, we entered into a loan and security agreement, or the SVB Loan Agreement, with SVB, or the Lender, providing for up to \$20.0 million in a series of term loans. Upon entering into the SVB Loan Agreement, we borrowed \$7.5 million, or the Term Loan. We used approximately \$6.9 million of the proceeds from the Term Loan to repay all amounts owed under the SVB-Oxford Term Loan, which included a prepayment charge of \$0.1 million. The SVB Loan Agreement has substantially different terms than the SVB-Oxford Term Loan. In accordance with the FASB Accounting Standards Codification, or ASC, 405, *Extinguishment of Liabilities*, and ASC 470-50, *Debt Modifications and Extinguishments*, we accounted for the transaction as a debt extinguishment. Accordingly, we recorded a loss of approximately \$0.5 million for the year ended December 31, 2018.

Under the terms of the SVB Loan Agreement, we could, at our sole discretion, borrow from the Lender up to an additional \$12.5 million by a specified date. The draw period for the additional loan expired without us drawing down the additional loan.

The Term Loan is due on the scheduled maturity date of May 1, 2023, or Maturity Date. Repayment of the Term Loan was interest only through November 30, 2020, followed by 30 equal monthly payments of principal plus accrued interest which commenced on December 1, 2020. The per annum interest rate for the outstanding Term Loan is the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25%. The interest rate as of December 31, 2020 was 5.50%. In addition, a final payment of 7.75% of the amount of the Term Loan will be due on the earlier of the Maturity Date, acceleration of the Term Loan, or prepayment of the Term Loan. The final payment is being accrued through interest expense using the effective interest method. If we elect to prepay the Term Loan, a prepayment fee equal to 1% of the then outstanding principal balance will also be due.

We are subject to customary affirmative and restrictive covenants under the SVB Loan Agreement. Our obligations under the SVB 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 SVB Loan Agreement.

The SVB Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the SVB 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 Lender's lien in the collateral or in the value of such collateral. In the event of default by us under the SVB Loan Agreement, the Lender 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 SVB 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, 2020 and 2019, we were in compliance with all financial covenants under the SVB Loan Agreement and there had been no material adverse change.

The following table summarizes future minimum payments under the SVB Loan Agreement as of December 31, 2020, in thousands:

\$ 3,328
3,160
1,849
8,337
(1,087)
7,250
(3,000)
\$ 4,250
\$  \$

#### 8. License Agreements

#### Janssen License Agreement

In December 2014, we entered into a license agreement with Janssen Pharmaceutica NV, or 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 had a first right to negotiate for an exclusive license back from us to develop and commercialize tipifarnib on terms to be negotiated in good faith. Janssen could exercise this right of first negotiation during a 60-day period following delivery of clinical data as specified in the agreement. In June 2018, Janssen declined to exercise this first right to negotiate.

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 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, February 2017, May 2017 and August 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, including our development candidate KO-539. 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.

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.

### 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 \$80.2 million payable upon occurrence of each stated event, of which \$0.5 million relates to the initiation of certain development activities, \$28.9 million relates to the achievement of specified regulatory approvals for the first indication and up to \$50.8 million relates to the achievement of specified levels of product sales. Additional payments will be due for each subsequent indication if specified regulatory approvals are achieved. As of December 31, 2020, we have paid milestone payments totaling \$0.1 million under the above-mentioned license 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.

## 9. Commitments and Contingencies

### **Operating Leases**

We adopted ASC 842, *Leases*, on January 1, 2019. We had a sublease with a related party for office space in San Diego, California, or Sublease, and a lease for office space in Cambridge, Massachusetts, that existed before January 1, 2019 and were classified as operating leases. In March 2019, the Sublease was amended to extend the expiration date from October 31, 2019 to April 30, 2020 with the monthly rent increased from approximately \$16,000 to approximately \$24,000 effective November 1, 2019. In April 2020, the Sublease was amended to extend the expiration date from April 30, 2020 to June 30, 2020 with no change to the amount of monthly rent. The Sublease was terminated in June 2020. See Note 12, Related Party Transactions, for further details of the Sublease. The lease for office space in Cambridge, Massachusetts expired on July 31, 2020.

In January 2020, we entered into an office lease agreement for our corporate offices in San Diego, California. This agreement was originally scheduled to commence in May 2020 but was subsequently amended with an amended commencement date of August 1, 2020 and an extended lease expiration date of November 30, 2025. We refer to such office lease agreement, as amended, as the San Diego Lease. The San Diego Lease provides for a one-time option to extend for a period of five additional years. The monthly base rent is approximately \$58,000 for the first year, with such amount increasing by 3.0% per year over the initial term. In addition, the San Diego Lease is subject to charges for common area maintenance and other costs. The San Diego Lease provides a four-month rent abatement period during the first year and approximately \$1.0 million in reimbursements for allowable tenant improvements, which effectively reduce the total lease payments owed for the San Diego Lease. For accounting purposes, the lease commencement date was determined to be March 2020 when we had control of the office space. We recorded an operating lease right-of-use, or ROU, asset and operating lease liability of approximately \$2.2 million on our balance sheet on the lease commencement date during the quarter ended March 31, 2020.

In March 2020, we entered into a lease agreement for office space in Boston, Massachusetts, or the Boston Lease, which commenced on April 1, 2020 and expires on July 31, 2024. The Boston Lease provides for a one-time option to extend the Boston Lease for a period of five additional years after the expiration of the initial lease term. Under the terms of the Boston Lease, monthly base rent is approximately \$105,500 for the first year, subject to an annual fixed percentage increase of 2.0% on April 1<sup>st</sup> of each subsequent year. In addition, we are obligated to pay for common area maintenance and other costs. Under the terms of the Boston Lease, we are required to maintain a standby letter of credit of approximately \$0.2 million during the term of the lease. We recorded an operating lease ROU asset and operating lease liability of approximately \$5.1 million on our balance sheet on the lease commencement date during the quarter ended June 30, 2020.

In May 2020, we entered into a two-year sublease for certain designated lab space in San Diego, California, which commenced on June 9, 2020. Under the terms of the sublease, the monthly base rent is approximately \$12,500 for the first year, subject to an annual fixed percentage increase of 5.0% in June of the following year. We are not obligated to pay for common area maintenance and other costs. We recorded an operating lease ROU asset and operating lease liability of approximately \$0.3 million on our balance sheet on the lease commencement date during the quarter ended June 30, 2020.

Maturities of our lease liabilities as of December 31, 2020 are as follows, in thousands:

### Year Ending December 31,

2021	\$ 2,141
2022	2,098
2023	2,080
2024	1,558
2025	722
Total lease payments	8,599
Less: imputed interest	(872)
Total operating lease liabilities	\$ 7,727

As of December 31, 2020 and 2019, total operating lease ROU assets were \$6.3 million and \$0.2 million, respectively. As of December 31, 2020, total operating lease liabilities were \$7.7 million, of which \$5.6 million were recorded as long-term lease liabilities. As of December 31, 2019, we had total operating lease liabilities of approximately \$0.3 million which

matured during the year ended December 31, 2020. As of December 31, 2020 and 2019, the weighted-average discount rate was 5.5% and 6.5%, respectively, and the weighted-average remaining lease term was 4.1 years and 0.5 years, respectively.

Total cash paid for amounts included in the measurement of operating lease liabilities, net of tenant improvement reimbursements, was \$0.3 million and \$0.5 million for the years ended December 31, 2020 and 2019, respectively. Operating lease ROU assets obtained in exchange for operating lease liabilities were \$7.5 million and \$0.7 million for the years ended December 31, 2020 and 2019, respectively.

Total operating lease expense was approximately \$1.7 million and \$0.5 million for the years ended December 31, 2020 and 2019, respectively. We have entered into short-term operating leases that are not recorded on the balance sheet as of December 31, 2020. Total rent expense for the years ended December 31, 2020, 2019 and 2018 was approximately \$2.0 million, \$0.6 million and \$0.5 million, respectively.

### 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.

# 10. Stockholders' Equity

In December 2020, we completed a public offering in which we sold an aggregate of 9,326,500 shares of common stock at a price of \$37.00 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$324.1 million.

In May 2020, we completed a public offering in which we sold an aggregate of 10,465,000 shares of common stock at a price of \$13.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$134.9 million.

In June 2019, we completed a public offering in which we sold an aggregate of 6,785,000 shares of common stock at a price of \$17.00 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$108.1 million.

In March 2019, we entered into an at-the-market issuance sales agreement with SVB Leerink LLC and Stifel, Nicolaus & Company, Incorporated, or the 2019 ATM facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to \$75.0 million. We have not yet sold any shares of our common stock under the 2019 ATM facility.

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

In January 2018, we sold an aggregate of 3,136,722 shares of our common stock at a weighted-average price per share of \$18.85, for net proceeds of approximately \$57.4 million, after deducting commissions and offering expenses, under an at-the-market issuance sales agreement, with Cowen and Company, LLC, which was amended in November 2017 and March 2018, or 2017 ATM facility. In July 2018, we terminated the 2017 ATM facility.

### 11. Share-Based Compensation

### **Equity Incentive Plan**

In March 2015, our board of directors adopted our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, which 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, consultants and members of our board of directors. The number of shares of our common stock available for future grant under the 2014 Plan will automatically increase on January 1 of each year through January 1, 2025 by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2021, an automatic increase pursuant to the 2014 Plan occurred, resulting in 2,647,764 additional shares of common stock available for future grants under the 2014 Plan. We issue shares of common stock upon the exercise of options with the source of those shares of common stock being newly issued shares.



As of December 31, 2020, 12,234,481 shares of common stock had been reserved for issuance under the 2014 Plan. As of December 31, 2020, 692,894 shares of common stock were available for future grants of equity awards under the 2014 Plan.

# 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 stock options is ten years. The following is a summary of stock option activity for the year ended December 31, 2020, 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, 2019	4,080	\$ 13.98			
Granted	2,549	\$ 15.47			
Exercised	(982)	\$ 9.94			
Canceled	(626)	\$ 15.18			
Outstanding at December 31, 2020	5,021	\$ 15.37	8.3	\$	87,172
Vested and expected to vest at December 31, 2020	5,021	\$ 15.37	8.3	\$	87,172
Exercisable at December 31, 2020	1,848	\$ 13.73	7.1	\$	34,979

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock at December 31, 2020 of \$32.66 per share and the exercise price of stock options that had strike prices below the closing price.

The following summarizes certain information regarding stock options, in thousands:

	Years Ended December 31,					
	2020		2019	2018		
Cash received from options exercised during the period	\$ 9,766	\$	2,562	\$	1,035	
Intrinsic value of options exercised during the period	\$ 13,348	\$	4,311	\$	1,822	

The assumptions used to estimate the fair value of stock options granted to employees using the Black-Scholes model were as follows:

	Years Ended December 31,					
	 2020	2019			2018	
Weighted-average grant date fair value per share	\$ 10.15	\$	10.93	\$	12.95	
Expected volatility	74.4% — 76.1%		73.1% — 77.2%		76.5% — 79.4%	
Expected term (in years)	5.50 - 6.08		5.50 - 6.08		5.50 - 6.08	
Risk-free interest rate	0.4% — 2.0%		2.1% — 2.8%		2.1% - 2.8%	
Expected dividend yield	—		—		_	

In estimating fair value for stock options issued under the 2014 Plan, expected volatility was based, in part, on our historical volatility and the 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. Actual forfeitures are applied as they occur, and any compensation cost previously recognized for awards for which the requisite service has not been completed is reversed in the period that the award is forfeited.

As of December 31, 2020, unrecognized estimated compensation expense related to stock options was \$30.9 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 are 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 maintained a repurchase right where shares of restricted common stock were released from such repurchase right over a period of time of continued service by the recipient. The repurchase price for unvested stock awards was 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, 2020, there were no shares of common stock subject to repurchase.

No restricted stock awards were granted during the years ended December 31, 2020 and 2019. All previously issued restricted stock awards were fully vested as of December 31, 2018. The total fair value of restricted stock awards vested during the year ended December 31, 2018 was approximately \$14.8 million.

#### **Employee Stock Purchase Plan**

In March 2015, our board of directors adopted the 2015 Employee Stock Purchase Plan, or ESPP. The ESPP permits eligible employees to purchase our common stock at a discount through payroll deductions during defined offering periods. Eligible employees may elect to withhold up to 15% of their base earnings to purchase shares of our common stock at a price equal to 85% of the fair market value on the first day of the offering period or the purchase date, whichever is lower. Successive six-month offering periods under the ESPP began on May 21, 2018. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year through January 1, 2025 by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares of common stock, 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 2020, our board of directors elected not to increase the total number of shares of our common stock reserved for issuance under the ESPP in 2021.

For the years ended December 31, 2020, 2019 and 2018, cash received from the exercise of purchase rights was approximately \$0.5 million, \$0.4 million and \$0.1 million, respectively. As of December 31, 2020, we have issued 75,654 shares of common stock under the ESPP. As of December 31, 2020, 163,051 shares of common stock are reserved for future issuance under the ESPP.

The assumptions used to estimate the fair value of ESPP stock purchase rights using the Black-Scholes model were as follows:

	Years Ended December 31,				
	 2020		2019		2018
Weighted-average grant date fair value per share	\$ 8.59	\$	4.44	\$	3.87
Weighted-average exercise price per share	\$ 13.35	\$	11.01	\$	10.15
Expected volatility	55.3% — 91.9%		43.9% — 54.2%		53.8% — 54.4%
Expected term (in years)	0.50		0.50		0.50
Risk free interest rate	0.1% — 0.9%		1.9% — 2.5%		1.8% — 2.3%
Expected dividend yield	_		_		_

In estimating fair value for ESPP purchase rights issued, expected volatility was based on our historical volatility. The expected term is six months, which represents the length of each purchase period. The risk-free interest rates are based on the U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term. 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.

Total share-based compensation expense was comprised of the following, in thousands:

	Years Ended December 31,				
		2020		2019	2018
Research and development	\$	3,960	\$	3,427	\$ 4,623
General and administrative		8,847		5,982	4,031
Total share-based compensation expense	\$	12,807	\$	9,409	\$ 8,654
Stock options	\$	12,561	\$	9,265	\$ 5,889
Employee Stock Purchase Plan		246		144	43
Restricted stock awards		—			2,722
Total share-based compensation expense	\$	12,807	\$	9,409	\$ 8,654

For the year ended December 31, 2018, we recorded approximately \$0.1 million and \$2.6 million of share-based compensation expense related to restricted stock awards granted to employees and nonemployees, respectively.

## 12. Related Party Transactions

Our president and chief executive officer is also the sole managing member and a significant stockholder of Araxes Pharma LLC, or Araxes. The following is a summary of transactions with Araxes for the years ended December 31, 2020, 2019 and 2018:

#### Facility Sublease

We subleased office space in San Diego, California from Araxes pursuant to the Sublease. The Sublease commenced in June 2017 and would have expired on October 31, 2019. In March 2019, the Sublease was amended to extend until April 30, 2020, and the monthly rent increased to approximately \$24,000 per month effective November 1, 2019, corresponding to the increase in Araxes' monthly rent. In April 2020, the Sublease was amended to extend the expiration date to June 30, 2020 with no change to the amount of monthly rent. The Sublease was terminated in June 2020. Rent expense, including operating costs, related to the Sublease and the new Sublease, as applicable, for the years ended December 31, 2020, 2019 and 2018 was approximately \$0.2 million, \$0.4 million and \$0.3 million, respectively.

#### Management Fees

We have a management services agreement with Araxes pursuant to which Araxes pays us monthly fees for management services calculated based on costs incurred by us in the provision of services to Araxes, plus a reasonable mark-up. For the years ended December 31, 2020, 2019 and 2018, we recorded approximately \$0.1 million, \$0.2 million and \$0.7 million, respectively, of management fee income. 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 \$382,000, 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, renewed 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 year ended December 31, 2019, we did not record any reimbursements for research and development expenses provided to Araxes. During the years ended December 31, 2019 and 2018, we recorded reimbursements of approximately \$0.1 million and \$0.2 million, respectively, for research and development services provided to Araxes, which was recorded as a reduction to research and development expenses on the statements of operations and comprehensive loss.

#### Services Agreements

We have a services agreement with Wellspring Biosciences, Inc., or Wellspring, a wholly-owned subsidiary of Araxes, pursuant to which we pay Wellspring for research and development services provided to us in an amount equal to the number of FTE's performing the services, at an annual FTE rate of \$400,000, plus actual expenses as reasonably incurred. The initial term of this services agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the years ended December 31, 2020, 2019 and



2018, we recognized approximately \$0.1 million, \$0.2 million and \$1.0 million, respectively, from research and development services provided to us under this agreement as research and development expense on the statements of operations and comprehensive loss.

We had a services agreement with ALG Partners, Inc., or ALG Partners, a recruiting and temporary staffing agency. Our chief operating officer is an immediate family member of the president of ALG Partners. For the years ended December 31, 2020 and 2019, expenses recognized as related party transactions with ALG Partners were approximately \$0.1 million in both years. There were no related party expenses with ALG Partners for the year ended December 31, 2018.

#### 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 \$0.5 million 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. To date, we have paid Araxes \$0.3 million in milestone payments. Additional payments will be due for each subsequent indication if specified regulatory approvals are achieved. 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. There were no milestone payments to Araxes during the years ended December 31, 2020, 2019 and 2018. Additionally, during the year ended December 31, 2020, we announced the termination of our KO-947 ERK inhibitor program.

#### 13. 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 provide a safe harbor contribution of 3.0% of the employee's compensation, not to exceed eligible limits. For the years ended December 31, 2020, 2019 and 2018, we incurred approximately \$0.6 million, \$0.3 million and \$0.2 million, respectively, in expenses related to the safe harbor contribution.

#### 14. Income Taxes

For the years ended December 31, 2020, 2019 and 2018, we did not record a provision for income taxes due to a full valuation against our deferred taxes.

Our effective income tax rate differs from the statutory federal rate of 21% for the years ended December 31, 2020, 2019 and 2018, due to the following, in thousands:

	Years Ended December 31,				
		2020		2019	2018
Income taxes at statutory federal rate	\$	(18,821)	\$	(13,259)	\$ (12,694)
State income tax, net of federal benefit		(7,684)		(4,810)	(4,447)
Research and development tax credits		(3,169)		(1,664)	(1,469)
Share-based compensation		(304)		708	870
Other		(120)		199	(8)
Valuation allowance		30,098		18,826	17,748
Income tax expense	\$		\$		\$ 



Significant components of our deferred tax assets and liabilities are shown below, in thousands:

	December 31,				
	2020		2019		
Deferred tax assets:					
Net operating loss carryforwards	\$	79,230	\$ 53,5	<b>590</b>	
Research and development tax credit carryforwards		7,944	4,7	'48	
Share-based compensation		2,638	2,1	.34	
Operating lease liabilities		2,278		73	
Accruals		1,915	1,3	353	
Other		641	6	592	
Total gross deferred tax assets		94,646	62,5	590	
Less valuation allowance		(92,523)	(62,4	25)	
Net deferred tax assets		2,123	1	65	
Deferred tax liabilities:					
Operating lease right-of-use assets		(1,868)	(	(68)	
Other		(255)	(	(97)	
Total gross deferred tax liabilities		(2,123)	(1	165)	
Net deferred tax assets	\$		\$	_	

As of December 31, 2020, we had federal net operating loss, or NOL, carryforwards of \$271.4 million, of which \$196.0 million can be carried forward indefinitely. The remaining federal net operating loss carryforwards of \$75.4 million will begin to expire in 2034, unless previously utilized. In addition, as of December 31, 2020, we had state loss carryforwards of \$324.0 million, of which \$323.5 million will begin to expire in 2034 and \$0.5 million will begin to expire in 2030, unless previously utilized. We also have federal and state research and development credit carryforwards of \$8.0 million and \$3.3 million, respectively, as of December 31, 2020. The federal research and development credits will begin to expire in 2034, unless previously utilized. Of the state research and development credits, \$2.0 million will carryforward indefinitely and \$1.3 million will begin to expire in 2031, unless previously utilized.

We file tax returns as prescribed by the tax laws of the jurisdictions in which we operate. Our tax years since inception are subject to examination by the federal and state jurisdictions due to the carryforward of unutilized net operating losses and research and development credits. We have not been, nor are we currently, under examination by the federal or any state tax authority.

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 and therefore has recorded a full valuation allowance against the deferred taxes. The valuation allowance at December 31, 2020 of \$92.5 million reflects an increase of \$30.1 million from December 31, 2019.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, or 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 previously 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 this study, we determined that an ownership change occurred but concluded the annual utilization limitation would be sufficient to utilize our pre-ownership change NOLs and research and development credits prior to expiration. We completed additional studies and concluded no further ownership changes occurred through December 31, 2018. We have not completed a study for 2020 or 2019, however, we do not expect any material limitations to the utilization of NOLs or research and development credits. 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.

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

	 December 31,				
	2020		2019		2018
Gross unrecognized tax benefits at the beginning of the year	\$ 1,741	\$	1,063	\$	615
Increases related to prior year tax positions					—
Increases from tax positions taken in the current year	1,237		678		448
Gross unrecognized tax benefits at the end of the year	\$ 2,978	\$	1,741	\$	1,063

Our practice is to recognize interest and penalties related to income tax matters in income tax expense. There was no accrued interest or penalties included in the balance sheets as of December 31, 2020 and 2019, and we have not recognized interest and penalties in the statements of operations and comprehensive loss for the years ended December 31, 2020, 2019 or 2018.

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.

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## CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

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### LICENSE AGREEMENT

This **LICENSE AGREEMENT** (the "*Agreement*") is made and effective as of the date of execution by the last Party to sign below (the "*Effective Date*"), by and between Kura Oncology, Inc., a company organized and existing under the laws of the State of Delaware having a business address at 11119 North Torrey Pines Road, Suite 125, San Diego, California, ("*Company*"), and Janssen Pharmaceutica NV, a company organized and existing under the laws of Belgium having a business address at Turnhoutseweg 30, 2340 Beerse, Belgium ("*Janssen*"). Company and Janssen are each referred to individually as a "*Party*" and together as the "*Parties.*"

### RECITALS

**WHEREAS,** Janssen owns, directly and through its Affiliates, certain rights relating to its proprietary compound known as tipifarnib (also known as R115777) and a certain back-up compound; and

**WHEREAS,** Company wishes to obtain from Janssen certain rights to develop and commercialize tipifarnib and such back-up compound for human use in the field of oncology, and Janssen is willing to grant such rights in accordance with the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

#### 1. DEFINITIONS AND INTERPRETATION

**1.1 Definitions.** Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings described below, or the meaning as designated in the indicated places throughout this Agreement.

"AAA" means the American Arbitration Association.

"Accounting Standards" means Generally Accepted Accounting Principles in the United States or the International Financial Reporting Standards, as appropriate, as generally and consistently applied in compliance with Applicable Laws throughout the relevant Party's organization at the relevant time.

*"Affiliate"* means, in reference to a particular Party, any corporation or other entity that directly or indirectly controls, is controlled by, or is under common control with such Party. For purposes of this definition, *"control"* or *"controlled"* means ownership, directly or indirectly, of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors in the case of a corporation, or more than fifty percent (50%) of the equity interest in the case of any other type of legal entity (or if the jurisdiction where such corporation or other entity is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such laws, provided that such ownership interest provides actual control over such entity), status as a general partner in any partnership, or any other arrangement whereby an entity controls or has the right to control the board of directors or equivalent governing body of the entity.

"Alliance Manager" shall have the meaning set forth in Section 3.2.

"*Applicable Laws*" shall mean the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees,

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directives, injunctions, orders, permits (including Marketing Authorizations) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item, including to the FCPA, Export Control Laws, and other laws and regulations pertaining to domestic or international corruption, commercial bribery, fraud, embezzlement, or money-laundering.

*"Bankruptcy"* means, with respect to a Party, that: (a) the Party has been declared insolvent or bankrupt by a court of competent jurisdiction; or (b) a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against the Party and such petition has not dismissed within ninety (90) days after filing; or (c) the Party has made or executed an assignment of substantially all of its assets for the benefit of creditors.

*"Bioequivalent"* means, with respect to the drug substance (or active pharmaceutical ingredient) contained in one pharmaceutical product in reference to the drug substance (or active pharmaceutical ingredient) of another pharmaceutical product, that the two substances are recognized by a Regulatory Authority as being both pharmaceutically and therapeutically equivalent to each other.

"Breaching Party" shall have the meaning set out in Section 14.2.

"Business Day" means any day, other than Saturday or Sunday, on which the banks in New York, New York and San Diego, California are generally open for business.

"Claims" shall have the meaning set out in Section 13.1.

"Combination Product" means (a) any Product containing or comprising a Compound and at least one (1) active ingredient that is not a Compound; or (b) any combination of a Product and another pharmaceutical product containing or comprising at least one (1) active ingredient that is not a Compound where the Product and such other product are not formulated together but are sold together and invoiced as one (1) product.

*"Commercialize"* means, in reference to a Product, performing any activities directed to marketing, promoting, offering for sale, or selling a Product for use in the Field, including detailing and medical affairs activities, and distribution and importation activities in support thereof.

"Commercially Reasonable Efforts" means the carrying out of obligations or tasks in a commercially diligent manner consistent with the efforts that a similarly situated company in the pharmaceutical industry would reasonably devote to a research, development or marketing program owned by such company or to which such company has exclusive rights, of similar market potential and at a similar stage of development, based on conditions then prevailing, and taking into account efficacy, safety, regulatory authority approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the products, ability to finance the program, medical and clinical considerations, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the products, including the royalties payable to licensors of patent or other rights, and the costs of development, manufacture and marketing.

"Company Indemnified Party" shall have the meaning set out in Section 12.2.

"Company Patent Rights" means all Development Program Patent Rights that include any claim Covering (a) any Reverted Product or Compound therein for which Janssen exercises its option rights under Section 15.2(b), (b) any method of using such Reverted Product or Compound therein in the Field, or (c) method of Manufacturing such Reverted Product or Compound therein. For the sake of clarity, Company Patent Rights include all related Patent Rights arising in the course of Prosecution of the foregoing Patent Rights.

*"Company Sublicensee"* shall mean any of Company's Affiliates or any Third Party to which Company grants a sublicense of rights granted by Janssen to Company under this Agreement, but not including any Third Party to the extent that it functions as a distributor of Product.

*"Compound"* means: (a) the compound known as R115777 or tipifarnib, which has the structure shown in <u>Exhibit 1</u>, or the compound known as R208176, which has the structure shown in <u>Exhibit 1</u>; or (b) or a Bioequivalent of either



such compound (such as a pharmaceutical salt, acid, base, hydrate, solvate, ester, polymorph, or stereoisomer thereof); or (c) an active metabolite, prodrug, or radiolabeled form of any of the foregoing defined in clause (a) or (b).

"Confidential Information" means any: (i) Know-How or other proprietary or unpublished business, scientific, technical, formulation, process, manufacturing, clinical, non-clinical, regulatory, marketing, financial or commercial information or data, which is generated by or on behalf of a Party or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party either during the Term for purposes contemplated by this Agreement or pursuant to the Confidentiality Agreement, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement; or (ii) sample of any compound, reagent, biological specimen, or other material which one Party or any of its Affiliates has supplied or otherwise made available to the other Party during the Term of this Agreement for purposes contemplated hereunder.

*"Confidentiality Agreement"* means the Confidential Disclosure Agreement between Janssen Research & Development, LLC (an Affiliate of Janssen) and Wellspring Biosciences LLC together with Araxes Pharma LLC dated November 8, 2013.

"Control" (and, with correlative meaning, "Controlled") means, with respect to any Know-How, Patent Rights or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise, but without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) of a Party to grant access, a license or a sublicense of or under Know-How, Patent Rights, or intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to the other Party, without breaching the terms of any agreement with a Third Party.

"Convertible Note" shall have the meaning set out in Section 6.1(b).

*"Cover"* means, with respect to a claim of any Patent Rights in reference to a specified invention or technology, reading on, or literally encompassing such invention or technology under principles of applicable patent law, whether generically or specifically.

"Date of Delivery" shall have the meaning set out in Section 2.2(b).

**"Develop"** means, in reference to a Compound or Product, performing any Pre-Phase I research or development, clinical trials (including Phase I Studies, Phase II Studies, and post-marketing studies), and other activities to study a Compound or Product and develop it toward approval, and to maintain approval, for Commercialization of the Product in the Field, including toxicology and ADME tests, analytical method development, stability testing, process development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, pre- and post-approval clinical studies or trials, regulatory affairs, and regulatory activities.

*"Development Plan"* means the written plan of activities to be performed by or on behalf of Company hereunder to Develop any Licensed Product for use in the Field, as such plan may be supplemented or otherwise amended from time to time.

*"Development Program"* means the activities conducted by or on behalf of Company after the Effective Date in Developing any Compound or Products for use in the Field.

"*Development Program Invention*" means an invention (whether or not patentable) arising in the Development Program directly from any Development activities performed by or on behalf of Company hereunder, including any invention made in the Development Program pertaining to the Manufacture, administration, delivery, dosing, or use in the Field of any Compound or Product.

"Development Program IP" means the Development Program Know-How and Development Program Patent Rights, collectively.

**"Development Program Know-How"** means any and all Know-How generated or developed in the Development Program, which Know-How is necessary or reasonably useful to Develop, Manufacture, use, import, offer for sale, sell, or otherwise Commercialize any Compound or Product in the Field and in the Territory, including for purposes of illustration: any Development Program Inventions; clinical trial data, non-clinical data or other information relating to any form of any Compound or Product, any method of using any Compound or Product in the Field, any method of Manufacturing, or delivering any Compound or Product, the use of any Compound in any Combination Product, any companion diagnostic for use in Developing or Commercializing a Product in the Field, any method of testing, or characterizing any Compound or Product; and any data and other information contained in any regulatory filings relating to any Compound or Product.

**"Development Program Patent Right"** means any Patent Right filed after the Effective Date, and Controlled by Company, that includes (as filed or at any other time during its pendency in a Patent Office) any claim Covering any Development Program Invention and is necessary or reasonably useful to Develop, Manufacture, use, import, offer for sale, sell, or otherwise Commercialize any Compound or Product in the Field and in the Territory. For purposes of illustration, Development Program Patent Rights may include one or more claims Covering any Compound or Product form, any method of using any Compound or Product in the Field, any method of Manufacturing, or delivering any Compound or Product, the use of any Compound in any Combination Product (excluding, for the avoidance of doubt, Patent Rights directed to other active ingredients alone), or any companion diagnostic for use in Commercializing any Product in the Field.

*"Dispute"* means any dispute, claim, or controversy arising from or regarding this Agreement, including the interpretation, application, breach, termination or validity of any provision hereof.

"EMA" means the European Medicines Agency and any successor thereto.

*"Excluded Claim"* means a dispute, controversy or claim that concerns (i) the validity, enforceability or infringement of a patent, trademark or copyright; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

"Exercise Notice" shall have the meaning set out in Section 2.2(c).

*"Existing Third Party Agreements"* means the agreements between Janssen or an Affiliate and a Third Party that are listed in <u>Exhibit 5</u>, as such agreements and Exhibit may be amended from time to time, subject to Section 11.3(a). For clarity, the Existing Third Party Agreements exclude the [\*\*\*] License.

*"Export Control Laws"* shall mean all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including, but not limited to, the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

"FCPA" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended.

"FDA" means the United States Food and Drug Administration and any successor thereto.

"Field" means the treatment, prevention, palliation or diagnosis of any human oncology diseases, disorders or medical conditions, [\*\*\*].

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*"First Commercial Sale"* means the first arm's length sale of a Product in a country in the Territory by Company or any Company Sublicensee to a Third Party following receipt of Marketing Authorization in such country, if such Marketing Authorization is required. For clarity, a sale by Company or Company Sublicensee to a wholesaler shall be considered a commercial sale.

"Generic Product" shall have the meaning set out in Section 6.3(c)(ii).

"Good Clinical Practice" or "GCP" means the then-current good clinical practice standards applicable to the clinical Development of a Compound or Product under Applicable Law, including ICH guidelines.

*"Good Laboratory Practice"* or *"GLP"* means the then-current good laboratory practice standards applicable to the Development of a Compound or Product under Applicable Law, including 21 C.F.R. Part 58.

*"Good Manufacturing Practice"* or *"GMP"* means the then-current good manufacturing practice standards applicable to the Manufacturing of a Compound or Product under Applicable Law, including 21 C.F.R. parts 210 and 211 and all applicable FDA rules, regulations, orders and guidances.

*"IND"* means an investigational new drug application filed with the FDA or the corresponding application filed with the Regulatory Authority in any other country, for authorization to proceed with the clinical investigation of a Product in any country or group of countries, as defined in the Applicable Laws.

"Indemnified Losses" has the meaning set out in Section 12.1.

"Indemnified Party" has the meaning set out in Section 12.3(a).

"Indemnifying Party" has the meaning set out in Section 12.3(a).

"*Indication*" means a specific therapeutic or prophylactic application or use in the Field for which a Compound or Product is being Developed in the Development Program. For the avoidance of doubt, the Parties acknowledge that there may be more than one Indication for any given histology or tumor type, such as for front-line treatment, relapsed refractory treatment, and maintenance treatment of the same tumor type.

"Janssen Indemnified Party" shall have the meaning set out in Section 12.1.

"Janssen IP" means the Janssen Patent Rights and Janssen Know-How.

*"Janssen Know-How"* means all Know-How Controlled by Janssen or any of its Affiliates as of the Effective Date that is specific to any Compound or Product and contained in the records identified in <u>Exhibit 3</u>, as such Exhibit may be amended from time to time, including such Know-How pertaining to: processes; techniques; toxicological, pharmacological, clinical, and chemical data; specifications; medical uses; adverse reactions; and manufacture and quality control methods.

*"Janssen Patent Rights"* means all Patent Rights Controlled by Janssen or any of its Affiliates identified in <u>Exhibit 2(A)</u> and <u>Exhibit 2(B)</u>, and any Patent Rights related thereto Controlled by Janssen or any of its Affiliates that are filed or issued after the Effective Date.

*"Janssen TM Rights"* means the Trademark Rights Controlled by Janssen or any of its Affiliates identified in <u>Exhibit 4</u>, and any Trademark Rights related thereto Controlled by Janssen or any of its Affiliates that are filed or registered after the Effective Date.

*"JJDC"* shall have the meaning set out in Section 6.1(b).

*"Joint Development Committee"* or *"JDC"* means a joint committee established by the Parties pursuant to Section 3.3 to monitor and discuss Development of Product hereunder.

*"Know-How"* means all technical information, know-how and data, including: inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, expertise and information, relevant to the development, manufacture, use or sale of and/or which may be useful in studying, testing, developing, producing or formulating products, or intermediates for the synthesis thereof.

*"MAA"* means an application for the authorization for marketing of a Product in any country or group of countries outside the United States, and all supplements, including all documents, data and other information concerning the Product, as defined in the Applicable Laws and filed with the Regulatory Authority of a given country or group of countries.

"Major Market Country" means each of the following countries: [\*\*\*].

*"Manufacturing"* means, in reference to a Compound or Product, performing any activities to manufacture the Compound or Product into final form for end use in the Field, including producing intermediates or building blocks used to manufacture the Compound of the Product, manufacturing such intermediates or building blocks into Compound (e.g., in bulk form), formulating the Compound into Product in finished dosage form, filling, finishing, packaging, labeling, performing quality assurance testing and release, and shipping and storing the packaged Product.

*"Marketing Authorization"* means the grant of any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use and sale of a Product in a regulatory jurisdiction, including where required, pricing and reimbursement approvals.

"NDA" means a new drug application and all supplements filed with the FDA, including all documents, data and other information concerning a Product which are necessary for, or included in, a Marketing Authorization to use, sell, supply and market the Product in the United States.

"Net Sales" means the gross amounts invoiced on sales, or gross operating revenues earned for other commercial dispositions, of a Product by Company or any Company Sublicensee to a Third Party purchaser that is not a Company Sublicensee in an arms-length transaction, less the following customary deductions, determined in accordance with Accounting Standards, to the extent specifically and solely allocated to such Product and actually taken, paid, accrued, allowed, included or allocated based on good faith estimates in the gross sales prices with respect to such sales (and consistently applied as set forth below):

(a) normal and customary trade, cash and/or quantity discounts, allowances, and credits allowed or paid, in the form of deductions actually allowed or fees actually paid with respect to sales of such Product (to the extent not already reflected in the amount invoiced) excluding commissions for commercialization;

(b) excise taxes, use taxes, tariffs, sales taxes and customs duties, and/or other government charges imposed on the sale of Product to the extent included in the price and separately itemized on the invoice price (but specifically

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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excluding, for clarity, any income taxes assessed against the income arising from such sale) (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable);

(c) outbound freight, shipment and insurance costs to the extent included in the price and separately itemized on the invoice price;

(d) compulsory payments and cash rebates related to the sales of such Product paid to a governmental authority (or agent thereof) pursuant to Applicable Laws by reason of any national or local health insurance program or similar program, to the extent allowed and taken; including government levied fees as a result of healthcare reform policies;

(e) retroactive price reductions, credits or allowances actually granted upon rejections or returns of Product, including for recalls or damaged good and billing errors; and

(f) rebates, chargebacks, and discounts (or equivalent thereof) actually granted to managed health care organizations, pharmacy benefit managers (or equivalent thereof), federal, state/provincial, local or other governments, or their agencies or purchasers, reimbursers, or trade customers.

All aforementioned deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount consistent with Company's or the Company Sublicensee's (as the case may be) business practices consistently applied across its product lines and in accordance with Accounting Standards and verifiable based on its sales reporting system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to Product and other products of Company or the Company Sublicensee such that Product does not bear a disproportionate portion of such deductions.

In the event Product is sold as a Combination Product and the Third Party customer receives a specific discount for such "bundling" of products (for clarity, this situation describes bundling of two or more separate products, each in finished dosage form, and not a fixed combination of two active pharmaceutical ingredients), the Net Sales of such Combination Product, for the purposes of determining royalty payments due hereunder, shall be determined by multiplying the relevant Net Sales by the fraction A/(A+B), where A is the weighted (by sales volume) average sale price in a particular country of the Product in the previous calendar year when sold separately and B is the weighted average sale price in that country in the previous calendar year of the other product sold separately. In the event that such average sale price cannot be determined for either the Product or the other product it has been sold with, in combination, (1) for purposes of determining any royalties due hereunder, the bundling discount granted shall be considered as having been granted in its entirety with respect to the other product only and shall not be applied to the sales of any Product or (2) Net Sales for purposes of determining royalties due shall be multiplied by an adjustment factor which will be the fraction equal to one divided by the number of active ingredients in such Combination Product.

"Non-Breaching Party" shall have the meaning set out in Section 14.2.

"Other Licensee" means any other Third Party identified in a notice by Janssen to Company as having been granted licensee rights to develop and commercialize Compounds or Products outside of the Field.

"Paragraph IV Certification" shall have the meaning set forth in Section 8.3(a).

"Patent Expenses" means the actual out-of-pocket fees, expenses and disbursements (including payments made to Third Party agents) paid by a Party to any Third Party such as its outside patent counsel or agent, or any Patent Offices, in connection with the Prosecution of particular Patent Rights, including the costs of patent interference and opposition proceedings, reissues, and reexaminations.

*"Patent Office"* means the United States Patent and Trademark Office, European Patent Office, or other government agency or office responsible for the examination of patent applications or granting of patents in a country, region, or supra-national jurisdiction.

**"Patent Rights"** means, with respect to a particular invention, any and all original (priority-establishing) patents and patent applications filed anywhere in the world including any claim covering the invention, including provisional and nonprovisional applications, and all related applications thereafter filed including any claim covering such invention or including a common priority right, including any continuations, continuations-in-part, divisional and substitute applications, any patents issued or granted from any such patent applications, and any reissues, renewals, reexaminations, extensions (including by virtue of any supplementary protection certificates) of any such patents, and any confirmation patents, inventor's certificates or registration patents or patents of addition based on any such patents, and all foreign counterparts or equivalents in any country or jurisdiction of any of the foregoing.

"Patent Term Extension" means an extension of the term of any issued patent, or a right of protection equivalent to such an extension, granted under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the member states of the European Union, or another similar law or regulation in any other country or jurisdiction. For clarity, a pediatric extension extending the term of any patent shall not be deemed a Patent Term Extension.

*"Phase I Study"* means a study in humans which provides for the first introduction into humans of a product, conducted in normal volunteers or patients to generate information on product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in Federal Regulation 21 C.F.R. §312.21(a) and its foreign equivalents.

"*Phase II Study*" means a study in humans of the safety, dose ranging and efficacy of a Product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase III Study or to file for 21 C.F.R. Subpart H accelerated approval, as further defined in Federal Regulation 21 C.F.R. §312.21(b) and its foreign equivalents.

**"Phase III Study"** means a pivotal study in humans of the efficacy and safety of a Product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file an NDA or MAA to obtain regulatory approval to market the product, as further defined in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents.

"POC Data Package" means a package of materials comprising copies of written reports providing all raw data (excluding, for the avoidance of doubt, any private patient data or any other information that cannot be provided under Applicable Law) from the POC Trial in Company's possession and Control and other information, including summaries, analyses, findings, conclusions and other results from the POC Trial in Company's possession and Control that is reasonably required for Janssen to make a decision about exercising the ROFN.

"POC Trial" means a Phase II Study of the Compound tipifarnib in HRAS mutant patients in the Field, as more fully described in the Development Plan.

*"Pre-Phase I"* means the initial portion of a development program prior to initiation of a Phase I Study, which starts with the selection of a compound and includes initiation of GMP scale-up activities and GLP toxicological studies. For illustrative purposes, Pre-Phase I development activities typically include toxicological (full-scale GLP toxicology for obtaining approval from a Regulatory Authority to administer Product to humans in clinical trials), pharmacological and any other studies required for filing an IND, as well as Product formulation and manufacturing development necessary to obtain the permission of Regulatory Authorities to begin a Phase I Study.

*"Product"* means any preparation, kit, article of manufacture, composition of matter, material, formulation, dosage or administration form, or product containing or comprising a Compound, alone or together with one or more active or inactive ingredients.

"*Prosecuting*" means, with regard to specified Patent Rights, preparing, filing, prosecuting, maintaining, and defending such Patent Rights in Patent Office proceedings or appeals therefrom, including with respect to any reexamination, reissue, interference, revocation, invalidation, protest, or opposition proceedings. For the avoidance

of doubt, "Prosecuting" excludes any infringement suits or other legal proceedings to enforce the specified Patent Rights, regardless of whether or not such proceedings also involve the defense of the Patent Rights in suit.

*"Regulatory Authority"* means a federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing or sale of a pharmaceutical product in a country or territory, including the FDA and the EMA.

*"Regulatory Exclusivity"* means a right granted by a Regulatory Authority in a country with respect to a Product affording the ability to preclude a Third Party from commercializing a product that could compete with such Product in such country, either through data exclusivity rights, new chemical entity designation, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.

**"Regulatory Filing"** means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to a Compound or Product, or its use or potential or investigative use in humans, including any documents submitted to any Regulatory Authority and all supporting data, including INDs, supportive documents enabling a clinical program, NDAs and MAAs, and all correspondence with any Regulatory Authority with respect to any Compound or Product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

"Reverted Products" shall have the meaning set out in Section 14.2(a).

"ROFN" shall have the meaning set forth in Section 2.2(a).

"ROFN Term" shall have the meaning set forth in Section 2.2(a).

"Royalty Term" shall have the meaning set forth in Section 8.2.

"Senior Officers" means the designated senior representative of Janssen and the Chief Executive Officer of Company.

"Supply Costs" shall have the meaning set out in Section 4.6(b).

"Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments, or fees of any nature (including any interest thereon).

"Term" shall have the meaning set forth in Section 13.1.

"Territory" means the entire world.

"Third Party" means any entity other than Janssen or Company or an Affiliate of Janssen or Company.

"Third Party Infringement" shall have the meaning set forth in Section 8.3(a).

"Third Party Sublicense" shall have the meaning set forth in Section 6.2(d).

"*Trademark Rights*" means all registered and unregistered trademarks (including all common law rights thereto), service marks, trade names, brand names, logos, taglines, slogans, certification marks, internet domain names, trade dress, corporate names, business names and other indicia of origin, together with the goodwill associated with any of the foregoing, and all applications, registrations, extensions, and renewals thereof throughout the world, and all rights therein provided by international treaties and conventions.

"United States" or "U.S." means the United States of America and its territories and possessions.

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"[\*\*\*] License" means the Non-Exclusive License Agreement between [\*\*\*] and Janssen Pharmaceutica NV dated as of [\*\*\*].

"Valid Claim" means, with respect to referenced Patent Rights, (a) a published and pending claim of a patent application that is included in the Patent Rights [\*\*\*] for such claim and [\*\*\*] or [\*\*\*], or (b) [\*\*\*] included in the Patent Rights in any country that (i) [\*\*\*]; (ii) has not [\*\*\*]; (iii) has not been [\*\*\*], or [\*\*\*], has been [\*\*\*]; and (iv) has not been [\*\*\*] or not [\*\*\*] in such country from which [\*\*\*].

#### "ZARNESTRA Mark" means the trademark "ZARNESTRA".

1.2 Interpretations. In this Agreement, unless the context requires otherwise:

(a) the headings are included for convenience only and shall not affect its construction;

(b) references to "persons" includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;

(c) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(d) the words "comprise", "comprising", "contain", "containing", "include" and "including" are used in their open, non-limiting form, and shall be understood to include the words "without limitation" even if not expressly stated;

(e) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;

(f) any reference to a specified enactment, statute, regulation, or other provision of any Applicable Law is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted at the relevant time;

(g) all references to "dollars" or "\$" shall mean United States dollars; and

(h) the Exhibits and other attachments form part of the operative provisions of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the recitals and the Exhibits and attachments. In the event of any inconsistency between the Exhibits and the terms of the body of this Agreement, the terms of the body of this Agreement shall prevail.

# 2. GRANT OF RIGHTS

#### 2.1 Grant of Commercial License to Company.

(a) Under Janssen IP. Subject to the terms and conditions of this Agreement (including Article 6), Janssen hereby grants to Company an exclusive (even as to Janssen and its Affiliates, subject to the ROFN pursuant to Section 2.2), sublicensable (subject to Sections 2.2 and 2.4), license during the Term, under the Janssen IP, to Develop, use, offer for sale, sell, and otherwise Commercialize Compounds and Products in the Field throughout the Territory, and to make, have made, use, and import Compounds and Products throughout the Territory for such purposes.

(b) Under ZARNESTRA® Trademark. Subject to the terms and conditions of this Agreement (including Article 6), Janssen hereby grants to Company an exclusive (even as to Janssen and its Affiliates, subject to the ROFN pursuant to Section 2.2), sublicensable (subject to Sections 2.2 and 2.4), license during the Term, under the Janssen TM Rights, to use the ZARNESTRA Mark and the goodwill pertaining thereto throughout the Territory in the Field, solely in connection with the exercise of Company's license under Section 2.1(a) (including use on labeling, package inserts, monographs, packaging materials, promotional materials, and marketing material). Janssen will not grant any Third Party a license under the Janssen TM Rights to use the ZARNESTRA Mark and the goodwill pertaining thereto in connection with the Commercialization of any Product.

(c) Option for Sublicense under [\*\*\*] License. Janssen, upon authorization by the [\*\*\*], grants Company an exclusive option, exercisable by notice from Company to Janssen at any time hereunder during the term of the [\*\*\*] License, to be granted authorization or a non-exclusive sublicense, under the Patent Rights then Controlled by Janssen under the [\*\*\*] License, solely for purposes of exercising any rights granted to Company under Section

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2.1(a) above, provided that Company agrees to and shall assume all responsibility for making all payments that become due to Janssen's licensor under the [\*\*\*] License on account of any activities by Company or any Company Sublicensees in exercise of its sublicense rights under the [\*\*\*] License. Promptly after Company exercises such option, the Parties shall negotiate and execute a written sublicense agreement documenting the grant of sublicense rights under the [\*\*\*] License to Company and Company's payment obligations as provided above. For clarification, this Section 2.1(c) does not limit Janssen's right to grant to any Third Party an option to be granted authorization or a non-exclusive sublicense under the Patent Rights then Controlled by Janssen under the [\*\*\*] License solely for purposes other than exercising the rights granted to Company under Section 2.1(a) above.

## 2.2 Right of First Negotiation.

(a) ROFN Grant. Subject to the terms and conditions of this Agreement, Company hereby grants to Janssen a first right to negotiate, during the ROFN Term, for an exclusive license back from Company, under the Development Program IP and the Janssen IP and Janssen TM Rights, to Develop and Commercialize Compounds and Products in the Field in any or all countries of the Territory on commercially reasonable terms to be negotiated in good faith by the Parties and that reasonably reflect Company's further Development of Compounds and Products (the "*ROFN*"). Janssen may exercise the ROFN at any time during the sixty (60) -day period following the Date of Delivery by Company to Janssen of the POC Data Package or such longer or shorter period agreed in writing by the Parties (the "*ROFN Term*"). For the avoidance of doubt, until expiration of the ROFN Term, without Janssen's exercise of the Option, Company shall not grant any Third Party any right to Develop (except as a subcontractor on Company's behalf) or Commercialize any Compounds in the Field. If a POC Trial is not initiated or completed within a reasonable time after the Effective Date, then upon a Party's request to the other, the Parties shall confer and attempt to negotiate a redefinition of the ROFN Term that is reasonable in light of the circumstances. For clarity, nothing in this Section 2.2 shall prohibit Company from negotiating and completing any transaction for the sale of all or substantially all of its business or assets (whether by merger, sale of stock, sale of assets, or otherwise), provided that any successor in interest to Company would remain subject to all obligations of Company hereunder, including the ROFN.

(b) Delivery of POC Data Package. Following completion of the POC Trial of a Product under the Development Plan, Company will provide Janssen with the POC Data Package. If, within [\*\*\*] days after the date Company first provides the POC Data Package to Janssen, Janssen provides written notice to Company requesting additional information that would reasonably be expected to be included in the POC Data Package, then Company shall use Commercially Reasonable Efforts to provide Janssen such requested additional information. The date that Company initially provides the POC Data Package or, if Janssen requests additional information in accordance with this Section 2.2(b), the date that Company provides additional information for inclusion in the POC Data Package or advises Janssen in writing that such additional information cannot be provided after using Commercially Reasonable Efforts, as applicable, shall be the "Date of Delivery" of the POC Data Package.

(c) Exercise of ROFN. Subject to the terms and conditions of this Agreement, Janssen may exercise the ROFN at any time during the ROFN Term by sending written notice of such exercise ("*Exercise Notice*") to Company.

(d) Effect of Expiration or Termination of ROFN. If Janssen does not exercise the ROFN during the ROFN Term by providing an Exercise Notice to Company, then the ROFN shall terminate and Company shall be free to grant rights to Compounds and Products in the Field to one or more Third Parties. If Janssen exercises the ROFN during the ROFN Term by providing an Exercise Notice to Company, the Parties will negotiate in good faith to enter into a definitive license agreement within [\*\*\*] days after the Exercise Notice (as may be extended or shortened by written agreement of the Parties, the *"Negotiation Period"*). If Janssen gives Company an Exercise Notice during the ROFN Term but the Parties do not enter into a definitive license agreement during the Negotiation Period, then the obligations to negotiate a definitive license agreement shall terminate and Company shall be free to grant rights to Compounds and Products in the Field to one or more Third Parties, provided that during the [\*\*\*] month period following the last date of the Negotiation Period, Company shall not enter into any agreement granting any Third Party any such rights on financial terms that, overall, are more favorable to the Third Party than those last offered by Janssen to Company during the Negotiation Period.

**2.3 Reservation of Rights.** Subject to the ROFN and to the licenses and sublicenses that are or may be granted to each Party pursuant to Section 2.1 and/or 2.2 and the other terms and conditions of this Agreement, (i) Janssen retains all rights under the Janssen IP and Janssen TM Rights that are not expressly licensed to Company hereunder, including with respect to: (a) chemical compounds, other than Compounds, that are Covered by any claim of the

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Janssen Patent Rights; or (b) applications of Compounds and Products outside the Field, and Company agrees not to practice either any Know-How within the Janssen IP that is Janssen's Confidential Information subject to the confidentiality obligations and restrictions on use under Article 9 or any inventions that are Covered by any Valid Claims of the Janssen Patent Rights, except pursuant to the licenses expressly granted to Company in this Agreement and (ii) Company retains all rights under the Janssen IP that are not expressly sublicensed or licensed to Janssen pursuant to the exercise of the ROFN and to the Development Program IP that are not expressly licensed to Janssen pursuant to the exercise of the ROFN or as provided in Section 14.2(b), and Janssen agrees not to practice either any Development Program Know-How that is Company's Confidential Information subject to the confidentiality obligations and restrictions on use under Article 9 or any inventions that are Covered by any Valid Claims of the Development Program Patent Rights, except pursuant to the licenses expressly granted to Janssen as contemplated by this Agreement. No right or license under any Patent Rights or Know-How of either Party is granted or shall be granted by implication. All rights or licenses under a Party's intellectual property rights are or shall be granted only as expressly provided in the terms of this Agreement or any other written agreement between the Parties.

**2.4 Sublicenses.** Upon expiration of the ROFN Term or, if the ROFN has been exercised during the ROFN Term, expiration of the Negotiation Period pursuant to Section 2.2 above, Company shall have the right to grant sublicenses of the rights granted to it under Section 2.1 of this Agreement to its Affiliates and to Third Parties, provided that:

(a) any sublicense agreement (it being acknowledged that the grant of limited rights to use materials under materials transfer agreements, contract research agreements and clinical trial agreements is not considered a sublicense for this purpose) shall be in writing and, with the exception of the financial terms, be on substantially the same terms as this Agreement;

(b) any such sublicense agreement shall provide for the termination of the sublicense upon termination of this Agreement, except that any such sublicense to a Third Party shall not terminate upon termination of this Agreement but instead shall remain in full force and effect if the sublicensee is not then in material breach of its sublicense agreement and such sublicensee provides to Janssen within [\*\*\*] days after termination of this Agreement a written agreement to be bound as licensee under the terms and conditions of this Agreement as to a field within the Field and a territory within the Territory in which such sublicensee has been granted rights under its sublicense agreement; and

(c) Company shall be liable for all acts or omissions of its sublicensees and shall at all times, and at its own cost, enforce compliance by the sublicensee with the terms of the sublicense agreement.

**2.5 Subcontracting.** Company may subcontract the performance of Development, Manufacturing and Commercialization activities with respect to Compounds and Products to Affiliates or Third Parties at its discretion.

## 3. ALLIANCE MANAGEMENT

**3.1 General.** Except as may otherwise be expressly provided herein or as provided in any definitive agreement entered into by the Parties pursuant to Section 2.2, the Parties acknowledge and agree that Company is undertaking the responsibility for performance of the Development Program.

**3.2 Alliance Managers.** Within [\*\*\*] days after the Effective Date, each Party will appoint a representative having a general understanding of pharmaceutical development and commercialization issues ("*Alliance Manager*"). The Alliance Managers will be primarily responsible for facilitating the flow of information and otherwise promoting routine communications between the Parties hereunder with regard to the Development Program. Each Party may replace its Alliance Manager on written notice to the other Party.

## 3.3 Joint Development Committee.

(a) Establishment of JDC. Promptly after the Effective Date, the Parties shall establish a Joint Development Committee, composed of the Alliance Managers and [\*\*\*] additional representatives from Company and [\*\*\*] additional representatives from Janssen as its members. Each Party will designate by written notice its initial members to serve on the JDC. Each Party may replace its representatives on the JDC by written notice to the other Party.

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(b) JDC Responsibilities. The JDC, which will have no decision-making authority, will monitor the activities of Company in the Development Program and serve as a forum for reviewing Company' progress and results of the Development Program.

(c) JDC Meetings. The JDC shall meet at least semi-annually through completion of the POC Trial and at such other times as the Parties may agree. The first meeting of the JDC shall be held as soon as reasonably practicable following the Effective Date. Meetings shall be held at such place or places as are mutually agreed or by teleconference or videoconference, provided that at least one representative of Janssen and one representative of Company are present at any JDC meeting. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives on the JDC, to attend JDC meetings on an ad hoc basis. The JDC meetings will be chaired by Company. The chairperson shall set agendas for JDC meetings in advance. Company will be responsible for recording, preparing and, within a reasonable time, issuing draft minutes of each JDC meeting to each Party's Alliance Manager for review, who upon their approval shall issue final minutes to the Parties.

(d) Expenses. Each Party shall bear all its own costs, including expenses incurred by its JDC members or by any additional non-member participants of such Party in connection with their attendance at JDC meetings and other activities related to the JDC.

(e) POC Trial Design Input. Promptly after [\*\*\*], Company shall use Commercially Reasonable Efforts to provide the JDC with Company's initial Development Plan, which shall include a description of the clinical study design for the POC Trial. Company may supplement and amend the Development Plan and shall use Commercially Reasonable Efforts to provide the JDC with any such supplement or amendment. The Development Plan, and any supplements or amendments thereto, shall be discussed at a JDC meeting, and Company shall reasonably consider the input from discussions at JDC meetings regarding the design of the POC Trial and any other plans for any Phase II Study or Phase III Study of any Compound or Product in the Development Program.

(f) Review of Plans and Results. In advance of each JDC meeting, Company will provide the JDC representatives with a summary regarding the Development activities performed by or on behalf of Company since the last JDC meeting (if any), including a description of data, results, and other information generated in, and any activities planned for, Developing any Compounds or Products. Without limiting the generality of the foregoing, such summaries shall include (a) the status and results of any Development activities, including, non-clinical and/or preclinical studies and activities (including toxicology and pharmacokinetic studies); and (b) the Regulatory Filings and Marketing Authorization applications with respect to any Compound and Product that Company or any Company Sublicensee has filed, sought, or obtained.

(g) No Authority to Modify Agreement. For the avoidance of doubt, the JDC shall have no authority to modify any provision set forth in the body or in any Exhibit of this Agreement, including any payment conditions or terms, periods for performance, or obligations of the Parties as set forth in this Agreement, which may be modified only by written agreement of the Parties.

(h) Disbanding of the JDC. Upon expiration of the ROFN Term or, if the ROFN has been exercised during the ROFN Term, expiration of the Negotiation Period, the JDC shall be disbanded.

## 4. DEVELOPMENT PROGRAM

**4.1 Responsibility; Diligence.** Company (directly and through Company Sublicensees) will be responsible, at its own expense, for further Development of Compounds and Products in the Field in the Territory. Company (directly and through Company Sublicensees) shall use Commercially Reasonable Efforts to Develop [\*\*\*] through Marketing Authorization in [\*\*\*]. For the avoidance of doubt, the foregoing diligence requirement shall not be construed so as to necessitate that Company seek Marketing Authorization in all [\*\*\*] simultaneously.

**4.2 Records.** Company shall, and shall require its subcontractors to, maintain in accordance with Applicable Law complete and accurate records in segregated laboratory notebooks of all work conducted in furtherance of the Development of Compounds and Products, including all raw data, observations, conclusions, and analyses. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in sufficient detail and in a manner appropriate for patent and regulatory purposes.

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**4.3 Use of Animals.** In conducting any Development Program activities involving any animals, (i) the animals shall be provided with humane care and treatment in accordance with current generally accepted veterinary practice, and (ii) in accordance with Janssen's Guidelines on the Care & Use of Laboratory Research Animals appended to this Agreement as <u>Exhibit 6</u>.

**4.4 Standards for Conduct.** Company shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, Development activities with Compounds and Products in in good scientific manner and in compliance with Applicable Law, Good Clinical Practice, and Good Laboratory Practice.

**4.5 Development Reports.** Following the disbanding of the JDC, Company shall submit to Janssen [\*\*\*] written progress reports by [\*\*\*] of the Term covering Company's (and Company Sublicensees') activities related to the Development of each Product in the Field in the Territory, the status of obtaining Marketing Authorization, and other activities undertaken in order to meet the diligence requirement set forth in Section 4.1, until First Commercial Sale of such Product in the Field in the United States, which reports will be again required if, and for so long as, all sales of such Product are suspended or discontinued in all countries during the Term. Upon Janssen's reasonable request, Company shall supplement any such Development progress report with other information in its possession that is pertinent to the Development efforts with respect to Products in the Field in the Territory for as long as the respective diligence obligation under Section 4.1 applies. For the avoidance of doubt, all information contained in such reports shall be deemed Company's Confidential Information.

## 4.6 Drug Supply for Development.

(a) **Responsibility.** Following the Effective Date, Company will be solely responsible, itself and through its Affiliates and sublicensees at their own expense, for Manufacturing or having Manufactured Compound and Product for Development purposes, including for producing clinical supplies. The Manufacturing of supplies of Compound and Product for human use shall be performed in accordance with Applicable Law and Good Manufacturing Practice.

(b) Supply from Janssen's Inventory. Notwithstanding the foregoing, if Company wishes to acquire all quantities of Compound or Product along with the intermediate T1994 used in the synthesis of a certain Compound ("Existing Supply") from Janssen's existing supply, including for purposes of Kura supplying patients in accordance with Section 4.6(c) below, Company will notify Janssen within [\*\*\*] days of the Effective Date, and Janssen will thereafter ship promptly to Company or its designee, [\*\*\*] related to the Existing Supply [\*\*\*] (*"Supply Costs"*), such available Existing Supply, which is provided to Company "AS IS" except for confirmation that such Existing Supply is being provided [\*\*\*]. Company agrees to pay the Supply Costs. Upon receipt of such Existing Supply, the Supply costs shall be due from Company and payable within [\*\*\*] days of Company receipt of an invoice from Janssen. Company acknowledges that any such supply of EXISTING SUPPLY is without any representations or warranties except as expressly provided in this Section 4.6(b), including any warranty of merchantability or fitness for a particular purpose. Company further acknowledges that, if Company doesn't notify Janssen within [\*\*\*] days of the Effective Date, and that there is no guarantee that there will be any amount available at any given time for transfer to Company under this Section 4.6(b).

(c) Supply to Existing Patients. Notwithstanding Section 4.6(b), Company acknowledges that there are ongoing clinical trials under certain agreements, and a certain number of patients continue to receive Compound pursuant thereto or thereafter for compassionate use purposes. Company agrees that it shall assume the responsibility to continue to supply of Compound to such patients under such purposes or allow Janssen retain supply to supply such patients under such purposes. Company shall notify Janssen within [\*\*\*] days from the Effective Date whether or not it will allow Janssen to supply such patients for such purposes.

**4.7 Know-How Transfer and Assistance.** Janssen shall transfer, at Company's expense, to Company or its designee, copies of the Janssen Know-How documentation listed in <u>Exhibit 3</u> (including any updates thereto) (which shall be treated as Janssen's Confidential Information, with respect to Janssen Know-How and during the Term of this Agreement, and Company's Confidential Information too), including that relating to Development and Manufacture of the Compound and Product as used by or on behalf of Janssen or its Affiliates in any clinical or non-clinical studies, and shall complete shipment (in one shipment or on a rolling basis) of all Janssen Know-How within Janssen's or its Affiliates' possession during the period running [\*\*\*] days from the Effective Date and use

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Commercially Reasonable Efforts to transfer any other Janssen Know-How within a reasonable timeframe. Janssen will prioritize for shipment copies of Regulatory Filings within the Janssen Know-How documentation. For the period running [\*\*\*] days after Company's receipt of the copies of the Janssen Know-How and for no more than a cumulative of [\*\*\*] hours, Janssen will provide reasonable assistance requested by Company to facilitate its understanding of the Janssen Know-How by making one representative of Janssen reasonably available for meetings or teleconferences and e-mail communications regarding the content of the Janssen Know-How documentation. In addition, if Janssen determines that it or its Affiliate has the right to assign or otherwise transfer under Applicable Law and any Existing Third Party Agreements, Janssen will itself or through its Affiliates as appropriate, assign or otherwise transfer to Company (considering, e.g., Applicable Law), any Regulatory Filings pertaining to the Compound tipifarnib relevant to its use in the Field that are held by Janssen or any of its Affiliates, or, if Janssen determines that it or its Affiliate does not have the right to assign or otherwise transfer any Regulatory Filings pertaining to the Compound tipifarnib relevant to its use in the Field, provide Company with a right of cross-reference or access to any such Regulatory Filings, with the right to grant Company Sublicensees and Third Parties performing Development or Manufacturing activities on behalf of Company or Company Sublicensees the further right of cross-reference or access to such Regulatory Filings, as appropriate. Janssen and its Affiliates will not assign or otherwise transfer any Regulatory Filings pertaining to any Compound relevant to its use in the Field that are held by Janssen or any of its Affiliates to any Other Licensee. To the extent Regulatory Filings are assigned or otherwise transferred to Company, Company (directly or through Company Sublicensees) shall provide Janssen or its Affiliates with a right of cross-reference or access to any such Regulatory Filings to the extent Janssen or any of its Affiliates develops Compounds outside the Field and will grant to any Other Licensee a right of cross-reference or access to any such Regulatory Filings for purposes outside the Field, as appropriate. For clarity, Janssen is not obligated to provide any other assistance beyond that which is set forth in Section 4.7, except as may be agreed upon by the Parties in a separate written service agreement.

**4.8 Regulatory Submissions.** Company (directly or through its Company Sublicensees) shall be responsible for submitting (or having submitted) all Regulatory Filings after the Effective Date, for maintaining a safety database, and for obtaining and maintaining all Marketing Authorizations for Products in the Field. Company (directly or through Company Sublicensees) shall use Commercially Reasonable Efforts to coordinate with Janssen or with any Other Licensee as necessary to compile, maintain, and report adverse event and other relevant safety data from use of Compounds and Products as required by Applicable Laws. Janssen agrees to include in any license agreement with an Other Licensee a comparable agreement of such Other Licensee to coordinate with Company as necessary to compile, maintain, and report adverse event and other relevant safety data from use of Compounds and Products as required by Applicable Laws. All Regulatory Filings submitted in connection with obtaining Marketing Authorizations to test or market a Compound or Product in the Field after the Effective Date shall be owned by and submitted by and in the name and at the sole expense of, Company or a Company Sublicensee or subcontractor. If Janssen exercises the ROFN, Company will reasonably cooperate with and provide reasonable assistance to Janssen, in connection with the transition of development activities and filings to any Regulatory Authority relating to the Program Compounds or Products in the Field, including by executing any required documents, transferring to Janssen all of Company's right, title and interest in and to the IND filed by Company with respect to the Product, and providing copies of all reasonably required documentation.

**4.9 Later Discovered Know-How**. In the event that after the Effective Date Janssen or the Company discovers Know-How Controlled by Janssen or its Affiliates which was not listed in Exhibit 3 and is necessary or reasonably useful to Develop, Manufacture, use, import, offer for sale, sell, or otherwise Commercialize any Compound or Product in the Field in the Territory (collectively "Discovered Know-How"), that is readily available, Janssen will provide such Discovered Know-How to the Company and such Discovered Know-How shall be deemed to be Janssen Know How under this Agreement.

## 5. COMMERCIALIZATION

**5.1 Responsibility; Diligence.** Company (directly and through Company Sublicensees) will be responsible, at its own expense, for Commercialization of Compounds and Products in the Field in the Territory. Company (directly and through its Company Sublicensees) shall use Commercially Reasonable Efforts to Commercialize Products in countries where Marketing Authorization has been obtained.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

**5.2 Legal Compliance.** Company agrees that in performing any Commercialization activities with respect to any Compounds or Products as contemplated hereunder, it shall, and shall use reasonable measures to cause its Affiliates, Company Sublicensees, and subcontractors to, comply with all applicable current international regulatory standards and other Applicable Laws.

**5.3 Commercialization Reports.** Company shall submit to Janssen annual written progress reports concurrently with the royalty report provided pursuant to Section 7.1(c) for the last calendar quarter of each year of the Term following First Commercial Sale of the applicable Product in the Field in the United States covering Company's (and any of Company Sublicensees') activities related to the Commercialization of each Product in the Field in the Territory undertaken in order to meet the diligence requirement set forth in Section 5.1. Upon Janssen's reasonable request, Company shall supplement any such progress reports with other information in its possession that is pertinent to the diligence requirement set forth in Section 5.1.

**5.4 Use of ZARNESTRA Mark.** Company shall have the right, but not the obligation, to use the ZARNESTRA Mark as provided in Section 2.1(b). All goodwill associated with Company's use of the ZARNESTRA Mark will inure to the benefit of Janssen. All representations of the ZARNESTRA Mark that Company intends to use shall first be submitted to Janssen for approval, such approval not to be unreasonably withheld or delayed. Janssen will notify Company promptly in writing with respect to any objections Janssen may have with respect to the ZARNESTRA Mark use and Company shall promptly comply with Janssen's reasonable directions regarding the use of the ZARNESTRA Mark. For the avoidance of doubt, this Agreement does not grant Company any license or other rights to any other trademarks, designs, logos, slogans, taglines, trade names or trade dress that Janssen owns or otherwise controls.

# 6. FINANCIAL PROVISIONS

## 6.1 Upfront and Convertible Note.

(a) As partial consideration for the rights and obligations as set forth herein, Company shall pay Janssen a non-refundable license fee of one million US dollars (US\$1,000,000). Janssen shall invoice Company promptly after the Effective Date, and Company shall make such payment within [\*\*\*] days of receipt thereof.

(b) Not more than [\*\*\*] days following the Effective Date, and subject to Janssen's receipt of the funds set forth in subsection (a) above, Johnson & Johnson Innovation—JJDC, Inc., an Affiliate of Janssen ("*JJDC*"), will loan one million US dollars (\$1,000,000) to Company on the terms set forth in the form of convertible promissory note attached hereto as <u>Exhibit 9</u> (the "*Convertible Note*").

(c) In connection with this Section 6.1, JJDC will make the representations and warranties to Company set forth on Exhibit 10.

(d) The entirety of this Section 6.1 shall survive termination of this Agreement to the extent that the provisions of this Section 6.1 have not been complied with in full prior to such termination.

## 6.2 Milestone Payments.

(a) Development Milestones. Each of the milestone payments identified in this Section 6.2(a) shall be due one time only upon the first achievement by Company or any Company Sublicensee of the specified milestone event with respect to any Compound or Product in the Field. For clarity, the milestone payment for each of milestone events described in clauses (i) and (iii) specified below shall be due one time only, and the milestone payment for each of milestone events described in clauses (ii) and (iv) shall be due one time only with respect to each additional (e.g., second, third, fourth, etc.) Indication. In further consideration of the license rights granted to Company under Section 2.1, Company shall promptly provide written notification to Janssen, at Beerse (Belgium), Turnhoutseweg 30, Attention: Finance Manager ([\*\*\*]) upon achievement of each Development Milestone. Such notification shall indicate that the Development Milestone was achieved and request that Janssen send a written invoice for such milestone to a specific address, if such address is different than that indicated in Section 15.11: Notices. Within [\*\*\*] days of the receipt of the invoice for each of the corresponding Development Milestones listed below, Company shall pay by wire transfer the amount listed in each invoice to Janssen to the bank account identified in Section 7.2.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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Development Milestone Event	Milestone Payment (USD)			
(i) [***]	\$	[***]		
(ii) [***]	\$	[***]		
(iii) [***]	\$	[***]		
(iv) [***]	\$	[***]		

(b) Sales Milestones. In further consideration of the license rights granted to Company under Section 2.1, solely upon the first occurrence during the Term of aggregate worldwide Net Sales of all Products (cumulative over time, whether within [\*\*\*] or more after the First Commercial Sale) surpassing the sales threshold identified below, Company shall immediately provide written notification to Janssen, at Beerse (Belgium), Turnhoutseweg 30, Attention: Finance Manager ([\*\*\*]) upon achievement of each Sales Milestone. Such notification shall indicate that the one-time corresponding sales milestone was achieved and request that Janssen send a written invoice for such milestone to a specific address, if such address is different than that indicated in Section 15.2: Notices. Within [\*\*\*] days of the receipt of the invoice for each of the corresponding Sales Milestones listed below, Company shall pay by wire transfer the amount listed in each invoice to Janssen to the bank account identified in Section 7.2. For the avoidance of doubt, if in the same reporting period multiple sales milestones are first attained, then the payments for all such milestones attained as specified below shall be due.

Sales Threshold (aggregate worldwide Net Sales of Products) in US dollars	Milestone Payment (USD)
>[***]	\$ [***]
> [***]	\$ [***]
> [***]	\$ [***]
>[***]	\$ [***]

(c) Clarification. For the avoidance of doubt, different milestones as specified in this Section 6.2 may be achieved by the same or a distinct Compound or Product. Additionally, should a Compound or Product be replaced or backed up by another Compound or Product, no additional milestone payments shall be due under Section 6.2 for milestone events completed by the replacement or back-up Compound or Product for which corresponding milestone payments were previously made to Company with respect to such replaced Compound or Product.

(d) Third Party Sublicense. In the event that Company sublicenses any of its rights to Compounds and/or Products to any Company Sublicensee that is a Third Party ("Third Party Sublicense"), Company would pay Janssen [\*\*\*] percent ([\*\*\*]%) of all monetary compensation received by Company from the Company Sublicensee, including upfront and lump-sum payments and milestone payments, in consideration of the grant of a sublicense under the rights granted by Janssen to Company under this Agreement (excluding the amounts described below); however, (i) in the case of milestone payments for the milestone events set forth in Section 6.2, Company would pay Janssen the greater of (A) [\*\*\*] percent ([\*\*\*]%) of such milestone payments and (B) such milestone payment otherwise due under Section 6.2 of this Agreement, but not both; and (ii) if Company receives a milestone from a Third Party for a milestone event that is not listed in Section 6.2, Company would pay Janssen [\*\*\*] percent ([\*\*\*]%) of the milestone from the sublicensee. For example, if Company receives a milestone payment of \$[\*\*\*] from a Company Sublicensee that is a Third Party for receipt of [\*\*\*], Company would pay Janssen \$[\*\*\*] (which is greater than [\*\*\*] percent ([\*\*\*]%) of \$[\*\*\*]). In no event will the payment under this Section 6.2(d) apply to: (i) debt financing of Company or its Affiliate, (ii) amounts received by Company or its Affiliate as the purchase price, at fair market value, for equity securities of Company or its Affiliate; (iii) reimbursements to Company or its Affiliate of costs for filing, prosecuting and maintaining Patent Rights; (iv) reimbursement to Company or its Affiliate for the cost of research and/or development activities performed or services or materials provided by Company or its Affiliate, and (v) royalty payments or similar payments based on Net Sales. Company shall immediately provide written notification to Janssen, at Beerse (Belgium), Turnhoutseweg 30, Attention: Finance Manager ([\*\*\*]) upon achievement of each Third Party Sublicense. Such notification shall indicate that a Third Party Sublicense was achieved and request that Janssen send a written invoice for any payment then due under this Section 6.2(d) to a specific address, if such address is different than that indicated in Section 15.2: Notices. Within [\*\*\*] days of the receipt of the invoice for any payment due under this Section 6.2(d), Company

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shall pay by wire transfer the amount listed in each invoice to Janssen to the bank account identified in Section 7. If any Third Party Sublicense monetary compensation received by Company is in a currency other than US Dollars, the payment due under this Section 6.2(d) shall be calculated in such currency and then converted into their US Dollar equivalent using the closing exchange rate as published by The Wall Street Journal, Western U.S. Edition for the day the Third Party Sublicense compensation was achieved by Company.

## 6.3 Royalty Payments.

(a) Royalty Basis and Rate. In partial consideration of the license rights under Section 2.1, royalties shall be due from Company on aggregate Net Sales of Products during the Royalty Term, and royalties shall be determined on a Product-by-Product and country-by-country basis where either: (i) [\*\*\*]; (ii) [\*\*\*]; or (iii) [\*\*\*] years from First Commercial Sale. Royalties due each calendar year of the Royalty Term shall be calculated by multiplying the applicable incremental Net Sales of Products against the applicable royalty rate identified below, subject to any applicable adjustments or reductions provided for in Section 6.3(c), with each royalty rate referred to below applying only to that increment of annual Net Sales that falls within the incremental sales bracket for such royalty rate.

	Royalty
Aggregate annual Net Sales of Products	Rate
Less than or equal to \$[***] million	[***]%
Greater than \$[***] million	[***]%

To illustrate, if, for example, cumulative annual worldwide Net Sales of Products upon which royalties are due and payable as provided in this Section 6.3 were \$[\*\*\*] during any year of the Royalty Term, then absent any adjustments or reductions pursuant to Section 6.3(c), the royalties due would be calculated as follows: ([\*\*\*]) + ([\*\*\*]). For the avoidance of doubt, royalties due under this Section 6.3 shall be payable only once with respect to the same unit of Product, and different formulations (e.g., dosage strengths, delivery forms) of a Compound and Bioequivalents thereof shall be deemed the same Product.

(b) Royalty Term. Royalties due on Net Sales of Products will be payable on a Product-by-Product and country-by-country basis until the later of (a) the expiration of the last to expire Valid Claim of the Janssen Patent Rights Covering either the Product or the Compound contained therein as a composition or any method of use of such Product or Compound in the Field in such country, (b) the expiration of any Regulatory Exclusivity with respect to such Product in such country, and (c) ten (10) years from First Commercial Sale (the *"RoyaltyTerm"*). Following the Royalty Term on a Product-by-Product and country-by-country basis, Company's licenses with respect to such Product in such country under Section 2.1 shall continue in effect, but become fully paid-up, royalty-free, perpetual and irrevocable.

## (c) Adjustments to Royalties.

(i) Compulsory Licenses. If at any time in any country a Third Party shall, under the right of a compulsory license granted or ordered to be granted by a competent governmental authority in a given country (other than failure of a court to enjoin infringement as a remedy in a patent infringement proceeding), be granted a license, under any Janssen Patent Rights licensed to Company hereunder, to sell in such country, or manufacture for distribution or sale by or on behalf the government in such country, any Product with respect to which royalties are payable pursuant to Section 6.3(a) at a royalty rate that is less than the applicable royalty rate for a given tier of incremental annual Net Sales as provided in Section 6.3(a), and such Product is sold by such Third Party during any calendar quarter during the Royalty Term, then [\*\*\*].

(ii) Generic Competition. In the event that one or more Third Parties (other than any Company Sublicensee) markets a product containing or comprising a Compound and the same other active ingredient(s), as applicable, as a Product being Commercialized by Company or Company Sublicensees in a given country (a "Generic Product"), from and after the [\*\*\*] in which the [\*\*\*] by Company and Company Sublicensees [\*\*\*] by Company and Company Sublicensees [\*\*\*] by Company and Company Sublicensees [\*\*\*] Generic Product in such country[\*\*\*] and such [\*\*\*] by Company can be [\*\*\*] the royalties to be paid by Company on Net Sales of such Product in such country [\*\*\*] of the royalties otherwise due to Janssen [\*\*\*] with respect to such Product in such country.

(iii) Limitation. In no event will the adjustments under Section 6.3(c)(i) and (ii) taken together reduce the royalties otherwise due to Janssen in any quarter with respect to a Product in a country by more than [\*\*\*] percent ([\*\*\*]%).

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED



## 7. REPORTS AND PAYMENT TERMS

#### 7.1 Payment Terms.

(a) Notice of Milestone Events and Milestone Payments. Written notice of achievement of each milestone event shall be provided as set forth in Section 6.3(a) or (b), as applicable. Payments for achieving milestones shall be made as set forth in Section 6.3(a) or (b), as applicable.

(b) Invoices. Any payment for an amount due to Janssen under this Agreement shall be payable, except as otherwise expressly provided herein, within [\*\*\*] days after Company' receipt of an invoice from Janssen for such amount. Each invoice shall specifically refer to this Agreement.

(c) Royalty Reporting and Payments. Within [\*\*\*] days after the end of each calendar quarter Company shall submit to Janssen a sales report to the address listed in Section 15.2 setting forth, on a Product-by-Product and country-by-country basis, the gross sales, the deductions taken from gross sales, the Net Sales of Product and a calculation of the amount of royalty payment due on such Net Sales. This report shall also include the exchange rates and other methodology used in converting Net Sales into US dollars, from the currencies in which sales were made in order to determine the appropriate royalty tier and royalty payable. Royalty payments shall made within [\*\*\*] days from receipt by Company of an invoice from Janssen for the amount reflected in the sales report under this Section 7.1 (c).

**7.2 Remittance.** All payments shall be made in immediately available funds by electronic transfer, by Company or an Affiliate on its behalf, to the bank account identified below or such other bank account as Janssen may designate in writing to Company. Any payments due and payable under this Agreement on a date that is not a Business Day may be made on the next Business Day. If, at any time, legal restrictions prevent the prompt remittance of part of or all of the royalties due hereunder with respect to any country where Products are sold, Company shall have the right and option to make such payments by depositing the amount thereof in local currency to Janssen's account in a bank or depository in such country or by using such lawful means or methods as Company may determine.

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Name of Bank: [***]
Bank address: [***]
[***]
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Company Name and Address: Janssen Pharmaceutica NV Turnhoutseweg 30 B2340 Beerse, Belgium

Taxpayer Identification Number: [\*\*\*] SWIFT Code: BIC code: [\*\*\*] Account Number: [\*\*\*] / IBAN : [\*\*\*]

**7.3 Currency.** All payments under this Agreement shall be payable in United States dollars. With respect to sales of a Product invoiced in a currency other than US dollars, such amounts and the amounts payable hereunder shall be converted into their US dollars equivalent using an exchange rate equal to the simple monthly period average of the rates of exchange for the currency on the first and last day of each calendar month of the country from which such payments are payable as published by *The Wall Street Journal*, Western U.S. Edition, during the calendar quarter in which the applicable sales were made.

### 7.4 Taxes.

(a) Company will make all payments to Janssen under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment.

(b) Any Tax required to be withheld on amounts payable under this Agreement will be paid by Company on behalf of Janssen to the appropriate governmental authority, and Company will furnish Janssen with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Janssen and deducted from the

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amounts otherwise payable under this Agreement. All payments to Janssen under this Agreement are inclusive of VAT, if any.

(c) Company and Janssen will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Company to secure a reduction in the rate of applicable withholding Taxes. On or before the Effective Date, Janssen will deliver to Company an accurate and complete Internal Revenue Service Form W-8BEN-E certifying that Janssen is entitled to the applicable benefits under the Income Tax Treaty between Belgium and the United States.

## 7.5 Records and Audit Rights.

(a) Maintenance of Records. Each Party shall keep (and, in the case of Company, Company shall cause the Company Sublicensees to keep) complete, true and accurate books and records in accordance with its Accounting Standards in sufficient detail for the other Party to determine the payments due and costs incurred under this Agreement, including with respect to Patent Expenses and royalties. Each Party will keep such books and records for at least [\*\*\*] years following the date of the payment to which they pertain.

(b) Audit Right. Upon the written request of Janssen with respect to payments made by Company pursuant to Article 6, not more than [\*\*\*] in each calendar year, Company shall permit an independent certified public accounting firm of nationally recognized standing selected by Janssen and reasonably acceptable to Company to have confidential access during normal business hours to such of the records of Company and its applicable Company Sublicensees as may be reasonably necessary to verify the accuracy of the payments made under this Agreement for any period ending not more than [\*\*\*] years prior to the date of such request. The accounting firm shall provide each Party a correct and complete copy of the report summarizing the final results of such audit, which shall be treated as Company's Confidential Information. Janssen shall obligate its accounting firm to keep Company's information confidential, and shall at the request of Company cause Janssen's accounting firm to execute a reasonable confidentiality agreement prior to commencing any such audit.

(c) Audit Fees. The fees charged by such accounting firm shall be paid by Janssen; provided, however, that if the audit uncovers an under- or over-payment in favor of Company exceeding [\*\*\*] percent ([\*\*\*]%) of the total amount due in accordance with this Agreement, then the fees of such accounting firm shall be paid by Company. Any underpayments discovered by such audit will be paid promptly by Company within [\*\*\*] days of the date that Janssen delivers to Company such accounting firm's written report, or as otherwise agreed upon by the Parties, plus interest calculated in accordance with Section 7.6. For any overpayments discovered by such audit Company shall receive a credit equal to such overpayment against the royalty otherwise payable to Janssen.

**7.6 Late Payments.** Interest shall be payable by Company on any amounts payable to Janssen under this Agreement which are not paid by the due date for payment. All interest shall accrue and be calculated on a daily basis (both before and after any judgment) at the rate of [\*\*\*] percent ([\*\*\*]%) per annum above the then-current prime rate quoted by Citibank in New York City (but in no event in excess of the maximum rate permissible under Applicable Laws), for the period from the due date for payment until the date of actual payment. The payment of such interest shall not limit Janssen from exercising any other rights it may have as a consequence of the lateness of any payment.

## 8. INTELLECTUAL PROPERTY RIGHTS

**8.1 Ownership.** Inventorship of all inventions arising in the course of the Development Program and Development Program Patent Rights shall be determined in accordance with inventorship pursuant to U.S. patent laws

## 8.2 Patent Prosecution.

## (a) Janssen Patent Rights.

(i) Prosecution Control. Janssen will have the right to control the Prosecution of the Janssen Patent Rights, using outside patent counsel directed by Janssen, provided that Company shall have the right to review and comment on drafts of substantive patent submissions prior to their filing in Patent Offices. Company shall reimburse Janssen for [\*\*\*] percent ([\*\*\*]%) of [\*\*\*] incurred by Janssen in the Prosecution of Janssen Patent Rights in the Territory. Janssen shall keep Company regularly and fully informed of the status of Janssen Patent Rights in the Territory and provide copies of all substantive documentation submitted to, or received from, the Patent Offices in connection therewith. After the Effective Date, Janssen shall not, without Company prior written consent, forgo or discontinue

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Prosecution of any Janssen Patent Right in any country in the Territory prior to obtaining from the Patent Office having jurisdiction in such country allowance or issuance of at least one claim Covering a Compound being Developed or Commercialized by Company in such country.

(b) Development Program Patent Rights. At all times during the Term (subject to the terms of any definitive agreement entered into by the Parties prior to the end of the Negotiation Period), Company shall have the sole right to Prosecute the Development Program Patent Rights at its own expense.

(c) Protection of Privileged Advice Shared for Common Interest. For the avoidance of doubt, any opinions or other advice of any qualified legal personnel (whether a

patent attorney or other counsel) representing a Party hereunder communicated to the other Party or both Parties, directly by such legal personnel or indirectly such as through a patent liaison for common interest purposes contemplated hereunder (including under Section 8.3), shall be held in strict confidence to protect the privileged nature thereof, and not disclosed to any Third Party without the prior written consent of both Parties, each under the advice of its respective legal counsel.

## 8.3 Patent Infringement.

(a) Notice. During the Term, each Party will promptly notify the other of (i) any actual or threatened infringement by a Third Party of any Janssen Patent Rights of which it becomes aware, including any certification filed by a Third Party pursuant to 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) or any notice under comparable U.S. or foreign law (a "*Paragraph IV Certification*"), which references the foregoing; or (ii) any actual or threatened challenge to any Janssen Patent Rights by a Third Party (collectively, "*Third Party Infringement*"). The Parties will consult with each other through each Party's patent attorneys to attempt to agree on a joint program of action in response to any Third Party Infringement.

(b) Action Against Third Parties. If the Parties fail to agree on a joint program of action with respect to Third Party Infringement of any Janssen Patent Rights, subject to this Section 8.3(b), Janssen will have the sole right to bring and control any legal action (including by initiating any lawsuit or other proceeding) as it reasonably determines appropriate in connection with the Third Party Infringement with respect to Janssen Patent Rights, and if the action involves a Third Party's sales of a Product in the Field, Company shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. With respect to any Third Party Infringement with respect to Janssen Patent Rights that involves a Third Party's sales of a Product in the Field, if Janssen fails to bring any legal action with respect to, or to terminate, such Third Party Infringement (i) within [\*\*\*] days following the notice of alleged infringement with respect to such Janssen Patent Rights, but in any event no less than [\*\*\*] days before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, or (ii) solely with respect to a Paragraph IV Certification involving such Janssen Patent Rights, within the later of [\*\*\*] days following Company's receipt of notice thereof and [\*\*\*] Business Days before the statutory deadline under Applicable Law, upon written agreement from all Other Licensee(s), not to be unreasonably withheld or delayed, Company shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(c) Conduct of Enforcement Action. The Party conducting any such action under this Section 8.3 shall have full control over the conduct of an action under this Section 8.3, including settlement thereof; provided, however, that in no event shall either Party, through any such action, enter into any settlement arrangement or make any admission of invalidity of, or otherwise impair the other Party's rights in any Janssen Patent Rights without the other Party's prior written consent.

(d) Assistance. At the request and expense of the Party controlling a Third Party Infringement action with respect to Janssen Patent Rights, the other Party shall provide reasonable assistance in connection with such Third Party Infringement action, including by executing any required documents, participating in discovery (including producing documentation and providing access to employees or relevant persons), and joining as a party to the action if required. The Party controlling such Third Party Infringement action shall reimburse the reasonable out-of-pocket expenses of the other Party incurred in providing such assistance within [\*\*\*] days after receipt of an itemized invoice and supporting documentation therefor.

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(e) Allocation of Awards. Unless otherwise agreed to by the Parties as part of any cost-sharing arrangement, any recoveries resulting from an action under this Section 8.3 relating to a claim of Third Party Infringement with respect to Janssen Patent Rights (after payment of costs and expenses relating to such action incurred by each Party) will be [\*\*\*]; provided, however, that, if Company brought and controlled such action, [\*\*\*].

**8.4 Development Program Patent Rights.** At all times during the Term (subject to the terms of any definitive agreement entered into by the Parties prior to the end of the Negotiation Period), (a) Company shall have the sole right to sole right to bring and control any legal action (including by initiating any lawsuit or other proceeding) as it reasonably determines appropriate in connection with any actual or threatened infringement by a Third Party of any Development Program Patent Rights of which it becomes aware, including any Paragraph IV Certification which references the foregoing or any actual or threatened challenge to any Development Program Patent Rights by a Third Party, (b) Company shall have full control over the conduct of an action under this Section 8.4, including settlement thereof, and (c) any recoveries resulting from an action under this Section 8.4 will be retained by Company.

**8.5 Trademarks.** Notwithstanding the provisions of Section 2.1(b), Company and the Company Sublicensees shall have the right to brand, at their discretion, the Products using trademarks and trade names other than the ZARNESTRA Mark selected at their discretion and registered at their discretion in their own names.

**8.6 Patent Term Extensions.** The Parties agree to cooperate in an effort to avoid loss of any Janssen Patent Rights which may otherwise be available to the Parties hereto under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable U.S. or foreign laws, including by executing any documents as may be reasonably required. In particular, the Parties shall cooperate with each other in obtaining patent term extension or supplemental protection certificates or their equivalents in any country and region where applicable to the relevant Patent Rights. Company acknowledges that nothing herein prohibits Janssen from licensing any Third Party rights under the Janssen IP to any Compound or Products for use outside the Field, and that such a Third Party licensee of Janssen may receive Marketing Authorization for a Product outside the Field in a given country before Company receives Marketing Authorization for a Product outside the Field in a given country, Company compound or Products for use outside the Field by the time that Company Marketing Authorization for a Product in the Field in a given country, Company shall have the sole right to determine, if applicable, which of the Janssen Patent Rights the Parties will attempt to extend. Janssen shall use reasonable efforts to apply for a Patent Term Extension in such country of a relevant Janssen Patent Right, and Janssen shall thereafter provide all reasonable assistance to Company, including permitting Company to proceed with the application for such Patent Term Extension in the name of Janssen, if so required under Applicable Law.

**8.7 Patent Marking; No Endorsement.** Any patent markings on any Product made, used or sold by or on behalf of Company or any Company Sublicensee (or when the character of the Product precludes marking, the package containing any such Product) shall be made in accordance with all Applicable Laws relating to patent marking.

## 9. CONFIDENTIALITY

**9.1 Confidentiality Obligation.** All Confidential Information disclosed or made available by a Party (directly or through its Affiliates) to the other Party will be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use the Confidential Information of the other Party and its Affiliates for the purposes expressly permitted by this Agreement. Each Party shall hold as confidential such Confidential Information of the other Party and its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information, but no less than a reasonable standard of care. A recipient Party may only disclose Confidential Information of the other Party and its Affiliates to employees, agents, contractors, consultants and advisers of the recipient Party and its Affiliates, licensees (including Other Licensees in the case of disclosure of Janssen Know-How by Janssen to Other Licensees) and sublicensees and to Third Parties to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such persons and entities are bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement. The Janssen Know-How shall be considered Confidential Information of both Parties during the Term of this Agreement, and each Party shall be considered a disclosing Party and a recipient Party with respect thereto.

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**9.2 Exceptions.** The obligations under Section 9.1 shall not apply to any information within the Confidential Information to the extent the recipient Party can demonstrate by competent evidence that such information (provided that clauses (b), (c) and (d) shall not apply to Janssen as a recipient Party with respect to Janssen Know-How):

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;

(b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party;

(c) is disclosed to the recipient Party or any of its Affiliates on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates; or

(d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Confidential Information disclosed by the disclosing Party or its Affiliates under this Agreement.

# 9.3 Authorized Disclosures.

(a) Authorized Disclosures. In addition to disclosures allowed under Section 9.1, a Party may disclose information within the Confidential Information of the other Party and its Affiliates to the extent such disclosure is necessary in the following instances: (i) for Prosecuting Patent Rights as permitted by this Agreement; (ii) for making regulatory filings for Products the recipient Party has a license or right to develop hereunder; (iii) for prosecuting or defending litigation as permitted by this Agreement; (iv) for complying with applicable court orders or governmental regulations; (v) in the case of Janssen, for disclosing in confidence to Third Parties to the extent required to comply with Existing Third Party Agreements; and (vi) for disclosing in confidence to actual or bona-fide potential Third Party investors or other Third Party transactional partners and to their bankers, lawyers, accountants, agents, provided, in each case that each such Third Party investor or other transactional partner or advisor thereof is bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.

(b) Notification of Patent Filings. In the event a recipient Party or any of its Affiliates discloses to a Patent Office any Confidential Information of the other Party in connection with the Prosecution of any Patent Rights as permitted by this Agreement, the recipient Party shall notify the other Party of such disclosure, and, if requested, provide a copy of such disclosure as filed (which shall, to the extent it includes non-redacted information in addition to the Confidential Information of the other Party, be considered the recipient Party's Confidential Information).

## (c) Disclosure Required by Applicable Laws.

(i) In the event the recipient Party is required to disclose Confidential Information of the other Party by Applicable Laws, including to comply with any order of any court or governmental or regulatory authority, such disclosure shall not be a breach of this Agreement; provided that the recipient Party (i) informs the other Party as soon as reasonably practicable of the required disclosure, (ii) limits the disclosure to that reasonably required for the legal purpose and seeks protective treatment as available under Applicable Laws, and (iii) at the other Party's request and expense, reasonably assists in its attempt to intervene to directly limit or protect the disclosure of its Confidential Information.

(ii) In the event a Party seeks to make a disclosure of this Agreement or any terms hereof to a government or regulatory authority as required by United States SEC regulations or other Applicable Laws applying to securities or by the rules of any recognized stock exchange or quotation system, the other Party shall reasonably cooperate with respect to the timing, form and content of such required disclosure to the extent practicable under the circumstances, and, if so requested by it, the Party subject to such disclosure obligation shall use commercially reasonable efforts to obtain an order protecting to the maximum extent possible the confidentiality of such provisions of this Agreement as reasonably requested by the other Party. If the other Party does not provide consent as to the form or content of the required disclosure, such disclosure shall be limited to the minimum required, as reasonably determined by the disclosing Party in consultation with its legal counsel.

(d) Required Publication Regarding Clinical Trials. Regardless of any obligation of confidentiality hereunder, a Party may publish information regarding any of its clinical trials of Products in accordance with its policy regarding

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public disclosure of such information consistently applied, and shall register information relating to clinical studies of Products as required by applicable law (e.g., with www.clinicaltrials.gov when required by United States law).

**9.4 Duration of Obligations.** The obligations with respect to maintaining the confidentiality of and restrictions on use of Confidential Information shall apply during the Term of this Agreement and continue for a period running [\*\*\*] years thereafter.

## **10. PUBLICATIONS AND PUBLICITY**

**10.1 Scientific Publications.** Company may make oral or written publications (such as any abstracts, manuscripts, posters, slide presentations or other materials) of any activities or results relating to the Development Program without the written consent of Janssen, except as expressly provided in this Section 10.1. Prior to expiration of the ROFN Term or, if the ROFN has been exercised during the ROFN Term, expiration of the Negotiation Period, Company may make oral or written publications (such as any abstracts, manuscripts, posters, slide presentations or other materials) of any activities or results relating to the Development Program in accordance with the procedures in this Section 10.1. Janssen shall have the right to review and comment on a draft of any such material proposed for publication by Company, including for purposes of ensuring that none of its Confidential Information is disclosed without its permission. Company shall deliver a complete draft to Janssen at least [\*\*\*] days prior to submitting the material to a publisher or initiating any other release. Janssen shall review any such material and give its comments Company within [\*\*\*] days of the delivery of such draft to Janssen. Company shall comply with Janssen's request to: delete from any such proposed publication material prior to its submission or release any references to Janssen and/or any of its Confidential Information; and/or delay any submission or release for a period of up to an additional [\*\*\*] days to permit Company to prepare and file, or have prepared and filed, any patent applications for any Development Program Inventions as contemplated hereunder. For the avoidance of doubt, this Section 10.1 shall not apply to public disclosures required by Applicable Laws or the rules of any recognized stock exchange or quotation system as applicable, which are governed by Section 9.3(c)(ii) above.

**10.2 Publicity.** Janssen hereby consents to Company's issuance of the press release attached hereto as Exhibit 8 after execution of this Agreement. No other press release, announcement, or other public statement, whether oral or written, disclosing the existence of this Agreement, any terms hereof, or any information relating to this Agreement or performance hereunder shall be made, either directly or indirectly, by a Party without the prior written consent of the other Party, except as may be legally required by Applicable Laws or judicial order, without first obtaining the consent of the other Party as to the nature, text, and timing of such announcement, which consent shall not be unreasonably withheld. A Party desiring to make any such public announcement shall provide the other Party with a draft thereof at least [\*\*\*] Business Days prior to the date on which such Party would like to make the public announcement. For the avoidance of doubt, this Section 10.2 shall not prohibit either Party from making any public statement as required to comply with any duty of disclosure it may have pursuant to Applicable Laws or the applicable rules of any recognized stock exchange or quotation system as applicable. A Party may reissue a press release or public announcement or make such other public statement if the contents of such press release, public announcement or public statement have previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates.

**10.3 Use of Names.** Nothing contained in this Agreement will be construed as conferring any right to a Party to use in advertising, publicity or other promotional activities any name, trade name, trademark or other designation of the other Party or any of its Affiliates (including a contraction, abbreviation or simulation of any of the foregoing).

### 11. REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMERS

11.1 Representations and Warranties by Each Party. Each Party represents and warrants to the other Party as of the Execution Date that:

(a) it is duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

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(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity); and

(d) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party; or (iii) to its knowledge, violate any Applicable Laws.

11.2 Additional Representations and Warranties by Janssen. Janssen represents and warrants to Company as of the Effective Date that:

(a) <u>Exhibit 2(A)</u> lists all Patent Rights existing as of the Effective Date that are owned by Janssen or any of its Affiliates and include any claim Covering any Compounds or their manufacture or use, or any Product in clinical development as of the Effective Date or its formulation or use; <u>Exhibit 2(B)</u> lists all sublicensable Patent Rights that are licensed by Janssen or any of its Affiliates and include any claim Covering any Compounds or their manufacture or use, or any Product in clinical development as of the Execution Date or its formulation or use; and to the knowledge of Janssen, neither Janssen nor any of Affiliates owns or otherwise controls any Patent Rights necessary or reasonably useful to Develop, Manufacture, use, import, offer for sale, sell, or otherwise Commercialize any Compound or Product as formulated by Janssen for its clinical trials in the Field in the Territory other than those listed on <u>Exhibit 2(A)</u> and <u>Exhibit 2(B)</u>;

(b) Janssen or an Affiliate thereof is the sole and exclusive owner of the Patent Rights listed in <u>Exhibit 2(A)</u>, and is listed (or is in the process of becoming listed) in the records of the appropriate United States and/or foreign governmental agencies as the sole and exclusive owner of record or exclusive licensee for each registration, grant and application included in such Patent Rights, except as otherwise noted therein;

(c) to the knowledge of Janssen, the Janssen Know-How contained in the records listed in <u>Exhibit 3</u>, which will be updated within [\*\*\*] days of the Effective Date, includes all Know-How in Janssen's or its Affiliates' possession and Control as of the Effective Date that is necessary or reasonably useful to Develop, Manufacture, use, import, offer for sale, sell, or otherwise Commercialize any Compound or Product in the Field in the Territory;

(d) to the knowledge of Janssen, the records listed in <u>Exhibit 5</u> includes all Existing Third Party Agreements material to the Development or Commercialization of any Compound in the Field in the Territory;

(e) Janssen has the right to grant to Company the license under the Janssen Patent Rights and Janssen TM Rights in accordance with Section 2.1(a) and (b) and the right to obtain a sublicense under the [\*\*\*] License in accordance with Section 2.1(c);

(f) Janssen has provided to Company true and complete copies of the [\*\*\*] License as in effect on the Effective Date (excluding the financial terms), the [\*\*\*] License is in full force and effect, and Janssen has complied with all terms of the [\*\*\*] License material to this Agreement;

(g) to the knowledge of Janssen, Janssen has the right to use and disclose and to enable Company to use and disclose (in each case under appropriate conditions of confidentiality) the Janssen Know-How;

(h) to the knowledge of Janssen and except to the extent not yet due, all necessary and material application, registration, maintenance and renewal fees in respect of the

pending or extant Janssen Patent Rights listed in <u>Exhibit 2(A)</u> and <u>Exhibit 2(B)</u> in existence as of the Effective Date have been paid and, except to the extent not yet due, all necessary documents and certificates have been filed with the relevant Patent Offices for the purpose of maintaining such Janssen Patent Rights;

(i) to the knowledge of Janssen, there are no claims, judgments or settlements against Janssen relating to the Janssen Patent Rights listed in <u>Exhibit 2(A)</u> and <u>Exhibit 2(B)</u>;

(j) to the knowledge of Janssen, there is no actual infringement of any Janssen Patent Rights by any Third Party; and

(k) Janssen or an Affiliate thereof is the sole and exclusive owner of the Trademark Rights listed in Exhibit 4.

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## 11.3 Covenants.

(a) No Conflict. Janssen shall not grant any right or enter into any agreement with any Third Party that would conflict with any of Company's rights or Janssen's obligations under this Agreement or amend any Existing Third Party Agreement or the [\*\*\*] License in a manner that would conflict with any of Company's rights or Janssen's obligations under this Agreement. Company shall not grant any right or enter into any agreement with any Third Party that would conflict with any of Janssen's rights or Company's rights or Company's number of the second s

(b) Intellectual Property Ownership and Confidentiality. Each Party shall require that all of its and its Affiliates' employees, consultants, contractors and agents involved in the Development, Manufacture or Commercialization of Compounds or Products have entered into written confidentiality and invention assignment agreements that are consistent with the terms of this Agreement and pursuant to which they assign any rights they may have in any inventions relating to Compounds or Products made during such work to such Party; provided, however, that such invention assignment requirement shall not apply with respect to a contractor or consultant that is a university or other non-profit research institution or academic collaborator if a non-exclusive license (with or without any right to obtain an exclusive license), with right to grant sublicenses, to any such inventions relating to Compounds or Products made during work performed by such contractor or consultant and to corresponding Patent Rights thereon is granted to such Party so as to preserve each Party's ability to exercise its rights as provided hereunder without any payment obligation to any such contractor or consultant.

(c) Compliance with Law. Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws, including FCPA. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws. Without limiting the foregoing, each Party agrees that it shall, and shall cause its Affiliates and sublicensees to, (a) comply with all applicable international, national, state regional and local laws and regulations, including FCPA, in performing its obligations and/or exercising its rights hereunder, including with respect to any use, manufacture, sale or import of Products, (b) observe all applicable United States and foreign laws with respect to the transfer of Products and related

technical data to countries other than the United States, including all Export Control Laws, and (c) manufacture Products in compliance with applicable government importation laws and regulations of a particular country for Products made outside the particular country in which such Products are used, sold or otherwise exploited. In furtherance of the foregoing, each Party and its subcontractors and sublicensees shall conduct their activities hereunder in accordance with the guidelines set forth in Exhibit 7 (Compliance with Laws and the FCPA).

**11.4 Debarment.** Company shall not use in conducting any applicable Development activities with respect to Compounds or Products under this Agreement any person who has been:

(a) debarred, or proposed to be debarred under Section 306(a) or 306(b) of the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the rules, regulations and guidelines promulgated thereunder, or under 42 U.S.C. Section 1320-7;

(b) sanctioned by, suspended, debarred, excluded or otherwise ineligible to participate in any federal or state health care program, including Medicare and Medicaid or in any federal procurement or non-procurement programs; or

(c) charged with or convicted of any felony or misdemeanor under 42 U.S.C. Section 1320a-7(a) or 42 U.S.C. Section 1320a-7(b)(1)-(3), or otherwise proposed for exclusion.

Company will promptly inform Janssen, but in no event later than [\*\*\*] Business Days, if Company becomes aware that its or any of its Affiliates or sublicensees or subcontractors, or any employee of Company or any of its Affiliates or sublicensees or subcontractors, in each case performing any Development activities under this Agreement or in support of the Marketing Authorizations, is not in compliance with any of the criteria set forth in this Section 11.4 on or after the Effective Date.

**11.5 Limitations.** Notwithstanding anything contained in this Agreement, Janssen gives no warranty and makes no representation that any patent application within the Janssen Patent Rights shall proceed to grant or that any patent within the Janssen Patent Rights will be valid and enforceable. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING

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ANY WARRANTIES OF NON-INFRINGEMENT OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT AND/OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY COMPOUND OR PRODUCT WILL BE SUCCESSFUL.

## **12. INDEMNIFICATION; INSURANCE**

**12.1 Indemnification by Company.** Company shall, and shall require the Company Sublicensees to, indemnify and hold harmless Janssen and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (each, a *"Janssen Indemnified* 

*Party*"), from and against any losses, damages and liability, including reasonable legal expense and attorneys' fees (collectively, *"Indemnified Losses*"), incurred by any Janssen Indemnified Party as a result of any Third Party demands, claims or actions, including product liability claims (collectively, *"Claims"*) against any Janssen Indemnified Party arising or resulting from: (a) the negligence or willful misconduct of Company in performing Company' obligations or exercising Company' rights under this Agreement; (b) the breach of any of the covenants, warranties and representations made by Company to Janssen under this Agreement; (c) Development Program activities conducted by or on behalf of Company; or (d) the Development, Manufacture, use, sale, offer for sale, other Commercialization or importation of any Compounds or Products in the Field in the Territory by Company or any of its Affiliates or Company Sublicensees. Notwithstanding the foregoing, Company shall not be responsible for the indemnification of any Janssen Indemnified Party to the extent that the Indemnified Losses of such Janssen Indemnified Party were caused by: (i) the negligence or willful misconduct of such Janssen Indemnified Party to rights reserved to Janssen.

**12.2 Indemnification by Janssen.** Janssen shall indemnify and hold harmless Company and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (each, an *"Company Indemnified Party"*), from and against Indemnified Losses incurred by any Company Indemnified Party arising or resulting from: (a) the research, Development, Manufacture, use, sale, offer for sale, other commercialization or importation of any Compounds and/or Products by or on behalf of Janssen or any of its Affiliates, licensees or sublicensees (other than Company); (b) the negligence or willful misconduct of Janssen in performing Janssen's obligations or exercising Janssen's rights under this Agreement; or (c) the breach of any of the covenants, warranties and representations made by Janssen to Company under this Agreement. Notwithstanding the foregoing, Janssen shall not be responsible for the indemnification of any Company Indemnified Party; or (ii) any breach by Company of its covenants, obligations, warranties or representations pursuant to this Agreement.

### 12.3 Indemnification Procedure.

(a) Notification. Any Janssen Indemnified Party or Company Indemnified Party seeking indemnification hereunder (*"Indemnified Party"*) shall notify the Party against whom indemnification is sought (*"Indemnifying Party"*) in writing reasonably promptly after the assertion against the Indemnified Party of any Claim in respect of which the Indemnified Party intends to base a claim for indemnification hereunder, but the failure or delay so to notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby.

(b) Indemnifying Party Right to Handle Claims. Subject to the provisions of Section 12.3(d) and (e) below, the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within [\*\*\*] days after receipt of the notice from the Indemnified Party of any Claim, to assume the defense and handling of such Claim at the Indemnifying Party's sole expense, in which case the provisions of Section 12.3(c) below shall govern.

(c) Indemnifying Party Handling of Claims. The Indemnifying Party shall select counsel reasonably acceptable to the Indemnified Party in connection with conducting the defense and handling of such Claim, and the Indemnifying Party shall defend or handle the same in consultation with the Indemnified Party, and shall keep the Indemnified Party timely apprised of the status of such Claim. The Indemnifying Party shall not, without the prior written

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consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder, or would involve any admission of wrongdoing on the part of the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party, at the request and expense of the Indemnifying Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense. Notwithstanding the foregoing, in the event the Indemnifying Party fails to conduct the defense and handling of any Claim in good faith after having assumed such, then the provisions of Section 12.3(e) below shall govern.

(d) Right of Indemnified Party to Assume Handling of Claims. If the Indemnifying Party does not give written notice to the Indemnified Party, within [\*\*\*] days after receipt of the notice from the Indemnified Party of any Claim, of the Indemnifying Party's election to assume the defense and handling of such Third Party Claim, the provisions of Section 12.3(e) below shall govern.

(e) Indemnified Party Handling of Claims. Unless Section 12.3(c) applies, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

**12.4 Insurance.** Each Party, at its own expense, shall maintain liability insurance in an amount consistent with industry standards during the Term, but in no event shall such insurance be in an amount less than [\*\*\*] dollars (\$[\*\*\*]) per occurrence/annual aggregate during the Term. In addition, during the term of Commercialization of any Product and for a period of at least [\*\*\*] years thereafter, Company shall maintain product liability insurance in an amount not less than [\*\*\*] dollars (\$[\*\*\*]) per occurrence and annual aggregate. A Party responsible for the conduct any clinical studies hereunder shall maintain clinical trial insurance in compliance with all Applicable Law pertaining to the

jurisdictions in which such clinical studies are conducted. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon its written request. Each Party shall notify the other [\*\*\*] days in advance of cancelation of any such insurance.

**12.5 Materials Provided As Is.** Subject to Section 4.6(b), Company acknowledges that compounds, reagents, and other materials supplied by Janssen hereunder are experimental in nature and provided as is, without any warranties as to merchantability or fitness for a particular purpose. Company further acknowledges that all of such materials' properties or characteristics are not known, and agrees that it shall use such materials with reasonable care and shall assume responsibility for any losses or injuries incurred by it or its Affiliates or subcontractors or sublicensees through use of such materials.

# **13. TERM AND TERMINATION**

**13.1 Term.** The term of this Agreement (the *"Term"*) will commence on the Effective Date and, subject to earlier termination in accordance herewith, shall expire on the last to occur of: (a) the expiry of the last-to-expire patent term, or conclusion of Prosecution of the last-to-be-Prosecuted, of the Janssen Patent Rights; or (b) the expiration of the last-to-expire Royalty Term.

# 13.2 Termination for Cause by Either Party.

(a) By Janssen for Company's Lack of Diligence. In the event that Company fails to use Commercially Reasonable Efforts to Develop and Commercialize [\*\*\*] with respect to any [\*\*\*] as described in Sections 4.1 and 5.1, then (without limiting Janssen's right to seek termination of the entire Agreement pursuant to Section 13.2(b) below if such breach by Company is material to the Agreement in its entirety) Janssen may terminate Company's license rights under this Agreement with respect to such [\*\*\*] upon written notice to Company, provided that Company will have a period of three (3) months following receipt of such notice to demonstrate to Jansen's

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reasonable satisfaction that Company has not failed to use Commercially Reasonable Efforts in accordance with Section 4.1 or 5.1. Notwithstanding anything to the contrary in this Agreement, Company' and the Company Sublicensees' collective efforts and resources expended toward Developing and Commercializing any Products throughout the Territory shall be considered in determining whether Company has met its diligence obligations under Sections 4.1 and 5.1 with respect to any particular [\*\*\*].

(b) By Either Party for the Other Party's Material Breach. If either Janssen or Company (in such capacity, the "*Breaching Party*") is in material breach of this Agreement (excluding any breach described in Section 13.2(a), in which case such provision shall govern), the other Party (in such capacity, the "*Non-Breaching Party*") may give written notice to the Breaching Party specifying the claimed particulars of such breach, and in such event, if the breach is not cured within forty-five (45) days after such notice ([\*\*\*] days in the event of failure to make any payment when due), the Non-Breaching Party shall have the right thereafter to terminate this Agreement by giving written notice to the Breaching Party to such effect, provided, however that if such breach (other than failure to make any payment when due) is capable of being cured but cannot be cured within such [\*\*\*] day period and the

Breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the Breaching Party shall have an additional [\*\*\*] days to cure such breach.

(c) Suspension of Time Periods for Curing Breach. From the date of initiation of any measures under Section 15.6 to resolve a Dispute pertaining to an alleged breach under Section 13.2(a) or (b) and until such time as such Dispute has been finally resolved under Section 15.6, the running of the time periods under this Section 13.2 as to which a Party must cure a breach of this Agreement shall be suspended as to the subject matter of the Dispute.

(d) By Either Party for the Other Party's Bankruptcy. In the event of the Bankruptcy of a Party (or its successor in interest in the event this Agreement is assigned as permitted hereunder), the other Party may terminate this Agreement by notice to the bankrupt Party.

**13.3 Termination Without Cause by Company.** Company may terminate this Agreement upon one hundred eighty (180) days' prior written notice to Janssen.

# **14. EFFECT OF TERMINATION**

**14.1 Effect of Termination of Rights in Particular Country.** Upon any early termination with respect to any [\*\*\*] under Section 13.2(a), any licenses and sublicenses granted by Janssen to Company with respect to such [\*\*\*] will terminate and revert to Janssen, and the Territory shall be redefined to exclude such [\*\*\*] from the scope of the Territory, and the terms of Section 14.2 below shall apply *mutatis mutandi* with respect to such [\*\*\*].

**14.2 Effect of Termination by Janssen under Section 13.2(b) or by Company under Section 13.3.** Upon any early termination of this Agreement in its entirety by Janssen pursuant to 13.2(b) or by Company pursuant to Section 13.3:

(a) The licenses and sublicenses granted by Janssen to Company will terminate and revert to Company (except any license in any country that has become perpetual and irrevocable as provided in Section 6.3(b)).

(b) If Company has initiated clinical development of, or obtained Marketing Authorization for, any Compounds or Products or Commercialized any Products (each a *"Reverted Product"*), Company shall promptly provide to Janssen a summary of the status of the Development and Commercialization of any such Reverted Products up to such termination and: (i) Janssen shall have, and Company hereby grants to Janssen, a paid-up, exclusive option, during the [\*\*\*]-year period running from termination of this Agreement, to elect to develop and commercialize any such Reverted Products; and (ii) during such option period, prior to notice of Janssen's election decision or upon Company's reasonable request, Janssen shall permit Company to undertake activities to wind down in a commercially reasonable manner any ongoing development or commercialization activities with respect to each such Product for which Company's license rights under this Agreement have been terminated (subject to

Company' obligation under Section 6.3 to pay any royalties that may accrue during such wind-down period on account of Net Sales of such Reverted Products from the supply on hand as of the termination). Promptly after Company' receipt of a notice within the [\*\*\*]-year option exercise period of Janssen's election to take over

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development and commercialization of such a Reverted Product, the Parties shall negotiate in good faith and enter into a written confirmatory agreement under which: (x) Company shall grant Janssen a worldwide, exclusive, sublicenseable right and license to develop and commercialize such Reverted Product under the Company Patent Rights (if any) and applicable Development Program Know-How (including data submitted to Regulatory Authorities) Controlled by Company (directly or through its Affiliates or sublicensees), subject to the rights under any sublicense granted to a Company Sublicensee that survives termination as provided in Section 2.4; and (y) Janssen shall pay Company a royalty on Net Sales of such Reverted Product at a rate of [\*\*\*], with provisions parallel to those set forth in Sections 6.3 and 7 hereof applicable mutatis mutandi to Janssen's royalty payments. Moreover, if Janssen reasonably requests in the notice of its exercise of such option rights under this Section that Company also grant Janssen rights to trademarks Controlled by Company that are directly associated with the Reverted Product, or to any valuable core or platform technology utilized by Company to manufacture or commercialize the Product that is Covered by Patent Rights Controlled by Company, the confirmatory agreement shall specify the terms (including any agreed-upon transfer cost payments from Janssen to Company) under which Company would transfer to such requested rights in trademarks associated with the Reverted Product and/or licenses under such Patent Rights (solely to the extent necessary for the development and/or commercialization of the Reverted Product), which terms will be commercially reasonable and fair considering the particular reason for termination. For clarification, any license granted to Janssen as described in this Section 14.2(b) will include the right to use clinical and regulatory data and information generated by Company for regulatory purposes relating to the Reverted Products. In connection with any exclusive license to Reverted Products granted under this Section 14.1(b), Company shall transfer and assign to Janssen all of its right, title and interest in and to all U.S. and foreign Marketing Authorizations with respect to the Reverted Products and all drug master files and drug dossiers with respect to the Reverted Products (other than those related to manufacturing facilities).

(c) Company or Company Sublicensees shall continue, to the extent that Company or Company Sublicensees continue to have stocks of usable Reverted Products, to fulfill orders received for Products in the Territory until [\*\*\*] months following the date of termination. For Reverted Products sold by Company or Company Sublicensees after the effective date of a termination, Company shall continue to pay royalties pursuant to Section 6.3. Prior to the end of such [\*\*\*] month period, Company shall provide Janssen written notice of an estimate of the quantity of Reverted Products and shelf life remaining in the inventory of Company or Company Sublicensees and Janssen shall have the right, upon its election to take an exclusive license to Reverted Products under Section 14.2(b), to purchase any such quantities of Reverted Products from Company and Company Sublicensees at a price mutually agreed by the Parties. In addition, Company shall use commercially reasonable efforts to transition to Janssen upon Janssen's request any arrangement with any contractor from which Company had arranged to obtain supplies of Reverted Products (or the Compounds therein), to the extent permitted under any such agreement with such contractor. In the event that Reverted Products are manufactured by Company or its Affiliate, then, upon request by Janssen, Company shall continue to provide Janssen with such materials at a price to be agreed by the Parties for not longer than [\*\*\*] months.

(d) In the event that Company has any Development activities with regard to any Reverted Products ongoing, the Parties shall negotiate in good faith and adopt a plan to wind-down the development activities in an orderly fashion or, at Janssen's election of exclusive license rights pursuant to Section 14.2(b), promptly transition such Development activities for any Reverted Products to Janssen or its designee, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of any Reverted Product and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws.

(e) The provisions of this Section 14.2 shall survive such termination for so long as Janssen or any of its Affiliates, licensees or sublicensees Develops or Commercializes any Reverted Product hereunder.

(f) Except as provided in this Section 14.2, Company will immediately cease to use, distribute, or market the Reverted Products.

(g) Upon Janssen's request, Company will promptly return, or at Janssen's option, destroy, any Janssen Know-How or any materials containing the Janssen Know-How or any Confidential Information of Janssen in Company' possession, except for one archival copy to safekeep for legal purposes and such records as may be required to be retained by Company by Applicable Laws, all of which shall continue to be subject to the confidentiality and non-use obligations in Article 9.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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## 14.3 Effect of Termination by Company under Section 13.2. Upon termination of this Agreement by Company pursuant to Section 13.2:

(a) The licenses and sublicenses granted by Janssen to Company will terminate and revert to Janssen (except any license in any country that has become perpetual and irrevocable as provided in Section 6.3(b).

(b) Company or Company Sublicensees shall continue, to the extent that Company or Company Sublicensees continue to have stocks of usable Reverted Products, to fulfill orders received for Reverted Products in the Field until [\*\*\*] months following the date of termination. For Products sold by Company or Company Sublicensees after the effective date of a termination, Company shall continue to pay royalties pursuant to Section 6.3. Except as provided in this Section 14.2(b), Company will cease to use, distribute, or market the Products.

(c) Following the period set forth in Section 14.2(b), each Party will promptly return, or at the other Party's option, destroy any Know-How of such other Party or any materials containing such Know-How or any Confidential Information of such other Party in its or its Affiliates' possession, except for one archival copy to safekeep for legal purposes and such records as may be required to be retained by such Party by Applicable Laws, all of which shall continue to be subject to the confidentiality and non-use obligations in Article 9.

**14.4 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation (including any payment obligations in Article 6) accruing prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry. Without limiting the foregoing, the provisions of Articles 1, 9, 14 (including the additional sections referenced therein) and 15 and Sections 7.5, 8.1, 10.2, 10.3, 11.5, 12.1, 12.2, 12.3 and 12.5, and any other provisions that should survive as apparent from the express terms thereof in the context of this Agreement, shall survive expiration or termination of this Agreement.

**14.5 Exercise of Right to Terminate.** The exercise by either Party of an early termination right provided for under Article 14 shall not give rise to the payment of damages or any other form of compensation or relief to the other Party on account of such exercise.

**14.6 Damages; Relief.** Subject to Section 14.5, early termination of this Agreement under Article 14 shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

**14.7 Rights in Bankruptcy.** All rights and licenses and sublicenses granted under or pursuant to this Agreement by a Party to the other are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (or comparable provisions of laws of other jurisdictions), licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code (or comparable provisions of laws of other jurisdictions). The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code (and comparable laws of other jurisdictions). The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code (and comparable laws of other jurisdictions), the Party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under subsection (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party. All rights, powers and remedies granted hereunder to a Party as a licensee of any intellectual property rights as provided in this Section 14.7 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity, in the event of the commencement of a Bankruptcy case by or against the granting Party under Applicable Law, and the licensee Party, in addition to the rights, powers and remedies e

## **15. GENERAL PROVISIONS**

[***]	= CERTAIN	CONFIDENTIAL	INFORMATION	OMITTED

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**15.1 Assignment.** Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that (a) either Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of any other Party, provided that the Party assigning to an Affiliate any part of this Agreement shall remain liable and responsible to the non-assigning Party for the performance and observance of all such duties and obligations by such Affiliate; and (b) either Party may assign this Agreement in its entirety to a successor to all or substantially all of its business relating to Compounds and Products, whether by merger, sale of stock, sale of assets or otherwise, provided that in the event of a transaction (whether this Agreement is actually assigned or is assumed by the acquiror by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiror to such transaction (if other than one of the Parties to this Agreement) existing before such transaction, or arising after such transaction through activities conducted in good faith separately and independently by such acquiror or its Affiliates and without use of any Confidential Information of the acquired Party, as can be demonstrated by adequate evidence, shall not become subject to this Agreement. The assigning Party shall provide the other Party with prompt written notice of any such assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Any attempted assignment in contravention of the foregoing shall be void.

**15.2 Performance by Affiliates; Company Performance by Subcontractor.** Subject to the terms and conditions of this Agreement, any obligation of a Party under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, either by such Party directly or by any Affiliate of such Party that such Party causes to satisfy, meet or fulfill such obligation, in whole or in part. Each Party shall remain liable for the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party under the terms and conditions of this Agreement. Company has engaged Wellspring Biosciences LLC to perform certain Development services for and on behalf of Company pursuant to a Services Agreement dated October 1, 2014, as may be amended in accordance with its terms, and Company shall remain liable for the performance of all actions, agreements and obligations to be performed by Wellspring by or on behalf of Company under the terms and conditions of this Agreement.

**15.3 Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their commercially reasonable efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

**15.4 Special, Indirect and Other Losses.** IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 9 OR TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM SUBJECT TO INDEMNIFICATION PURSUANT TO ARTICLE 12. PAYMENTS ACCRUED AND PAYABLE UNDER ARTICLE 6 AND NOT PAID WHEN OWED SHALL BE TREATED AS GENERAL DAMAGES (NOT SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR ECONOMIC LOSSES OR LOST PROFITS).

**15.5 Governing Law.** This Agreement shall be governed by and construed under the laws of the State of New York, U.S., without reference to its conflicts of law principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law (without limiting the Parties' rights and obligations under Section 15.6). The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement.

## 15.6 Dispute Resolution.

(a) Resolution of Disputes. The Parties shall negotiate in good faith and use reasonable efforts to settle any Dispute arising from or related to this Agreement or the breach thereof. If the Parties cannot resolve the Dispute within [\*\*\*] days of a written request by either Party to the other Party, the Parties agree to hold a meeting, attended by the Senior Officers (or their designee with executive authority), as appropriate in light of the subject matter of the Dispute, to attempt in good faith to negotiate a resolution of the Dispute prior to pursuing other available remedies. If, within [\*\*\*] days after such written request, the Parties have not succeeded in negotiating a resolution of the Dispute, and a Party wishes to pursue the matter, each such Dispute that is not an Excluded Claim shall be resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (AAA) as then in effect, and judgment on the

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either Party intends to commence binding arbitration of such Dispute, such Party will provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [\*\*\*] days after the receipt of such notice, the other Party may by written notice to the Party initiating binding arbitration, add additional issues to be resolved.

(b) Arbitration Panel. The arbitration shall be conducted by a panel of three (3) neutral arbitrators, none of whom is a current or former employee or director, or a then-current stockholder, of either Party or their respective Affiliates. Unless otherwise agreed by the Parties, each of the arbitrators will be a lawyer with at least fifteen (15) years of experience with a law firm or corporate law department or who was a judge of a court of general jurisdiction, and who has reasonable experience in arbitrating contract disputes within the pharmaceutical and biotechnology sector. Within [\*\*\*] days after receipt of the original notice of binding arbitration (the "**Notice Date**"), each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [\*\*\*] Business Days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.

(c) Limited Discovery. It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [\*\*\*] days after selection of the third arbitrator, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within [\*\*\*] months from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

(d) Governing Law. The arbitrators will, in rendering their decision, apply the governing law set forth in Section 15.5.

(e) Interim Relief. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages, except as may be permitted by Section 15.4. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' and any administrative fees of arbitration.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED



(f) No Disclosure. Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the Dispute would be barred by the applicable New York statute of limitations.

(g) Enforcement of Arbitration Award. The Parties consent to the jurisdiction of any appropriate court for the venue in which the arbitration is held for the enforcement of these provisions and the modification, vacation or affirmation of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction shall act in the same fashion. Each Party has the right before or, if the arbitrators cannot hear the matter within an acceptable period, during the arbitration to seek from the appropriate court provisional remedies such as preliminary injunction, to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration. Each Party hereto waives its right to trial of any issue by jury.

**15.7 Injunctive Relief.** Notwithstanding the provisions of Section 15.6, each Party acknowledges that, in the event of a breach of an obligation under Article 9 to maintain in confidence the other Party's Confidential Information, the other Party shall have the right, in addition to any other rights available under Applicable Laws, to seek from any court of competent jurisdiction injunctive relief to restrain any breach or threatened breach of, or otherwise to specifically enforce, any covenant or obligation of such Party under such provisions.

**15.8 Force Majeure.** Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other non-performance hereunder (excluding, in each case, the obligation to make payments when due) if such delay or non-performance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, act of God or of the government of any country or of any local government, or by cause unavoidable or beyond the control of any Party hereto. In such event, the Party affected will use commercially reasonable efforts to resume performance of its obligations.

**15.9 Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement, including any of its Exhibits or other attachments, may be amended or modified other than by a written document signed by authorized representatives of each Party.

**15.10 Relationship of the Parties.** Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Company and Janssen, or to constitute one as the agent or employer of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

**15.11 Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (with delivery tracking and confirmation), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (with delivery tracking and confirmation), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (with delivery tracking and confirmation), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by notice):

If to Company:

11119 North Torrey Pines Road, Suite 125 San Diego, California Attn: Chief Executive Officer Fax: 858-500-8801

With a copy to:

Cooley LLP

**Execution Copy** 

4401 Eastgate Mall San Diego, CA 92121 Attn: L. Kay Chandler, Esq. Fax: +1-858-550-6420

If to Janssen:

Attn: Chairman Janssen Pharmaceutica NV Turnhoutseweg 30 2340 Beerse Belgium

With a copy to:

Chief Intellectual Property Counsel Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933, U.S.A. Fax: 732-524-2788

**15.12 Further Assurances.** Janssen and Company each hereby covenants and agrees, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

**15.13 No Third Party Beneficiary Rights.** This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

**15.14 Entire Agreement.** This Agreement, including its Exhibits and any other attachments, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the Confidentiality Agreement. In the event of any conflict between any provisions of the body of this Agreement and any Exhibit or other attachment hereto, the provisions of the body of this Agreement shall prevail.

**15.15 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

**15.16 Expenses.** Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

**15.17 English Language.** This Agreement is in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given under this Agreement, and all written, electronic, oral or other communications between the Parties regarding this Agreement, shall be in the English language.

**15.18** Additional Agreements. Each Party further agrees that it has not entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement.

15.19 Effect of Laws. Nothing in this Agreement shall operate to:

(a) exclude any provision implied into this Agreement by law that may not be excluded by law; or

(b) limit or exclude any liability, right or remedy to a greater extent than is permissible under law.

#### 15.20 Government Approvals.

(a) Each Party will use commercially reasonable efforts to obtain any government approval required in its country of domicile to enable this Agreement to become effective, or to enable any payment hereunder to be made, or any other obligation hereunder to be observed or performed. Each Party will keep the other informed of progress in obtaining



any such government approval, and will cooperate with the other Party in any such efforts, and notwithstanding anything to the contrary herein, this Agreement shall become effective upon obtaining any such required government approval.

# [Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

## JANSSEN PHARMACEUTICA NV

By: <u>/s/ Tom Heyman</u>

Name:Tom HeymanTitle:Managing Director

By: /s/ Lude F. Lauwers

Name: Dr. Lude F. Lauwers, M.D. Title: Senior Vice President

Date: December 18, 2014

## SIGNATURE PAGE TO LICENSE AGREEMENT

# KURA ONCOLOGY, INC.

By: /s/ Troy Wilson

Name:Troy WilsonTitle:President and CEO

Date: December 18, 2014

**Execution** Copy

[\*\*\*]

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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# EXHIBIT 2(A)

# Janssen Patent Rights Owned by Janssen or an Affiliate as of the Effective Date

Docket No.	Serial No.	Filed	Grant No.	Assignee(s)	Status
[***]	[***]	[***]	[***]	[***]	[***]

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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# EXHIBIT 2(B)

# Janssen Patent Rights Licensed by Janssen or an Affiliate as of the Effective Date

US Patent No. [\*\*\*]

US [\*\*\*] (non-exclusively licensed to Janssen or Affiliate)

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

# Records of Janssen Know-How as of the Effective Date

[\*\*\*]

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

**Execution** Copy

# Janssen TM Rights as of the Effective Date

Trademark	Country	Status	Filing date	Filing No.	Registration date	Registration No.	Next renewal
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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# Existing Third Party Agreements as of the Effective Date

[\*\*\*]

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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## **Guidelines on Care and Use of Service Animals**

- All laboratory research animals housed or used in connection with the Development Program will be treated humanely. They will be housed and cared for in compliance with the Applicable Law governing animal care and use for research (e.g., the Animal Welfare Act (7 USC 2131), the National Research Council Guide for the Care and Use of Laboratory Animals, the EU Commission, or the Japanese Ministry of Health and Welfare).
- No laboratory animal will be subjected to unnecessary pain and/or distress. Where pain and/or distress are unavoidable, appropriate analgesics, anesthetics and tranquilizers will be used except where their use will interfere with the scientific results. Exceptions should be reviewed and approved on a case-by-case basis by the Institutional Animal Care and Use Committee (IACUC) or the Ethics Committee on Animal Experiments.
- Only humane and appropriate methods of euthanasia will be used, as described by the American Veterinary Medical Association Guidelines on Euthanasia (current version) and the EU Commission.
- Prolonged physical restraint will be used only after alternative procedures have been considered and found inadequate.
- Vivaria are or will be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- Purpose-bred animals will be used. In those geographic regions of the world where purpose-bred animals are not available, animals must be obtained through regulated dealers that meet reasonable criteria for the humane care and use of laboratory research animals.



#### **Compliance with Laws and the FCPA**

- 1.1. Each Party shall comply with all laws and regulations concerning its efforts in the Development Program where it is providing work under the Agreement. Each Party shall become familiar with the FCPA, its prohibitions and purposes, and shall not undertake any actions that may violate the FCPA. Accordingly, each Party hereby agrees that:
  - (i) no person shall be employed by it is an official or employee of any government or any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government);
  - (ii) no payment or offer to pay, or the giving or offering to give, anything of value to an official or employee of any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government), or to any political party or any candidate for political office, shall be made with the purpose of influencing any decisions favorable to either Party or its Affiliates in contravention of the FCPA or the laws of the country in which it is providing work;
  - (iii) it not pay, nor offer or agree to pay, nor caused to be paid, directly or indirectly, any political contributions, fees or commissions to any governmental employee or representative (including, but not limited to, any employee of any health or medical provider owned or controlled by the government) that could cause a violation of the FCPA;
  - (iv) it will not, directly or indirectly, in connection with the Agreement and the business resulting therefrom, offer, pay, promise to pay, or authorize the giving of money or anything of value to any governmental official or representative, to any political party or official thereof, or to any candidate for political office, or to any person, while knowing or being aware of the probability that all or any portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any government official, to any political party or official thereof, or to any candidate to political office, for the purpose of:
    - a. influencing any act or decisions of such official, political party, party official, or candidate in its official capacity, including a decision to fail to perform official functions; or
    - b. inducing such official, political party, party official, or candidate to use influence with the government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist either Party in obtaining or retaining business for or with, or directing business to, any third party.
  - (v) Each Party will immediately notify the other Party if it becomes aware of any apparent violation of the FCPA in connection with its activities hereunder.
  - 1.2. Each Party shall provide the other Party and its agents and representatives (collectively, "Agents"), as well as any regulatory authorities having regulatory oversight of the Party or its Affiliates, with access to its facilities, records (financial and otherwise), and supporting documentation as may be requested by any Agents in order to document or verify compliance with the provisions of this Exhibit. Each Party acknowledges that the provisions of this Exhibit granting the other Party certain audit rights shall in no way relieve the Party of any of its obligations under the Agreement, nor shall such provisions require the other Party to conduct any such audits.
  - 1.3. Each Party shall maintain true and accurate records necessary to demonstrate compliance with the Agreement (including the requirements of this Exhibit).
  - 1.4. If a Party fails to comply with any of the provisions of this Exhibit (irrespective of the size, nature or materiality of such violation), such failure may be treated by the other Party as a material breach.
  - 1.5. Notwithstanding anything to the contrary in the Agreement, a Party may disclose its terms and conditions (including any financial terms) to any government authority that it determines in good faith has a legitimate need for access to such information (including, but not limited to, any governmental authorities in the U.S. or those in the country where research is being provided).



#### **Company Press Release**

Kura Oncology Announces License Agreement with Janssen Pharmaceutica NV

LA JOLLA, California, Nov. XX, 2014 – Kura Oncology, Inc. announced today it has entered into an agreement with Janssen Pharmaceutica NV for an exclusive license, in the field of oncology, to develop and commercialize tipifarnib, a protein farnesyl transferase inhibitor, for treatment of patients with cancer. Kura intends to advance tibifarnib into Phase 2 clinical trials to evaluate its activity in well-defined target patient populations where certain solid tumors are driven by a novel oncogenic activating mutation as well as hematologic malignancies.

"Tipifarnib has demonstrated encouraging clinical activity in multiple patient populations and represents a promising clinical development opportunity with the right patient selection strategy," said Troy Wilson, President and Chief Executive Officer of Kura Oncology. "We intend to leverage an understanding of the cancer genome as well as advances in patient selection to accelerate clinical development of tipifarnib in well-defined target populations."

Under the terms of the agreement, Kura assumes sole responsibility for development and commercialization of tipifarnib in the field of oncology.

#### About Kura Oncology

Kura Oncology, Inc. is a biopharmaceutical company focused on the development of innovative products for the treatment of patients with cancer. The company focuses on small molecule drug candidates targeting driver oncogenes or signaling pathways associated with cancer, with development stage programs aimed at rapid clinical readout and accelerated development and commercialization. Kura was founded in 2014 and is based in La Jolla, California and Cambridge, Massachusetts.



#### **Convertible Note**

THIS CONVERTIBLE PROMISSORY NOTE AND THE SECURITIES ISSUABLE UPON ANY CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER ANY APPLICABLE STATE SECURITIES LAWS, AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED BY ANY PERSON, INCLUDING A PLEDGEE, UNLESS (1) EITHER (A) A REGISTRATION WITH RESPECT THERETO SHALL BE EFFECTIVE UNDER THE SECURITIES ACT, OR (B) THE COMPANY SHALL HAVE RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT IS AVAILABLE, AND (2) THERE SHALL HAVE BEEN COMPLIANCE WITH ALL APPLICABLE STATE SECURITIES OR "BLUE SKY" LAWS.

#### KURA ONCOLOGY, INC.

#### **CONVERTIBLE PROMISSORY NOTE**

\$1,000,000

[•], 2014 San Diego, California

FOR VALUE RECEIVED, Kura Oncology, Inc., a Delaware corporation (the *"Company"*), promises to pay to Johnson & Johnson Innovation—JJDC, Inc., or its assignee (the *"Holder"*), the principal sum of One Million US Dollars \$1,000,000.00 (the *"Principal Amount"*), together with interest, in the manner provided herein.

#### 1. Maturity Date; No Pre-Payment.

(a) *Maturity Date.* Unless earlier converted as provided in Section 4 herein, an amount equal to the sum of the entire outstanding principal balance under this Note, plus all unpaid accrued interest hereon, shall be due and payable on the earliest to occur of: (i) May 31, 2016 (the "*Maturity Date*"), (ii) a Change of Control (as defined below), and (iii) the occurrence of an Event of Default (as defined below).

(b) *No Pre-Payment*. This Note may not be prepaid by the Company, either in whole or in part.

#### 2. Interest.

Interest on the unpaid Principal Amount shall accrue beginning on the date hereof at a rate equal to eight percent (8%) per annum, computed on the basis of the actual number of days elapsed and a year of 365 days from the date of this Note until the Principal Amount and all interest accrued thereon are paid or converted. Unless earlier converted as provided in Section 4 herein, interest shall not be due and payable until the Maturity Date or an earlier Change of Control or Event of Default.

#### 3. Events of Default.

(a) Definition of Event of Default. Any one or more of the following events shall constitute an "Event of Default":

(i) The Company fails to pay on the due date any of the Principal Amount or interest on this Note, or any other amount due under this Note, when and as the same shall become due and payable, whether at the due date thereof or at the date fixed for prepayment thereof or by acceleration thereof or otherwise, and such default shall continue unremedied for a period of five (5) business days after written notice thereof by the Holder;

(ii) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking (a) relief in respect of the Company or any subsidiary, or of a substantial part of the property or assets of the Company or any subsidiary, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law, (b) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for the Company or any subsidiary or for a substantial part of the property or assets of the Company or any subsidiary, or (c) the winding-up or liquidation of the Company or any subsidiary, and any such proceeding or petition shall continue undismissed for sixty (60) days after filing or an order or decree approving or ordering any of the foregoing shall be entered;

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(iii) The Company shall (a) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law, (b) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in Section 3(a)(ii) above, (c) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for the Company or any subsidiary or for a substantial part of the property or assets of the Company or any subsidiary, (d) file an answer admitting the material allegations of a petition filed against it in any such proceeding, (e) make a general assignment for the benefit of creditors, (f) become unable, admit in writing its inability or fail generally to pay its debts as and when they become due or (g) take any action for the purpose of effecting any of the foregoing.

(b) *Rights upon Event of Default*. Upon the occurrence of an Event of Default, the Holder may, by notice to the Company, declare the entire unpaid Principal Amount of this Note, all interest accrued and unpaid thereon and all other amounts payable under this Note to be forthwith due and payable, whereupon this Note, all such accrued interest and all such other amounts shall become and be forthwith due and payable. The Holder also may exercise from time to time any rights and remedies available to it by law.

## 4. Conversion.

(a) *Mandatory Conversion*. Subject to and in compliance with the provisions of this Section 4, at any time prior to the Maturity Date, upon the Company's receiving gross proceeds of at least \$10,000,000.00 (not including the aggregate principal amount of, and accrued interest on, the Note to be converted) in an offering or series of related offerings from the bona fide sale of Series A Preferred Stock or such other class of shares as are issued by the Company (a "*Qualified Equity Financing*"), the entire outstanding Principal Amount of this Note and all accrued and unpaid interest thereon shall automatically convert into shares of the Company's capital stock with equivalent rights and preferences (other than to account for the Company's obligation to Holder pursuant to Section 4(e) below) as the shares issued in such Qualified Equity Financing (such shares to be issued upon such conversion hereof, the "*Qualified Equity Financing Shares*") at a conversion price equal to the lowest per share purchase price paid for the shares offered in the Qualified Equity Financing.

(b) *Conversion Procedure*. Before the Holder shall be entitled to convert this Note into Qualified Equity Financing Shares pursuant to Section 4(a) above, the Holder shall surrender this Note, duly endorsed, at the office of the Company. The conversion shall be deemed to have been made immediately prior to the close of business on the date of the consummation of the Qualified Equity Financing. Thereupon, the Company shall promptly issue and deliver to the Holder a certificate or certificates for the number of Qualified Equity Financing Shares to which the Holder is entitled.

(c) *Note No Longer Outstanding*. Upon conversion of this Note, this Note shall no longer be deemed to be outstanding and all rights of the Holder as a holder of this Note shall cease.

(d) *Fractional Shares*. No fractional Qualified Equity Financing Shares shall be issued upon conversion of this Note. The Company shall, in lieu of issuing any fractional shares, pay the Holder cash equal to the product of such fraction multiplied by the applicable conversion price on the date of conversion.

(e) *Execution of Agreements Upon Conversion*. If this Note converts upon a Qualified Equity Financing pursuant to Section 4(a) above, then in connection therewith, the Holder and the Company will, if requested by either the Company or Holder, execute and deliver to each other such agreements (including, without limitation, a purchase agreement, investor rights agreement, right of first refusal/co-sale agreement and voting agreement (the "*Financing Agreements*")) as are executed and delivered by other investors in such financing. The Financing Agreements shall provide that, so long as the Company continues to develop and commercialize tipifarnib under that certain License Agreement, dated on or about the date of this Note, between Holder's affiliate (Janssen Pharmaceutica NV) and the Company, except with the written consent of the Holder, the Company may not, directly or indirectly (including without limitation by merger, consolidation, recapitalization, reclassification or otherwise), impose on the Holder what is commonly known as a "pay-to-play" provision or any similar provision in the Company's certificate of incorporation that, upon the failure of the Holder to participate in whole or in part in any future financing of the Company, would (i) cause or permit the conversion of the Holder's Qualified Equity Financing Shares into another class or series of capital stock or (ii)

otherwise modify the preferences, rights, privileges or powers of the Holder's Qualified Equity Financing Shares (such provision to be included in the applicable Financing Agreements, the "*Pay-To-Play Limitation*"); *provided, however*, that there shall be no obligation for any Financing Agreements to contain a Pay-To-Play Limitation at any time following the date of the closing of the sale of the Company's securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended, in connection with the firm commitment underwritten offering of its securities to the general public.

**5. Change of Control.** In the event of a Change of Control (defined below) prior to the closing of a Qualified Equity Financing, the Holder may elect to, at its sole discretion and upon written notice to the Company, be paid the sum of (i) one and one half times (1.5x) the outstanding Principal Amount plus (ii) accrued interest on this Note, payable upon consummation of the Change of Control. The Company shall provide written notice to the Holder of a Change of Control at least 15 days in advance of the consummation thereof. A "*Change of Control*" means (a) any merger with another company or an acquisition of the Company, whether by recapitalization, consolidation, sale of outstanding equity securities or otherwise, as a result of which the existing equity holders of the Company prior to such transaction hold less than fifty percent (50%) of the outstanding voting securities of the surviving entity after such transaction, or (b) a sale of all or substantially all of the assets of the Company.

#### 6. Miscellaneous.

(a) *No Stockholder Rights.* The Holder shall not be entitled to vote or receive dividends or be deemed the holder of any equity securities of the Company that may at any time be issuable on the conversion hereof for any purpose, nor shall anything contained herein be construed to confer upon the Holder, as such, any of the rights of a holder of equity securities of the Company or any right to vote for the election of directors or upon any matter submitted to holders of equity securities at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, or change of stock to no par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or otherwise until this Note shall have converted in accordance with Section 4 hereof.

(b) *Waiver and Amendment*. Any term of this Note may be amended or waived, either retroactively or prospectively, with the written consent of the Company and the Holder.

(c) *Notices and Addresses*. Any notice, demand, request, waiver, or other communication under this Note shall be in writing and shall be deemed to have been duly given on the date of service, if personally served or sent by telecopy or email; on the business day after notice is delivered to a courier or mailed by express mail, if sent by courier delivery service or express mail for next day delivery; and on the third day after mailing, if mailed to the party to whom notice is to be given, by first class mail, registered, return receipt requested, postage prepaid and addressed as follows:

Company:	Kura Oncology, Inc. 11119 N. Torrey Pines Road, Suite 125		
	La Jolla, CA 92037		
Holder:	Johnson & Johnson Innovation—JJDC, Inc. 410 George Street New Brunswick, NJ 08901		

(d) *Lost, Stolen or Mutilated Note*. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Note or any Note exchanged for it, and (in the case of loss, theft or destruction) of unsecured indemnity satisfactory to it, and upon reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of such Note, if mutilated, the Company will make and deliver in lieu of such Note a new Note of like tenor and unpaid Principal Amount and dated as of the original date of this Note.

(e) *Severability; Binding Effect*. Any provision of this Note which is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Note or affecting the validity or unenforceability of any of the terms and provisions of this Note in any other jurisdiction. This Note shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns.

(f) *Governing Law*. This Note shall be construed and enforced in accordance with and governed by laws of the State of Delaware, without giving effect to the conflict of laws principles thereof.

(g) *Jurisdiction and Service of Process*. Any legal action or proceeding with respect to this Note shall be brought in the courts of the State of Delaware. By execution and delivery of this Note, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. Each of the parties hereto irrevocably consents to the service of process of any of the aforementioned courts in any such action or proceeding by the mailing of copies thereof by certified mail, postage prepaid, to the party at its address set forth in Section 6(c) hereof.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, this Note has been executed and delivered as of the date first written above.

# Company:

# Kura Oncology, Inc.

By:

Name: Title:

# AGREED TO AND ACCEPTED:

Holder:

Johnson & Johnson Innovation - JJDC, Inc.

By:

Name: Title:

**Execution Copy** 

#### **JJDC Representations and Warranties**

In connection with the Convertible Note, JJDC represents and warrants to Company that:

(a) Purchase Entirely for Own Account. The applicable equity securities of Company to be acquired by JJDC will be acquired for investment for JJDC's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and JJDC has no present intention of selling, granting any participation in, or otherwise distributing the same. JJDC does not presently have any contract, undertaking, agreement or arrangement with any third party to sell, transfer or grant participations to such third party, with respect to any of the applicable equity securities of Company.

(b) Disclosure of Information. JJDC has had an opportunity to discuss Company's business, management, financial affairs and the terms and conditions of the offering of the applicable equity securities of Company with Company's management.

(c) Restricted Securities. JJDC understands that the applicable equity securities of Company 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 JJDC's representations as expressed herein. JJDC understands that the applicable equity securities of Company are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, JJDC must hold such equity securities 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. JJDC acknowledges that Company has no obligation to register or qualify the applicable equity securities of Company, or any securities into which such equity securities may be converted, for resale except as set forth in the Convertible Note. JJDC 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 equity securities of Company, and on requirements relating to Company which are outside of the JJDC's control, and which Company is under no obligation and may not be able to satisfy.

(d) No Public Market. JJDC understands that no public market now exists for the applicable equity securities of Company, and that Company has made no assurances that a public market will ever exist for such securities.

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

(f) Legends. JJDC understands that the stock certificates for the applicable equity securities of Company and any securities issued in respect of or exchange for such equity securities, 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 IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED".

(ii) Any legend set forth in, or required by, applicable financing agreements entered into in connection with the issuance and sale of the equity securities.

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

**Execution Copy** 

JOHNSON & JOHNSON INNOVATION - JJDC, INC.

By:	
Name:	
Title:	
Date:	

**Execution Copy** 

## CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

## AMENDED AND RESTATED ASSET PURCHASE AGREEMENT

THIS AMENDED AND RESTATED ASSET PURCHASE AGREEMENT (the "Agreement") is entered into as of February 12, 2015 ("Signing Date"), by and between KURA ONCOLOGY, INC., a Delaware corporation ("Purchaser"), and ARAXES PHARMA LLC, a Delaware limited liability company ("Seller"). The foregoing may be referred to individually as a "Party" and collectively as "Parties" in this Agreement.

WHEREAS, Seller and Purchaser entered into an Asset Purchase Agreement (the "*Prior Asset Purchase Agreement*"), effective December 23, 2014 (the "*Effective Date*");

WHEREAS, Seller and Purchaser desire to amend and restate the Prior Asset Purchase Agreement as set forth in this Agreement, effective as of the Effective Date.

Now, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

## **1. D**EFINITIONS

**1.1 "Affiliate"** shall mean, with respect to a given party, any corporation, company, partnership, joint venture or other entity that, directly or indirectly, through one or more intermediaries, is controlled by, controlling, or under common control with such party, as the case may be, but for only so long as such control exists. As used in this Section 1.1, "**control**" shall mean direct or indirect beneficial ownership of more than 50% (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in any corporation, company, partnership, joint venture, or other entity.

#### 1.2 "Assets" shall mean:

## (a) the Patent Rights;

(b) proprietary information, discoveries, methods, techniques, data, results and other information of Seller which uniquely relate to the Patent Rights (including without limitation laboratory notebooks), as further described on **Exhibit A**; and

(c) all claims (including claims for past infringement or misappropriation of intellectual property or intellectual property rights) and causes of action of Seller against third parties (regardless of whether or not such claims and causes of action have been asserted by Seller as of or prior to the Effective Date) pertaining to or arising out of any of the Patent Rights or any items described in Section 1.2(b), and all rights of indemnity, warranty rights, rights of contribution, rights to refunds, rights of reimbursement and other rights of recovery possessed by Seller pertaining to or arising out of such claims and causes of action (regardless of whether such rights are currently exercisable).

1.3 "Confidential Information" of a party shall mean, subject to the exceptions specified below, all information disclosed by such party (the "disclosing party") to the other party (the "receiving party"), whether in oral, written, graphic or electronic form. Notwithstanding the foregoing, the Assets shall be deemed the Confidential Information of Purchaser (*i.e.*, Purchaser shall be considered the disclosing party and Seller shall be considered the receiving party with respect thereto), and, except as otherwise provided in Article 5 hereof, the contents of this Agreement shall be considered the Confidential Information of both parties. The term "Confidential Information" shall not include information which the receiving party can demonstrate by competent written proof: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available; (b) is known by the receiving party at the time of receiving such information, as evidenced by its written records; (c) is hereafter furnished to the receiving party by a third party, as a matter of right and without restriction on disclosure; or (d) is independently developed by the receiving party without any breach of this Agreement; *provided, however*, that the exceptions set forth in the preceding clauses (b) and (d) shall not apply to the Assets.

1.4 "EMA" means the European Medicines Agency or its successor agency.

1.5 "FDA" shall mean the U.S. Food & Drug Administration or its successor agency.

**1.6 "IND"** shall mean an investigational new drug application (as more fully defined in Section 312.3 of Title 21 of the U.S. Code of Federal Regulations) filed with the FDA or the comparable application filed with any other Regulatory Authority outside of the United States of America, which application is required to commence human clinical trials in the applicable country or jurisdiction.

**1.7 "NDA"** shall mean a new drug application (as more fully defined in Section 314.5, *et seq.*, of Title 21 of the U.S. Code of Federal Regulations) filed with the FDA or the comparable application filed with any other Regulatory Authority outside the United States of America.

**1.8 "Net Sales"** means the gross amounts invoiced by Purchaser and its Affiliates and licensees for sales or other dispositions of Products to third parties that are not Affiliates or licensees, less the following items, as allocable to such Products (if not previously deducted from the amount invoiced): (a) trade, cash or quantity discounts, credits or allowances actually allowed; (b) charge back payments, administrative fees, price reductions and rebates allowed or granted to managed care organizations, government agencies or trade customers, including wholesalers and chain and pharmacy buying groups; (c) credits actually allowed for claims, allowances for damaged goods, retroactive price reductions or returned goods; (d) prepaid freight, postage, shipping, customs duties and insurance charges; and (e) sales taxes, value added taxes, duties and other governmental charges actually paid in connection with the sale, to the extent not reimbursed (but excluding what are commonly known as income taxes). Such amounts shall be determined in accordance with U.S. generally applicable accounting principles, consistently applied, and may include using accrual accounting where applicable. In no event will any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). Disposal or use of Products for marketing, regulatory or development purposes, such as clinical trials, compassionate use or indigent patient programs, without direct or indirect consideration, shall not be deemed a sale or disposition for purposes of this Net Sales definition.

**1.9 "Patent Rights"** shall mean (a) the patent applications listed in **Exhibit A** hereto; (b) patent applications that claim priority to any of the foregoing patent applications; (c) continuing applications of any of the foregoing patent applications, including divisions, substitutions, continuations and continuations-in-part (but, in the case of continuations-in-part, only to the extent the claims thereof are enabled by disclosure of the parent application); (d) patents issued or issuing from any of the foregoing patent applications; (e) reissues, reexaminations, restorations (including supplemental protection certificates) and extensions of any of the foregoing patents and patent applications; in each case, throughout the world, and regardless of whether any of the foregoing has been filed or has issued as of the Effective Date or is filed or issued at any time thereafter.

**1.10 "Phase II Trial"** means a clinical trial conducted on human study subjects with the disease or condition being studied for the principal purpose of achieving a preliminary determination of efficacy or appropriate dosage ranges or information regarding potential pharmacodynamic and predictive biomarkers, as further defined in Federal Regulation 21 C.F.R. § 312.21(b) and its foreign equivalents.

**1.11 "Phase III Trial"** means a controlled clinical trial in humans of the efficacy and safety of a Product, which is prospectively designed to demonstrate statistically whether such Product is effective and safe for use in a particular indication in a manner sufficient to file an NDA, as further defined in Federal Regulation 21 C.F.R. § 312.21(c) and its foreign equivalents.

**1.12 "Product"** shall mean a pharmaceutical product, in any form or formulation, that contains, comprises or incorporates any compound, the composition or method of manufacture or use of which is covered by a claim of the Patent Rights.

**1.13 "Regulatory Approval"** means any and all approvals (including price and reimbursement approvals, if required), licenses, registrations, exemptions or authorizations of a Regulatory Authority that are required for the manufacture, promotion, marketing, storage, import, export, transport, distribution, use, offer for sale, sale or other commercialization of a Product in the applicable country or regulatory jurisdiction.

**1.14 "Regulatory Authority"** shall mean any regulatory agency or governmental authority in a country or other regulatory jurisdiction (including, without limitation, any supra-national agency such as the European

Medicines Agency), the approval of which is necessary to market and sell a pharmaceutical product in such country or other regulatory jurisdiction.

#### 2. PURCHASE AND SALE OF ASSETS

**2.1 Purchase and Sale of Assets.** Subject to the terms and conditions of this Agreement, including, without limitation, payment in accordance with Article 3, and effective as of the Effective Date, Seller hereby sells, transfers, conveys, assigns and delivers to Purchaser all of Seller's right, title and interest in and to the Assets, free and clear of any liens, claims, liabilities, options, pledges, mortgages, security interests, restrictions and encumbrances of any kind, whether accrued, absolute, contingent or otherwise. Without derogating from the foregoing, and for the avoidance of doubt, it is hereby clarified that upon such sale and assignment, Purchaser shall have the absolute right, at Purchaser's sole cost and expense: (a) to seek to have any existing intellectual property rights in the Assets vested and/or registered in its name or as directed by it and to protect and enhance its ownership of the Assets by obtaining further and/or new intellectual property rights in the Assets, including the rights for Purchaser, its Affiliates and/or third parties licensed or otherwise authorized by Purchaser or its Affiliates, to research, develop, promote, market, sell, distribute, manufacture (or have manufactured), register, import, export or use the Assets and/or products which utilize or incorporate the Assets.

#### 2.2 Further Actions.

(a) From and after the Effective Date, Seller shall, without further consideration, execute and deliver such documents and other instruments of transfer, and take such other actions, as Purchaser determines in good faith to be necessary or appropriate in order to put Purchaser in possession of, and to vest in Purchaser, good, valid and unencumbered title to the Assets in accordance with this Agreement and to effect, record, evidence and perfect the assignment of the Assets to Purchaser. Without limiting the generality of the foregoing, Seller shall execute and deliver to Purchaser such documents and other instruments as Purchaser determines in good faith to be necessary or appropriate in order to transfer to Purchaser, and to put Purchaser in possession of and to vest in Purchaser, good, valid and unencumbered title to, the Patent Rights, and to effect, record, evidence and perfect Purchaser's ownership of the Patent Rights, including patent assignments that Purchaser may reasonably require.

(b) Seller hereby constitutes and appoints Purchaser, and any successor or assign of Purchaser, its true and lawful attorney-in-fact with full power of substitution for it and in its name, place and stead or otherwise on behalf of it, its successors and assigns, and for the benefit of Purchaser and any successor or assign of Purchaser, (i) to execute in the name of Seller and its successors and assigns, instruments of conveyance with respect to the Assets, (ii) from time to time to institute and prosecute in the name of Purchaser any and all proceedings at law, in equity or otherwise which Purchaser or any successor and assign of Purchaser may deem proper in order to collect, assert or enforce any claims, rights or titles of any kind in and to the Assets, (iii) to defend and compromise any and all actions, suits or proceedings in respect of any of the Assets, and (iv) to do any and all such acts and things in furtherance of the sale, transfer, conveyance, assignment and delivery of the Assets as Purchaser or any successor or assign of Purchaser shall deem advisable. Seller declares that the foregoing appointment and power of attorney are coupled with an interest and are and shall be irrevocable and perpetual.

(c) From and after the Effective Date, Seller shall execute, verify, and deliver (and/or cause its employees to execute, verify and deliver) such documents, perform such other acts, and provide such other assistance as Purchaser may reasonably request in order to apply for, prosecute, maintain, defend and enforce the Patent Rights in any jurisdiction, provided that Purchaser shall compensate Seller for the provision of such assistance (other than for mere execution, verification and delivery of documents) at a reasonable hourly rate to be mutually agreed by the parties for the time actually spent by Seller at Purchaser's request on providing such assistance.

#### **3.** PAYMENTS

**3.1 Purchase Price.** In full consideration of the assignments and other rights conveyed to or conferred upon Purchaser under Article 2 hereof, Purchaser shall:

(a) issue to Seller a convertible promissory note in the principal amount of five hundred thousand dollars (\$500,000) on the terms set forth in the form of convertible promissory note attached hereto as **Exhibit B** (the "*Convertible Note*");

(b) pay to Seller contingent payments (the "*Milestone Payments*") for the achievement of the following milestone events (the "*Milestone Events*") by Purchaser or its Affiliate or licensee in the amounts set forth below, which shall be payable [\*\*\*] days after the achievement of the applicable Milestone Event:

(i) \$[\*\*\*];
(ii) \$[\*\*\*];
(iii) \$[\*\*\*];
(iv) \$[\*\*\*];
(v) \$[\*\*\*];
(vi) \$[\*\*\*];
(vii) \$[\*\*\*]; and
(ix) \$[\*\*\*].

(c) pay to Seller royalties on Products sold by or on behalf of Purchaser or its Affiliates or licensees (the "*Royalties*") on a Product-by-Product and country-by-country basis during the period from the first commercial sale of a Product in a given country through the date of expiration of the last-to-expire of the Patent Rights that include a [\*\*\*] (the "*Royalty Period*"). Royalties due each calendar year during the Royalty Period shall be calculated by multiplying the incremental Net Sales of Products for such year against the applicable royalty rate identified below, subject to any applicable reductions provided for in Section 3.4, with each royalty rate referred to below applying only to that increment of Net Sales that falls within the incremental sales bracket for such royalty rate.

Annual aggregate Net Sales of Products	Royalty Rate
Less than or equal to \$[***]	[***]%
Greater than \$[***] and less than or equal to \$[***]	[***]%
Greater than \$[***]	[***]%

To illustrate, if, for example, aggregate annual worldwide Net Sales of Products upon which royalties are due and payable as provided in this Section 3.1(c) were [\*\*\*] during any year of the Royalty Period, then absent any reductions pursuant to Section 3.4, the royalties due would be calculated as follows: ([\*\*\*] x [\*\*\*]) + ([\*\*\*] x [\*\*\*]).

**3.2 Royalty and Milestone Payments**. Royalties due under Section 3.1(c) shall be paid no later than [\*\*\*] days following the end of each calendar quarter during the Royalty Period and accompanied by a reasonably detailed written accounting of Net Sales for the applicable calendar quarter in sufficient detail to permit confirmation of the accuracy of the Royalties paid. The Milestone Payments and Royalties shall be payable in U.S. dollars by wire transfer to a bank and account designated in writing by Seller, unless otherwise specified in writing by Seller. Except as otherwise provided in Section 3.1(b)(v), each of the Milestone Payments shall be payable one time only upon the first occurrence of the applicable Milestone Event, regardless of the number of Products developed or the indications for which any Product is developed. When conversion of payments from any foreign currency is required in connection with the payment of any Royalties, such conversion shall be made using the exchange rate used by Purchaser or, as applicable, its Affiliate or licensee, in its accounting system for the calendar quarter to which such payments relate. Purchaser shall be solely responsible for any payments due or payable to any third party in connection with the development or commercialization of any Product.

## [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

**3.3 Royalty Termination**. After the payment of all Milestone Payments and Royalties due and payable through the end of the Royalty Period, Purchaser shall have no further obligation to make any payments to Seller under Section 3.1(b) or (c).

**3.4 Royalty Reduction**. If Purchaser or any of its Affiliates or licensees 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 Purchaser or its Affiliate or licensee and its counsel would [\*\*\*], and if the [\*\*\*] to Seller and such third party(ies) [\*\*\*] percent ([\*\*\*]%), then the royalty percentage to be paid to Seller by Purchaser set forth above shall be reduced by the percentage calculated by the following formula: [\*\*\*], in which A is the [\*\*\*] and B is [\*\*\*] on the Product. For example, if, after [\*\*\*] \$[\*\*\*], the [\*\*\*] due to Seller and one non-Affiliate third party is [\*\*\*] percent ([\*\*\*]%), the reduction would be equal to [\*\*\*], or [\*\*\*]% and, the royalty percentages owed to Seller as set forth in Section 3.1(c) above would be reduced to [\*\*\*] percent ([\*\*\*]%). However, in no event shall the royalty amount payable to Seller for any [\*\*\*] be reduced below [\*\*\*] percent ([\*\*\*]%) of the royalty that would otherwise payable as set forth in Section 3.1(c), without reduction pursuant to this Section 3.4.

**3.5 Representations and Warranties**. In connection with Section 3.1(a), Seller represents and warrants to Purchaser as follows:

(a) Purchase Entirely for Own Account. The applicable equity securities of Purchaser to be acquired by Seller will be acquired for investment for Seller's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and Seller has no present intention of selling, granting any participation in, or otherwise distributing the same. Seller does not presently have any contract, undertaking, agreement or arrangement with any third party to sell, transfer or grant participations to such third party, with respect to any of the applicable equity securities of Purchaser.

(b) Disclosure of Information. Seller has had an opportunity to discuss Purchaser's business, management, financial affairs and the terms and conditions of the offering of the applicable equity securities of Purchaser with Purchaser's management.

(c) Restricted Securities. Seller understands that the applicable equity securities of Purchaser 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 Seller's representations as expressed herein. Seller understands that the applicable equity securities of Purchaser are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, Seller must hold such equity securities 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. Seller acknowledges that Purchaser has no obligation to register or qualify the applicable equity securities of Purchaser, or any securities into which such equity securities may be converted, for resale except as set forth in the Convertible Note. Seller 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 equity securities of Purchaser, and on requirements relating to Purchaser which are outside of the Seller's control, and which Purchaser is under no obligation and may not be able to satisfy.

(d) No Public Market. Seller understands that no public market now exists for the applicable equity securities of Purchaser, and that Purchaser has made no assurances that a public market will ever exist for such securities.

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

(f) Legends. Seller understands that the stock certificates for the applicable equity securities of Purchaser and any securities issued in respect of or exchange for such equity securities, 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

## [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

# REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED".

(ii) Any legend set forth in, or required by, applicable financing agreements entered into in connection with the issuance of the

equity securities.

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

**3.6** Audit Rights. Purchaser shall keep, and shall cause its Affiliates and licensees, as applicable, to keep records in sufficient detail with respect to the Royalties. Upon written request from Seller, Purchaser shall provide Seller with written certification from Purchaser's auditors concerning the accuracy of the calculation of Royalties and corresponding Royalties payments for each calendar quarter (or portion thereof, as applicable) within the Royalty Period. In the event the audit indicates any underpayment for a given calendar quarter (or portion thereof, as applicable) within the Royalty Period by Purchaser, Purchaser shall promptly pay Seller for the additional Royalties owed by Purchaser for such calendar quarter (or portion thereof, as applicable). Purchaser shall pay interest at [\*\*\*] regarding any underpayment from the time period commencing when the payment should have been made until the date of payment.

**3.7 Taxes.** Purchaser shall be responsible for the payment of any sales, use, transfer or similar taxes arising out of or in connection with the transactions contemplated by Article 2. Purchaser will make all payments to Seller under this Agreement without deduction or withholding for any taxes except to the extent that any such deduction or withholding is required by applicable law in effect at the time of payment. If any taxes are required to be withheld by Purchaser, Purchaser shall (a) deduct such taxes from the payment to Seller, (b) increase the sum payable to Seller by the amount necessary to yield to Seller an amount equal to the sum it would have received had no withholdings or deductions been made (c) timely pay the taxes to the proper taxing authority, and (d) send proof of payment to Seller and certify its receipt by the taxing authority promptly following such payment. The parties agree to cooperate in good faith to obtain the benefit of any tax treaty that may be applicable to the payments made or to be made under this Agreement. If Seller or any of its members (only in their capacity as members of Seller) is able to obtain credit for any taxes for which an additional payment is made by Purchaser under this Section ("Creditable Taxes") against any tax liability otherwise payable by Seller or any of its members (only in their capacity as members of Seller), Seller shall reimburse to Purchaser an amount equivalent to the Creditable Taxes. Seller shall provide Purchaser with evidence as Purchaser may reasonably request to review the amount of any Creditable Taxes.

#### 4. Representations And Warranties

**4.1 Mutual Representations and Warranties.** Each party represents and warrants to the other party that, as of the Effective Date: (a) the execution, delivery and performance of this Agreement by such party have been duly authorized by all necessary action on the part of such party; and (b) this Agreement constitutes the legal, valid and binding obligation of such party, enforceable against such party in accordance with its terms.

## [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

**4.2 Seller Representations and Warranties.** Seller hereby represents and warrants to Purchaser that, as of the Effective Date (but prior to giving effect to the transactions contemplated by Section 2.1): (a) Seller is the sole owner of the Assets, free and clear of any third party rights; (b) without limiting the generality of the foregoing, Seller has not granted any third party any license, or option to obtain a license, under the Patent Rights; (c) Seller has not received written notice from any third party alleging that the practice of any invention claimed by the Patent Rights infringes the patent or other intellectual property rights of such third party; and (d) Seller's execution, delivery and performance of this Agreement do not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound.

**4.3 Disclaimer.** Except as expressly set forth herein, the Assets are provided "as is" with all faults and without any warranty, whether express, implied, statutory or otherwise, and EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

**4.4 Limitation of Liability.** EXCEPT FOR PAYMENTS UNDER ARTICLE 3 OR LIABILITY FOR BREACH OF ARTICLE 5, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT; *provided, however*, that this Section 4.4 shall not be construed to limit either party's indemnification obligations under Article 6.

#### 5. Confidentiality

**5.1 Confidentiality.** The receiving party hereby agrees to keep confidential and not to publish or otherwise disclose or use for any purpose any Confidential Information of the disclosing party. The receiving party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. Neither Seller nor Purchaser shall issue any press release or other announcement with respect to the transactions contemplated by this Agreement without the consent of the other party, except that promptly following the Effective Date, Seller may issue a press release announcing that Seller has sold certain undisclosed patents to Purchaser, subject to Purchaser's prior review and approval of the form of such press release, which approval will not be unreasonably withheld, conditioned or delayed.

**5.2** Authorized Disclosure. Notwithstanding any other provision of this Agreement, the receiving party may disclose Confidential Information of the disclosing party: (a) to the extent required in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule; provided, however, that the receiving party shall advise the disclosing party in advance of such disclosure to the extent practicable and permissible by such order, law, regulation or stock exchange rule and any other applicable law, shall reasonably cooperate with the disclosing party, if requested, in seeking an appropriate protective order or other remedy, and shall otherwise continue to perform its obligations of confidentiality set out herein; and (b) to establish rights or defenses or enforce obligations under this Agreement.

#### 6. INDEMNIFICATION

**6.1 Indemnification by Purchaser.** Purchaser hereby agrees to save, defend and hold Seller, its affiliates (other than Purchaser) and their respective directors, officers, employees and agents (each, a *"Seller Indemnitee"*) harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees (collectively, *"Losses"*), to which any Seller Indemnitee may become subject as a result of any claim, demand, action or other proceeding by a third party to the extent such Losses arise out of (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product by or on behalf of Purchaser or any of its affiliates, assignees, licensees or contractors, including, without limitation, any losses arising from any product liability or personal injury claims or lawsuits; or (b) the prosecution, maintenance, enforcement or defense of the Patent Rights by or on behalf of Purchaser or any of its affiliates, assignees, licensees or contractors; except, in each case, to the extent such Losses result from Seller's breach of its representations, warranties or obligations under this Agreement.

**6.2 Indemnification by Seller.** Seller hereby agrees to save, defend and hold Purchaser, its affiliates (other than Seller) and their respective directors, officers, employees and agents (each, a *"Purchaser Indemnitee"*) harmless from and against any and all Losses to which any Purchaser Indemnitee may become subject as a result of any claim, demand, action or other proceeding by a third party to the extent such Losses arise out of Seller's breach of its representations, warranties or obligations under this Agreement.

**6.3 Control of Defense.** Any entity entitled to indemnification under this Article 6 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses, and the indemnifying party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses. The indemnified party shall provide the indemnifying party with all information in its possession and all assistance reasonably necessary to enable the indemnifying party to carry on the defense of any such Losses.

## 7. GENERAL PROVISIONS

**7.1 Governing Law; Jurisdiction.** This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding its conflicts of laws principles. The parties hereby irrevocably submit to the exclusive jurisdiction and venue of the federal courts located in San Diego, California, for any claim or controversy arising under this Agreement.

**7.2 Entire Agreement; Modification.** This Agreement (including the Exhibits hereto) is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, among the parties concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

**7.3 Non-Waiver.** The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

**7.4 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); *provided, however*, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to an affiliate of such party or a third party, whether by merger, sale of stock, sale of assets or otherwise, provided that, in the case of an assignment or transfer to an affiliate, the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such affiliate. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

**7.5 No Third Party Beneficiaries.** This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

**7.6 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

**7.7 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Seller, to:	Araxes Pharma LLC
	11119 N. Torrey Pines Road, Suite 125
	La Jolla, CA 92037
	Attention: Chief Executive Officer
	Facsimile No.: (858) 500-8801
if to Purchaser, to:	Kura Oncology, Inc.
	11119 N. Torrey Pines Road, Suite 125
	La Jolla, CA 92037
	Attention: Chief Executive Officer
	Facsimile No.: (858) 500-8801

or to such other address as the party to whom notice is to be given may have furnished to the other party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; and/or (c) on the fifth business day following the date of mailing if sent by mail.

**7.8 Interpretation.** The headings contained in this Agreement preceding the text of the articles and sections hereof are inserted for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against any party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, shall be in the English language.

**7.9 Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Facsimile signatures shall be as effective as original signatures.

#### [Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this Asset Purchase Agreement as of the Effective Date.

# ARAXES PHARMA LLC

By:	/s/ Heidi Henson	By:	/s/ Troy Wilson
Name:	Heidi Henson	Name:	Troy Wilson
Title:	CFO	Title:	President & CEO

KURA ONCOLOGY, INC.

[\*\*\*]

[\*\*\*]

[\*\*\*]

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

#### EXHIBIT B

#### **CONVERTIBLE NOTE**

THIS CONVERTIBLE PROMISSORY NOTE AND THE SECURITIES ISSUABLE UPON ANY CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER ANY APPLICABLE STATE SECURITIES LAWS, AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED BY ANY PERSON, INCLUDING A PLEDGEE, UNLESS (1) EITHER (A) A REGISTRATION WITH RESPECT THERETO SHALL BE EFFECTIVE UNDER THE SECURITIES ACT, OR (B) THE COMPANY SHALL HAVE RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT IS AVAILABLE, AND (2) THERE SHALL HAVE BEEN COMPLIANCE WITH ALL APPLICABLE STATE SECURITIES OR "BLUE SKY" LAWS.

#### KURA ONCOLOGY, INC.

#### **CONVERTIBLE PROMISSORY NOTE**

\$500,000

December 23, 2014 San Diego, California

FOR VALUE RECEIVED, Kura Oncology, Inc., a Delaware corporation (the "*Company*"), promises to pay to Araxes Pharma LLC, or its assignee (the "*Holder*"), the principal sum of Five Hundred Thousand US Dollars (\$500,000) (the "*Principal Amount*"), together with interest, in the manner provided herein.

## 1. Maturity Date; No Pre-Payment.

(a) *Maturity Date*. Unless earlier converted as provided in Section 4 herein, an amount equal to the sum of the entire outstanding principal balance under this Note, plus all unpaid accrued interest hereon, shall be due and payable on the earliest to occur of: (i) May 31, 2016 (the "*Maturity Date*"), (ii) a Change of Control (as defined below), and (iii) the occurrence of an Event of Default (as defined below).

(b) *No Pre-Payment*. This Note may not be prepaid by the Company, either in whole or in part.

#### 2. Interest.

Interest on the unpaid Principal Amount shall accrue beginning on the date hereof at a rate equal to eight percent (8%) per annum, computed on the basis of the actual number of days elapsed and a year of 365 days from the date of this Note until the Principal Amount and all interest accrued thereon are paid or converted. Unless earlier converted as provided in Section 4 herein, interest shall not be due and payable until the Maturity Date or an earlier Change of Control or Event of Default.

## 3. Events of Default.

(a) Definition of Event of Default. Any one or more of the following events shall constitute an "Event of Default":

(i) The Company fails to pay on the due date any of the Principal Amount or interest on this Note, or any other amount due under this Note, when and as the same shall become due and payable, whether at the due date thereof or at the date fixed for prepayment thereof or by acceleration thereof or otherwise, and such default shall continue unremedied for a period of five (5) business days after written notice thereof by the Holder;

(ii) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking (a) relief in respect of the Company or any subsidiary, or of a substantial part of the property or assets of the Company or any subsidiary, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law, (b) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for the Company or any subsidiary or for a substantial part of the property or assets of the Company or any subsidiary, or (c) the winding-up or liquidation of the Company or any subsidiary, and any such proceeding or petition shall continue

undismissed for sixty (60) days after filing or an order or decree approving or ordering any of the foregoing shall be entered;

(iii) The Company shall (a) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law, (b) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in Section 3(a)(ii) above, (c) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for the Company or any subsidiary or for a substantial part of the property or assets of the Company or any subsidiary, (d) file an answer admitting the material allegations of a petition filed against it in any such proceeding, (e) make a general assignment for the benefit of creditors, (f) become unable, admit in writing its inability or fail generally to pay its debts as and when they become due or (g) take any action for the purpose of effecting any of the foregoing.

(b) *Rights upon Event of Default*. Upon the occurrence of an Event of Default, the Holder may, by notice to the Company, declare the entire unpaid Principal Amount of this Note, all interest accrued and unpaid thereon and all other amounts payable under this Note to be forthwith due and payable, whereupon this Note, all such accrued interest and all such other amounts shall become and be forthwith due and payable. The Holder also may exercise from time to time any rights and remedies available to it by law.

## 4. Conversion.

(a) *Mandatory Conversion*. Subject to and in compliance with the provisions of this Section 4, at any time prior to the Maturity Date, upon the Company's receiving gross proceeds of at least \$10,000,000.00 (not including the aggregate principal amount of, and accrued interest on, the Note to be converted) in an offering or series of related offerings from the bona fide sale of Series A Preferred Stock or such other class of shares as are issued by the Company (a "*Qualified Equity Financing*"), the entire outstanding Principal Amount of this Note and all accrued and unpaid interest thereon shall automatically convert into shares of the Company's capital stock with equivalent rights and preferences as the shares issued in such Qualified Equity Financing (such shares to be issued upon such conversion hereof, the "*Qualified Equity Financing Shares*") at a conversion price equal to the lowest per share purchase price paid for the shares offered in the Qualified Equity Financing.

(b) *Conversion Procedure*. Before the Holder shall be entitled to convert this Note into Qualified Equity Financing Shares pursuant to Section 4(a) above, the Holder shall surrender this Note, duly endorsed, at the office of the Company. The conversion shall be deemed to have been made immediately prior to the close of business on the date of the consummation of the Qualified Equity Financing. Thereupon, the Company shall promptly issue and deliver to the Holder a certificate or certificates for the number of Qualified Equity Financing Shares to which the Holder is entitled.

(c) *Note No Longer Outstanding*. Upon conversion of this Note, this Note shall no longer be deemed to be outstanding and all rights of the Holder as a holder of this Note shall cease.

(d) *Fractional Shares*. No fractional Qualified Equity Financing Shares shall be issued upon conversion of this Note. The Company shall, in lieu of issuing any fractional shares, pay the Holder cash equal to the product of such fraction multiplied by the applicable conversion price on the date of conversion.

(e) *Execution of Agreements Upon Conversion.* If this Note converts upon a Qualified Equity Financing pursuant to Section 4(a) above, then in connection therewith, the Holder and the Company will, if requested by either the Company or Holder, execute and deliver to each other such agreements (including, without limitation, a purchase agreement, investor rights agreement, right of first refusal/co-sale agreement and voting agreement (the "*Financing Agreements*")) as are executed and delivered by other investors in such financing.

**5.** Change of Control. In the event of a Change of Control (defined below) prior to the closing of a Qualified Equity Financing, the Holder may elect to, at its sole discretion and upon written notice to the Company, be paid the sum of (i) one and one half times (1.5x) the outstanding Principal Amount plus (ii) accrued interest on this Note, payable upon consummation of the Change of Control. The Company shall provide written notice to the Holder of a Change of Control at least 15 days in advance of the consummation thereof. A "*Change of Control*" means (a) any merger with another company or an acquisition of the Company, whether by recapitalization, consolidation, sale of outstanding equity securities or otherwise, as a result of which the existing equity holders of the Company prior to

such transaction hold less than fifty percent (50%) of the outstanding voting securities of the surviving entity after such transaction, or (b) a sale of all or substantially all of the assets of the Company.

#### 6. Miscellaneous.

(a) *No Stockholder Rights*. The Holder shall not be entitled to vote or receive dividends or be deemed the holder of any equity securities of the Company that may at any time be issuable on the conversion hereof for any purpose, nor shall anything contained herein be construed to confer upon the Holder, as such, any of the rights of a holder of equity securities of the Company or any right to vote for the election of directors or upon any matter submitted to holders of equity securities at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, or change of stock to no par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or otherwise until this Note shall have converted in accordance with Section 4 hereof.

(b) *Waiver and Amendment*. Any term of this Note may be amended or waived, either retroactively or prospectively, with the written consent of the Company and the Holder.

(c) *Notices and Addresses*. Any notice, demand, request, waiver, or other communication under this Note shall be in writing and shall be deemed to have been duly given on the date of service, if personally served or sent by telecopy or email; on the business day after notice is delivered to a courier or mailed by express mail, if sent by courier delivery service or express mail for next day delivery; and on the third day after mailing, if mailed to the party to whom notice is to be given, by first class mail, registered, return receipt requested, postage prepaid and addressed as follows:

Company:	Kura Oncology, Inc.
	11119 N. Torrey Pines Road, Suite 125
	La Jolla, CA 92037
Holder:	Araxes Pharma LLC

Araxes Pharma LLC 11119 N. Torrey Pines Road, Suite 125 La Jolla, CA 92037

(d) *Lost, Stolen or Mutilated Note.* Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Note or any Note exchanged for it, and (in the case of loss, theft or destruction) of unsecured indemnity satisfactory to it, and upon reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of such Note, if mutilated, the Company will make and deliver in lieu of such Note a new Note of like tenor and unpaid Principal Amount and dated as of the original date of this Note.

(e) *Severability; Binding Effect.* Any provision of this Note which is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Note or affecting the validity or unenforceability of any of the terms and provisions of this Note in any other jurisdiction. This Note shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns.

(f) *Governing Law*. This Note shall be construed and enforced in accordance with and governed by laws of the State of Delaware, without giving effect to the conflict of laws principles thereof.

(g) *Jurisdiction and Service of Process*. Any legal action or proceeding with respect to this Note shall be brought in the courts of the State of Delaware. By execution and delivery of this Note, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. Each of the parties hereto irrevocably consents to the service of process of any of the aforementioned courts in any such action or proceeding by the mailing of copies thereof by certified mail, postage prepaid, to the party at its address set forth in Section 6(c) hereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, this Note has been executed and delivered as of the date first written above.

### Company:

### Kura Oncology, Inc.

By:

Name: Title:

### AGREED TO AND ACCEPTED:

Holder:

#### Araxes Pharma LLC

By:

Name: Title:

15.

#### CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

# 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 [\*\*\*].

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:

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(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 [\*\*\*] ([\*\*\*])

[\*\*\*] 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.

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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.

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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.

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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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

LICENSED PRODUCT or LICENSED 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.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

(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.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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 preferred stock, the "PREFERRED STOCK") equal to \$[\*\*\*] with respect to MICHIGAN and \$[\*\*\*] with

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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 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

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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 <u>Exhibit B-1</u>.

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.

(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.

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

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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:

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

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

[\*\*\*].

LICENSEE shall notify MICHIGAN within [\*\*\*] days after each MILESTONE deadline date above, as to whether 5.3 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 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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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 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.

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

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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 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

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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 outof-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 activities, including but not limited to discovery, relating to the defense and (b) the parties would make joint

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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

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

damage with respect to the manufacture, use or sale of LICENSED PRODUCTS, or LICENSED PROCESSES to LICENSEE, SUBLICENSEE or any other individual or entity, 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.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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.

# 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:

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(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 tradesecret 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.

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.

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

#### 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:

To LICENSEE:

Office of Technology Transfer University of Michigan 1600 Huron Parkway, 2nd Floor Ann Arbor, MI 48109-2590 Kura Oncology, Inc. 11119 North Torrey Pines Road Suite 125 La Jolla, CA 92037

Attn: [\*\*\*]

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.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

prerequisite to enforceability of the Agreement in such nation), LICENSEE shall, at its expense, 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.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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	By	/s/ Kenneth J. Nisbet	
(authorized representative)		-	Kenneth J. Nisbet	
			Assoc. Vice President for Research	
Printed	Name Troy Wilson	_	U-M Tech Transfer	
Title	Pres. & CEO	_		
Date	Dec. 22, 2014	Date	22 December 2014	

### **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 "<u>LICENSE</u>"), 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 <u>LICENSE</u> (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:	Ken	neth J. Nis	bet		
			-	1	1 -

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

# EXHIBIT A-1

# STOCK ISSUANCE AGREEMENT

THIS STOCK ISSUANCE AGREEMENT (the "<u>Agreement</u>") 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 "<u>LICENSEE</u>"), and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan ("<u>MICHIGAN</u>").

# 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. <u>Issuance of Shares</u>. 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 "<u>Michigan Equity</u>"). 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. <u>LICENSEE Representations and Warranties</u>. 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, "<u>Equity Rights</u>"), (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. <u>Michigan's Representations and Warranties</u>. 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. <u>Market Stand-Off</u>. 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.

5. <u>General</u>.

(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**

Ву	Ву
Name:	Name:
Title:	Title:

# EXHIBIT A-2

# STOCK ISSUANCE AGREEMENT

THIS STOCK ISSUANCE AGREEMENT (the "<u>Agreement</u>") 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 "<u>LICENSEE</u>"), and The Leukemia & Lymphoma Society, Inc., a [\_\_\_\_] ("<u>LLS</u>").

### 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 "<u>Amended Collaboration Agreement</u>"), 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 "<u>License</u>"), 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. <u>Issuance of Shares</u>. 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 "<u>LLS Equity</u>"). 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. <u>LICENSEE Representations and Warranties</u>. 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. <u>LLS' Representations and Warranties</u>. 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. <u>General</u>.

(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 ("<u>Amendment</u>") is entered into as of March 3, 2015 (the "<u>Amendment Effective Date</u>") by and between Kura Oncology, Inc. ("<u>Licensee</u>") 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 ("<u>Michigan</u>").

## RECITALS

A. Licensee and Michigan are parties to that certain Patent License Agreement, dated December 22, 2014 (the "<u>Agreement</u>").

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. <u>Section 1.12</u>. 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 <u>Section 2.10</u> 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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

Additional Patent Applications, either directly or through any other party. After LICENSEE exercises its option by providing an acceptable business plan to MICHIGAN describing LICENSED'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 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 obligated to pay multiple milestones or royalties to <u>MICHIGAN</u> or be subject to multiple diligence obligations to <u>MICHIGAN</u> 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 [\*\*\*]."

a. <u>Section 3.8.1</u>. 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

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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")."

4. <u>Section 3.8.2</u>. 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 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."

5. **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."

6. **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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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).

7. **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.

8. **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]

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

**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
		5	

# 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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED



# 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 [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED University of Michigan

September 29, 2016

Page 2

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 [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

## CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

# FIFTH AMENDMENT TO PATENT LICENSE AGREEMENT

This FIFTH AMENDMENT TO PATENT LICENSE AGREEMENT ("<u>Amendment</u>") is entered into as of May 24, 2017 (the "<u>Amendment Effective Date</u>") by and between Kura Oncology, Inc. ("<u>Licensee</u>") 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 ("<u>Michigan</u>").

# RECITALS

A. Licensee and Michigan are parties to that certain Patent License Agreement, dated December 22, 2014, as amended on March 3, 2015, July 22, 2015, September 29, 2016 and February 1, 2017 (the "<u>Agreement</u>").

B. The Parties have decided to further 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. <u>Article 1.</u> Article 1 of the Agreement is hereby amended to insert a new Section 1.11A as follows:

"1.11A "[\*\*\*]" means [\*\*\*]."

3. **Section 3.1(f)**. Section 3.1(f) of the Agreement is hereby amended to delete subparagraphs (4), (5) and (6) in their entirety and replace them with the following:

"(4) \$[\*\*\*]; (5) \$[\*\*\*];

(6) \$[\*\*\*]; and"

4. **Section 3.2.** Section 3.2 of the Agreement is hereby amended to replace "\$2,715,000" with "\$2,100,000".

5. **Continuing Effect.** All references to the "Agreement" in the Agreement shall hereinafter refer to the Agreement as further 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

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

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.

6. **<u>Counterparts</u>**. This Amendment may be executed in counterparts with the same force and effect as if each of the signatories had executed the same instrument.

**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/ Heidi Henson
Name:	Heidi Henson
Title:	CFO

By:	/s/ Kenneth J. Nisbet
Name:	Kenneth J. Nisbet
Title:	Assoc.V.P. for Research U-M Tech Transfer

## CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

## SERVICES AGREEMENT

THIS SERVICES AGREEMENT (this "Agreement"), effective as of October 1, 2014 (the "Effective Date"), is by and between, WELLSPRING BIOSCIENCES LLC, a Delaware limited liability corporation ("Wellspring"), and KURA ONCOLOGY, INC., a Delaware corporation (the "Company").

**WHEREAS**, the Company desires to engage Wellspring to provide the Company various services and make available to the Company certain resources of Wellspring on the terms set forth herein.

**NOW, THEREFORE**, in consideration of the above promises and for other good and valid consideration, the receipt and adequacy of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

## ARTICLE 1

## DEFINED TERMS

**1.1 "Company Confidential Information"** shall mean (a) the Company Work Product and (b) any and all other data, information, technology, samples and specimens of the Company or its products, product concepts, technologies, businesses, financial, marketing, clinical or regulatory affairs, manufacturing processes and procedures, or those of any other third party, whether written, graphic or oral, and whether or not furnished to or obtained by Wellspring, either directly or indirectly, during the course of performing Services hereunder; but excluding, in any event, the Methodology Information and Wellspring Work Product. Wellspring shall be considered the receiving party with respect to all Company Confidential Information.

**1.2 "Company Intellectual Property"** shall have the meaning provided in Section 2.5(a).

**1.3 "Company Work Product"** shall mean any and all results (including data) and products (interim and/or final) of the Services performed by Wellspring or its subcontractors, consultants or agents, whether tangible or intangible, including, without limitation, each and every invention (whether or not patentable), discovery, design, drawing, protocol, process, technique, formula, trade secret, device, compound, substance, material, pharmaceutical, method, software program (including without limitation, object code, source code, flow charts, algorithms and related documentation), listing, routine, manual and specification, whether or not patentable or copyrightable, that are made, developed, perfected, designed, conceived or first reduced to practice by Wellspring (or its subcontractors, consultants or agents), either solely or jointly with others, in the course of the Services. Notwithstanding the foregoing, Company Work Product shall specifically exclude Methodology Information.

**1.4 "Confidential Information**" shall mean the Wellspring Confidential Information or the Company's Confidential Information, as applicable.

1.5 "FTE" means the equivalent of [\*\*\*] over a twelve (12) month period [\*\*\*], which equal [\*\*\*] per year on or directly related to R&D Services.

**1.6** "FTE Costs" means the amount obtained by multiplying (a) the number of FTEs actually expended by or on behalf of Wellspring for a given period of time by (b) four hundred thousand U.S. dollars (U.S.\$400,000).

**1.7 "Materials"** shall mean any chemical or biological materials provided by the Company to Wellspring for use in the Services or procured by Wellspring specifically for use in the Services. For clarity, in the event a sequence or

## [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

structure is provided in lieu of physical quantities, the term "Materials" will be deemed to include such sequences or structures and the physical material derived therefrom.



**1.8 "Methodology Information"** shall mean any methods or processes used or developed by or for Wellspring in or for the provision of Services, or in any documentation, records, raw data, materials (other than Materials), specimens, work product, concepts, information, inventions, improvements, designs, programs, formulas, know-how, or writings related thereto, except those methods and/or processes, if any, disclosed or provided by the Company to Wellspring as specified in writing and agreed to by Wellspring.

**1.9 "Services"** shall have the meaning provided in Section 2.1.

1.10 "Term" shall have the meaning provided in Section 2.6.

**1.11 "Wellspring Confidential Information"** shall mean (a) the Wellspring Work Product and (b) all data, information, technology, samples and specimens of Wellspring or any other person or entity with which Wellspring has a commercial relationship (other than the Company) or their respective products, technologies, businesses, financial, marketing, clinical or regulatory affairs, manufacturing processes and procedures, or those of any other third party from whom Wellspring receives information on a confidential basis, whether written, graphic or oral, furnished to or obtained by the Company, either directly or indirectly, during the course of receiving Services hereunder, including, without limitation, Methodology Information, but excluding the Company's Work Product. The Company shall be considered the receiving party with respect to all Wellspring Confidential Information.

1.12 "Wellspring Intellectual Property" shall have the meaning provided in Section 2.5(a).

1.13 "Wellspring Key Team" shall mean the individuals as may be agreed to between Wellspring and the Company from time to time.

**1.14 "Wellspring Work Product"** shall mean any and all results (including data) and products (interim and/or final) of any activities or services performed by Wellspring on behalf of itself or any third party, other than in the course of performing the Services, whether tangible or intangible, including, without limitation, each and every invention (whether or not patentable), discovery, design, drawing, protocol, process, technique, formula, trade secret, device, compound, substance, material, pharmaceutical, method, software program (including without limitation, object code, source code, flow charts, algorithms and related documentation), listing, routine, manual and specification, whether or not patentable or copyrightable, and that are made, developed, perfected, designed, conceived or first reduced to practice by Wellspring, either solely or jointly with others, whether before, during or after the Term, including, without limitation, the Methodology Information.

## **ARTICLE 2**

## SERVICES

**2.1 Services.** Subject to the terms of this Agreement, for the Term determined pursuant to Section 2.6(a) hereof, Wellspring shall provide or cause to be provided to the Company such services, in the nature of those described on **Exhibit A**, as may reasonably be requested by the Company and reasonably approved by Wellspring from time to time following the date hereof (the "*Services*").

**2.2 Charges and Payment.** As compensation for its services hereunder, Wellspring shall be entitled to receive from the Company, and the Company is obligated to pay fees to Wellspring, for the provision of the Services. The Company shall pay Wellspring for the Services in accordance with the provisions of **Exhibit B** attached hereto.

## 2.3 General Obligations; Standard of Care.

(a) **Performance Requirements.** Wellspring shall use commercially reasonable efforts to provide Services subject to the terms of this Agreement and in accordance with its policies, procedures and practices then in effect, and shall exercise substantially the same care and skill as it exercises in performing similar activities to the services for itself.



(b) Changes. The parties acknowledge that Wellspring may make changes from time to time in the manner of performing the Services. Such changes shall be made in consultation with the Company.

(c) Compliance. Wellspring agrees to perform the Services in accordance with the terms and conditions contained in this Agreement and in compliance with all applicable federal, state and local laws and regulations, including without limitation, the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended ("FCPA"). In furtherance of the foregoing, Wellspring shall conduct its activities hereunder in accordance with the guidelines set forth in Exhibit C (Compliance with Laws and the FCPA).

(d) Communication. On a regular basis during the Term, the parties shall conduct meetings, either in person or by telephone or video conference, to discuss the progress and results of the Services.

(e) Services by Wellspring Key Team. It is the present intention of Wellspring that substantially all of the Services will be provided and/or overseen by members of the Wellspring Key Team, as agreed from time to time.

(f) Subcontracting. Wellspring may subcontract Services to third parties provided that Wellspring will ensure that it enters into an agreement with each subcontractor that, at a minimum, provides for ownership and allocation of intellectual property rights and for obligations of confidentiality of information, that are consistent with the intent and terms of this Agreement. Wellspring will remain liable to Company for the performance of any of its obligations hereunder that it delegates to a subcontractor.

## 2.4 Confidentiality.

(a) Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term of this Agreement and thereafter, the receiving party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other party. Each party may use the other party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, consistent with any restrictions on the use of Confidential Information received from a third party and communicated by the party disclosing such Confidential Information ("*Third Party Restrictions*"). To the extent that any Third Party Restrictions exceed the restrictions on the use of Confidential Information set forth in this Agreement, the parties each hereby agree to be bound by such Third Party Restrictions. The parties agree and acknowledge that certain Confidential Information may be required for submission to the U.S. Food and Drug Administration and/or federal or state regulatory bodies. The parties acknowledge and agree that such submissions, to the extent required by applicable law, shall not constitute a violation of the terms of this Agreement if permitted under any applicable agreement with a third party from whom the disclosing party obtained the Confidential Information. Each party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of such Confidential Information. Each party will promptly notify the other upon discovery of any unauthorized use or disclosure of such Confidential Information.

(b) Limitations. Confidential Information shall not include any information that the receiving party can prove by competent evidence: (i) was already known to the receiving party without any obligations of confidentiality prior to receipt from the other party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving party in breach of any obligation of confidentiality; (iv) was disclosed to the receiving party, other than under an obligation of confidentiality, by a third party who had no obligation not to disclose such information to others; or (v) was independently discovered or developed by the receiving party without the use of Confidential Information; *provided, however*, that any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions solely because certain individual features are published or available to the general public or in the rightful possession of a party unless the combination as a whole falls within any of the above exceptions.

(c) Authorized Disclosure. Notwithstanding Section 2.4(a), a party may disclose Confidential Information of the other party, without violating the obligations of this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body having jurisdiction, provided that such party gives reasonable prior written notice to the other party of such required disclosure and makes a reasonable effort to obtain, or to assist the other party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued.

(d) Use of Name/Publicity. Neither party shall use the other party's name in connection with any publication or promotion without the other party's written consent, except as required by federal, state or local laws, rules and regulations. Neither party shall disclose the specific content or terms of this Agreement without the prior written consent of the other party.

## **2.5 Intellectual Property Rights**

(a) Ownership. The Company shall own all right, title and interest in and to all Materials and Company Work Product, including, without limitation, all patent, copyright or other intellectual property rights therein, that is conceived or first reduced to practice by Wellspring (or its subcontractors, consultants or agents), either solely or jointly with others, in the course of performing the Services (collectively, the "*Company Intellectual Property*"), and neither this Agreement, nor the provision of the Services hereunder, shall give Wellspring any right, title or interest in or to any Company Intellectual Property except as provided in the following sentence. The Company hereby grants to Wellspring a non-exclusive, worldwide, fully-paid, royalty-free license, without the right to sublicense, under the Company Intellectual Property solely as necessary or appropriate to perform Services under this Agreement during the Term. Wellspring shall retain all right, title and interest in and to any and all Methodology Information and Wellspring Work Product, including, without limitation, all patent, copyright or other intellectual property rights therein (collectively, the "*Wellspring Intellectual Property*"), and neither this Agreement, nor the provision of the Services hereunder, shall give the Company any right, title or interest in or to any Wellspring Intellectual Property soley as necessary or appropriate to perform Services under this Agreement during the Term. Wellspring shall retain all right, title and interest in and to any and all Methodology Information and Wellspring Intellectual Property"), and neither this Agreement, nor the provision of the Services hereunder, shall give the Company any right, title or interest in or to any Wellspring Intellectual Property except except as provided in the following sentence. In the event that in the performance of the Services, Wellspring utilizes Wellspring Intellectual Property, Wellspring hereby grants to the Company a non-exclusive, worldwide, fully-paid, roya

(b) Assignment; Assistance. Wellspring hereby assigns all of Wellspring's right, title and interest in and to any Company Intellectual Property to the Company without royalty or any other consideration and agrees to execute all applications, assignments or other instruments reasonably requested by the Company in order for the Company to establish its ownership of such Company Intellectual Property and to obtain whatever protection for such Company Intellectual Property, including copyright and patent rights in any and all countries designated by the Company on such Company Intellectual Property as the Company shall determine. Wellspring agrees to assist the Company, or its designee, in every reasonable way (but at the Company's expense) to secure the Company's rights in Company Intellectual Property and any copyrights, patents or other intellectual property rights relating to all Company Intellectual Property in any and all countries designated by the Company, including the disclosure to the Company of all pertinent information and data with respect to all Company Intellectual Property, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title and interest in and to all Company Intellectual Property. Wellspring also agrees that its obligation to execute or cause to be executed any such instrument or papers shall continue after the expiration or termination of this Agreement. Wellspring agrees that, if the Company is unable because of Wellspring's unavailability, dissolution, or otherwise, to secure Wellspring's signature for the purpose of applying for or pursuing any application for any United States or foreign patents or copyright registrations covering the Company Intellectual Property assigned to the Company herein, then, until such time Wellspring becomes available it hereby designates and appoints the Company and its duly authorized officers and agents as Wellspring's agent and attorney-in-fact, to act for and on Wellspring's behalf to execute and file any such applications and to do all other lawfully permitted acts only to further the prosecution and issuance of patents and copyright registrations with the same legal force and effect as if executed by Wellspring.



#### 2.6 Term; Termination.

(a) **Term**. This Agreement shall be in effect from the Effective Date until December 31, 2015 (the "*Initial Term*") and shall be renewed automatically thereafter for additional consecutive periods of one (1) year each (each a "*Renewal Term*") unless either party gives notice to the other party of its intention to terminate at least thirty (30) days prior to the expiration of the Initial Term or then-current Renewal Term, as applicable (the Initial Term and all Renewal Terms, collectively, the "*Term*").

(b) Election to Terminate. The Company may terminate this Agreement either with respect to all, or with respect to any one or more, of the Services provided hereunder (including, without limitation, terminating the provision of Services by any member or members of the Wellspring Key Team) at any time and from time to time, for any reason or no reason, by giving written notice to Wellspring at least thirty (30) days prior to the date of such termination. Wellspring may terminate this Agreement either with respect to all, or with respect to any one or more, of the Services provided hereunder at any time and from time to time, for any reason or no reason, by giving written notice to the Company at least thirty (30) days prior to the date of such termination. In addition, the parties may at any time agree in writing to terminate this Agreement with respect to some or all of the Services, effective immediately or as indicated in such writing. In the event of any termination with respect to one or more, but less than all, Services, this Agreement shall continue in full force and effect with respect to any Services not terminated hereby.

(c) Payment Upon Early Termination. In the event of termination of this Agreement or any Services hereunder, Wellspring shall be paid for all work completed through the date of termination in accordance with this Agreement, including reasonable and documented out-of-pocket expenses and any non-cancelable commitments incurred by Wellspring in accordance with this Agreement. Wellspring shall refund to the Company any prepaid amounts not earned by Wellspring prior to the date of such termination, including as set forth in Section 2.2 hereof.

(d) Survival Upon Termination. Expiration or termination of this Agreement will not relieve either party of any obligation accruing prior to such expiration or termination. Article 1, Sections 2.2, 2.4, 2.5, 2.6(c), 2.6(d), 3.4 and 3.5, and Articles 4 and 5 will survive expiration or termination of this Agreement.

## ARTICLE 3

## REPRESENTATIONS AND WARRANTIES; DISCLAIMER; LIMITATION OF LIABILITY.

**3.1 Mutual Representations and Warranties.** Each party represents and warrants to the other that: (a) it has full power and authority to enter into this Agreement and to perform its obligations hereunder; (b) this Agreement is legally binding upon it, enforceable against it in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and (c) such party is not under any pre-existing obligation inconsistent with the provisions of this Agreement.

3.2 Wellspring Representations and Warranties. Wellspring hereby represents and warrants to the Company that:

(a) the Services shall be performed by qualified personnel in a good, timely, efficient and professional manner;

(b) Wellspring shall perform the Services in compliance with all applicable laws, rules and regulations, including but not limited to the U.S. Food, Drug and Cosmetic Act and the regulations promulgated thereunder. The parties acknowledge and agree that Wellspring does not warrant or represent that the results of the Services will be acceptable to any regulatory agency to which they are presented nor that the Company will be able to market or otherwise exploit any Company Work Product; and

(c) neither Wellspring nor any Wellspring subcontractors or personnel performing Services under this Agreement have been: (i) debarred, or proposed to be debarred under Section 306(a) or 306(b) of the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the rules, regulations and guidelines promulgated thereunder, or under 42 U.S.C. Section 1320-7; (ii) sanctioned by, suspended, debarred, excluded or otherwise ineligible to participate in any federal or state health care program, including Medicare and Medicaid or in any federal procurement or non-procurement programs; or (iii) charged with or convicted of any felony or misdemeanor under 42 U.S.C. Section 1320a-7(a) or 42 U.S.C. Section 1320a-7(b)(1)-(3), or otherwise proposed for exclusion. Wellspring will promptly inform the Company, but in no event later than four (4) Business Days, if Wellspring becomes aware that its or any of its subcontractors, or any employee of Wellspring or any of its subcontractors, in each case performing any Services related to development activities or in support of the marketing authorizations, is not in compliance with any of the criteria set forth in this Section 3.2(c) on or after the Effective Date.

#### 3.3 Company Representations and Warranties. The Company hereby represents and warrants to Wellspring that:

(a) to the extent this Agreement provides for the Company to provide Wellspring with any Materials, the Company has the right to provide such Materials to Wellspring for use as contemplated by this Agreement; and

(b) to the Company's knowledge, the use of such Materials as contemplated by this Agreement will not infringe the intellectual property rights of any third party.

**3.4 Disclaimer of Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, AND EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, WELLSPRING MAKES NO REPRESENTATIONS OR WARRANTIES AS TO THE QUALITY, SUITABILITY OR ADEQUACY OF THE SERVICES FOR ANY PURPOSE OR USE.

**3.5 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT; *provided, however*, that this Section 3.5 shall not apply to any breaches of Section 2.4 or be construed to limit either party's indemnification obligations under Article 4.

## **ARTICLE 4**

## INDEMNIFICATION.

**4.1 By the Company.** The Company hereby agrees to save, defend, indemnify and hold harmless Wellspring, its affiliates (other than the Company) and their respective officers, directors, employees, consultants and agents (each, a "*Wellspring Party*") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("*Losses*"), to which any Wellspring Party may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise directly or indirectly out of (a) the performance of the Services, (b) the development, manufacture, use, handling, storage, sale or other disposition of any product by the Company, or (c) the gross negligence or willful misconduct of any Company Party (as defined below) or the breach by the Company of any warranty, representation, covenant or agreement made by the Company in this Agreement, except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Wellspring of any warranty, representation, covenant or agreement made by Wellspring in this Agreement.

**4.2 By Wellspring.** Wellspring hereby agrees to save, defend, indemnify and hold harmless the Company, its affiliates and their respective officers, directors, employees, consultants and agents (each, a "*Company Party*") from and against any and all Losses to which any Company Party may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise directly or indirectly out of the gross negligence or willful misconduct of any Wellspring Party or the breach by Wellspring of any warranty, representation, covenant or agreement made by Wellspring in this Agreement, except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Company Party or the breach by the Company in this Agreement.

**4.3 Control of Defense.** In the event a party seeks indemnification under Section 4.1 or Section 4.2, it shall inform the other party (the "*Indemnifying Party*") of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration with no admission of fault), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim.

**4.4 Liability Insurance.** Each party agrees to maintain during the Term usual and customary liability, workers compensation and errors and omissions insurance in amounts consistent with industry standards and to provide a certificate of insurance evidencing such coverage to the other party upon request.

#### **ARTICLE 5**

#### MISCELLANEOUS

5.1 Taxes. Wellspring will pay any and all taxes levied on account of any payments made to it under this Agreement.

**5.2 Relationship of Parties.** Nothing in this Agreement shall be deemed or construed by the parties or any third party as creating the relationship of principal and agent, partnership or joint venture between the parties, it being understood and agreed that no provision contained herein, and no act of the parties, shall be deemed to create any relationship between the parties other than the relationship of independent contractor nor be deemed to vest any rights, interest or claims in any third parties.

**5.3 Integration.** This Agreement (including the Exhibits hereto) contains the complete, final and exclusive agreement of the parties relating to the subject matter hereof, and supersedes all prior and contemporaneous oral and written agreements or arrangements between the parties. To the extent this Agreement conflicts with any other agreements, written or oral, between the parties, this Agreement controls.

5.4 Modification and Amendment. This Agreement may be modified or amended only by a writing signed by both parties.

**5.5 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of California as applied to contracts entered into entirely in California by California residents.

**5.6 No Implied Licenses.** No right or license is granted under this Agreement by either party to the other, either expressly or by implication, except those specifically set forth herein.

**5.7 Severability.** If any provision of this Agreement should be held invalid or unenforceable, the remaining provisions shall be unaffected and shall remain in full force and effect, to the extent consistent with the intent of the parties as evidenced by this Agreement as a whole.

**5.8 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); *provided, however*, that the Company may assign this Agreement and its rights and obligations hereunder without Wellspring's consent in connection with the transfer or sale of all or substantially all of the Company's business to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

5.9 Headings. Section headings are for convenience of reference only and shall not be considered in the interpretation of this Agreement.

**5.10 Force Majeure.** In the event of a delay caused by inclement weather, fire, flood, strike or other labor dispute, act of God, act of governmental officials or agencies, or any other cause beyond the control of the parties, the party or parties so affected shall be excused from performance hereunder for the period of time attributable to such delay, which may extend beyond the time lost due to one or more of the causes mentioned above. In the event of any such delay, the parties may, in their sole discretion, amend this Agreement, as appropriate, by mutual written agreement.

**5.11 Notices.** Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing.

If to Wellspring:	Wellspring Biosciences LLC 11119 N. Torrey Pines Road, Suite 125 La Jolla, CA 92037
If to the Company:	Kura Oncology, Inc. 11119 N. Torrey Pines Road, Suite 125 La Jolla, CA 92037

All notices under this Agreement shall be deemed made upon receipt by the addressee as evidenced by the applicable written receipt or, in the case of a facsimile, as evidenced by the confirmation of transmission.

**5.12 Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

**5.13 Non-Waiver.** No failure or delay of one of the parties to insist upon strict performance of any of its rights or powers under this Agreement shall operate as a waiver thereof, nor shall any other single or partial exercise of such right or power preclude any other further exercise of any rights or remedies provided by law.

**5.14 Waiver of Conflicts**. Each party to this Agreement acknowledges that Cooley LLP ("*Cooley*"), special counsel to Wellspring with respect to this Agreement, has in the past represented and is now representing and may in the future represent the Company in matters unrelated to the transactions contemplated by this Agreement (the "*Services Agreement*"), including representation of the Company in matters of a similar nature to the Services Agreement. The applicable rules of professional conduct require that Cooley inform the parties hereunder of this representation and obtain their consent. Wellspring and the Company hereby (a) acknowledge that they are entitled to seek independent legal advice regarding the provisions of this paragraph and the granting of the consent provided for herein, (b) acknowledge that they have had an opportunity to ask for and have obtained information relevant to such representation, including disclosure of the reasonably foreseeable adverse consequences of such representation, (c) acknowledge that with respect to the Services Agreement, Cooley has represented solely Wellspring and not the Company or any stockholder, director or employee of the Company and (d) give their informed consent to Cooley's representation as special counsel to Wellspring in connection with the Services Agreement.

**5.15 Waiver of Corporate Opportunity.** In the event that one of the parties to this Agreement or any director, officer, employee or representative of such party (the "*Primary Party*") acquires knowledge of a potential transaction or other matter (including, but not limited to, any compounds or other assets or the opportunity to acquire interests thereof) and that may be an opportunity of interest (a "*Corporate Opportunity*") for the other party to this Agreement (the "*Other Party*"), then the Other Party (i) renounces any expectancy that the Primary Party offer an opportunity to participate in such Corporate Opportunity to the Other Party and (ii) to the fullest extent permitted by law, waives any claim that such opportunity constituted a Corporate Opportunity that should have been presented by the Primary Party to the Other Party or any of its affiliates.

## [REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

**IN WITNESS WHEREOF**, the parties have executed this Services Agreement effective as of the date first above written.

# WELLSPRING BIOSCIENCES LLC

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

# KURA ONCOLOGY, INC.

By:	/s/ Troy Wilson
Name:	Troy Wilson
Title:	President & CEO

## EXHIBIT A

## SERVICES

**1.** Subject to the provisions of Section 2 of the Agreement, Wellspring shall use commercially reasonable efforts to provide, among others, the following Services as may be requested from time to time by the Company:

- A. **Research and Development Services.** Wellspring shall provide to the Company general research and development services to be mutually agreed by the parties ("*R&D Services*").
- B. Other. Wellspring shall provide such other Services as mutually agreed between Wellspring and the Company ("Other Services").

#### EXHIBIT B

#### SERVICES FEES

- 1. In consideration for the Services provided, the Company shall pay to Wellspring the following, subject to adjustment pursuant to Section 2 below:
  - **A.** The Company shall pay a fee based on FTE Costs for FTEs expended in the provision of R&D Services. For clarity, FTE Costs include the costs of all consumables except as provided in paragraph C. below.
  - **B.** If the Company and Wellspring agree to the provision of any Other Services, the parties will mutually agree to a reasonable fee for such Services at such time.
  - C. In addition, the Company shall reimburse Wellspring for any reagent that is above U.S.\$[\*\*\*] and in the event that the Services include chemistry scale-up efforts that require specialized reagents or involve scale-up costs that exceed U.S.\$[\*\*\*], the Company will pay the cost of any specialized reagents required for such scale-up.
  - **D.** In the event that Wellspring subcontracts Services to a third party, the third party costs incurred by Wellspring will be passed through to Company without markup.
- 2. The fees for the Services set forth in Section 1 above shall be subject to the following:
  - **A.** The Service fees shall be payable in U.S. dollars (unless mutually agreed by the parties) and shall be subject to all applicable government regulations and rulings.
  - **B.** Wellspring shall provide the Company with documentation which may be required by the revenue authorities to support the fact that the Services fees represent arm's length remuneration for the benefits derived from the Services provided to the Company in that particular year.
  - **C.** If at any time the amount paid under this Agreement for the Services is subsequently adjusted by a tax administration for the purposes of calculating the income tax liability of either party, the parties agree that the amount of the adjustment shall be payable and receivable by either party, as the case may be, within 90 days of the issue date of the tax assessment under which the adjustment arises.
- 3. All payments hereunder shall be made in cash or by offset against any indebtedness owing to the Company by Wellspring. Wellspring shall invoice the Company at least quarterly for services provided during the previous quarter, in each case as actually incurred during such quarter in performing Services: (i) FTE Costs for FTEs for which Company is obligated to reimburse Wellspring (ii) any agreed upon fees for Other Services as described in Section 1B above, (iii) any excess supply costs as described in

Section 1C above, and (iv) any pass through expenses as described in Section 1D above. Wellspring shall include with each such invoice reasonably detailed information documenting FTE Costs and out-of-pocket costs incurred during the applicable time period. The Company agrees to pay all amounts due to Wellspring arising under this Agreement promptly upon receipt of any such invoice. The parties to this Agreement agree to discuss in good faith on a semi-annual basis during the term of this Agreement the necessity or desirability of adjusting the fees set forth in this Exhibit B.

4. The Company understands and acknowledges that Wellspring must reasonably allocate its staff resources among all of the companies to which Wellspring provides services. Notwithstanding any other provision of this Agreement, Wellspring may at any time, without notice or liability, change or eliminate the persons who provide the Services to the Company on behalf of Wellspring pursuant to this Agreement, provided that the Services continue to be provided to the Company on substantially the same levels as provided prior to such change or elimination. The Company expressly acknowledges that Wellspring is engaged in the business of providing drug development services to multiple companies and providing management, scientific, business development, financial and other operational services to those companies and that neither Wellspring nor any other company to which Wellspring provides services shall have any exclusivity or similar obligation to the Company, including without limitation any corporate opportunity obligation or any obligation to disclose or make available to the Company any information, potential transaction or other matter of which any such Wellspring Party becomes aware otherwise than solely in the course of performing Services under this Agreement on behalf of the Company.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

#### EXHIBIT C

#### **Compliance with Laws and the FCPA**

- 1.1. Wellspring shall become familiar with the FCPA, its prohibitions and purposes, and shall not undertake any actions that may violate the FCPA. Accordingly, Wellspring hereby agrees that:
  - (i) no person shall be employed by it who is an official or employee of any government or any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government);
  - (ii) no payment or offer to pay, or the giving or offering to give, anything of value to an official or employee of any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government), or to any political party or any candidate for political office, shall be made with the purpose of influencing any decisions favorable to either Party or its Affiliates in contravention of the FCPA or the laws of the country in which it is providing work;
  - (iii) it not pay, nor offer or agree to pay, nor caused to be paid, directly or indirectly, any political contributions, fees or commissions to any governmental employee or representative (including, but not limited to, any employee of any health or medical provider owned or controlled by the government) that could cause a violation of the FCPA;
  - (iv) it will not, directly or indirectly, in connection with the Agreement and the business resulting therefrom, offer, pay, promise to pay, or authorize the giving of money or anything of value to any governmental official or representative, to any political party or official thereof, or to any candidate for political office, or to any person, while knowing or being aware of the probability that all or any portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any government official, to any political party or official thereof, or to any candidate to political office, for the purpose of:
    - a. influencing any act or decisions of such official, political party, party official, or candidate in its official capacity, including a decision to fail to perform official functions; or
    - b. inducing such official, political party, party official, or candidate to use influence with the government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist either Party in obtaining or retaining business for or with, or directing business to, any third party.
  - (v) Wellspring will immediately notify the Company if it becomes aware of any apparent violation of the FCPA in connection with its activities hereunder.
- 1.2. Wellspring shall provide the Company and its agents and representatives (collectively, "Agents"), as well as any regulatory authorities having regulatory oversight of Wellspring, with access to its facilities, records (financial and otherwise), and supporting documentation as may be requested by any Agents in order to document or verify compliance with the provisions of this Exhibit. Wellspring acknowledges that the provisions of this Exhibit granting the Company certain audit rights shall in no way relieve Wellspring of any of its obligations under the Agreement, nor shall such provisions require the Company to conduct any such audits.
- 1.3. Wellspring shall maintain true and accurate records necessary to demonstrate compliance with this Agreement (including the requirements of this Exhibit).
- 1.4. If Wellspring fails to comply with any of the provisions of this Exhibit (irrespective of the size, nature or materiality of such violation), such failure may be treated by the Company as a material breach.
- 1.5. Notwithstanding anything to the contrary in the Agreement, each Party may disclose its terms and conditions (including any financial terms) to any government authority that it determines in good faith has a legitimate need for access to such information (including, but not limited to, any governmental authorities in the U.S. or those in the country where research is being provided).

## CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE KURA ONCOLOGY, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO KURA ONCOLOGY, INC. IF PUBLICLY DISCLOSED.

## MANAGEMENT SERVICES AGREEMENT

THIS MANAGEMENT SERVICES AGREEMENT (this "Agreement"), effective as of October 1, 2014 (the "Effective Date"), is by and between KURA ONCOLOGY, INC., a Delaware corporation ("Kura"), and ARAXES PHARMA LLC, a Delaware limited liability company (the "Company").

WHEREAS, the Company desires to engage Kura to provide the Company various services and make available to the Company certain resources of Kura on the terms set forth herein.

**NOW, THEREFORE**, in consideration of the above promises and for other good and valid consideration, the receipt and adequacy of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

### **ARTICLE 1**

#### **DEFINED TERMS**

**1.1 "Company Confidential Information"** shall mean (a) the Company Work Product and (b) any and all other data, information, technology, samples and specimens of the Company or its products, product concepts, technologies, businesses, financial, marketing, clinical or regulatory affairs, manufacturing processes and procedures, or those of any other third party, whether written, graphic or oral, and whether or not furnished to or obtained by Kura, either directly or indirectly, during the course of performing Services hereunder; but excluding, in any event, the Methodology Information and Kura Work Product. Kura shall be considered the receiving party with respect to all Company Confidential Information.

1.2 "Company Intellectual Property" shall have the meaning provided in Section 2.5(a).

**1.3 "Company Work Product"** shall mean any and all results (including data) and products (interim and/or final) of the Services performed by Kura or its subcontractors, consultants or agents, whether tangible or intangible, including, without limitation, each and every invention (whether or not patentable), discovery, design, drawing, protocol, process, technique, formula, trade secret, device, compound, substance, material, pharmaceutical, method, software program (including without limitation, object code, source code, flow charts, algorithms and related documentation), listing, routine, manual and specification, whether or not patentable or copyrightable, that are made, developed, perfected, designed, conceived or first reduced to practice by Kura, (or its subcontractors, consultants or agents), either solely or jointly with others, in the course of the Services. Notwithstanding the foregoing, Company Work Product shall specifically exclude Methodology Information.

1.4 "Confidential Information" shall mean the Kura Confidential Information or the Company's Confidential Information, as applicable.

**1.5 "Materials"** shall mean any chemical or biological materials provided by the Company to Kura for use in the Services or procured by Kura specifically for use in the Services. For clarity, in the event a sequence or structure is provided in lieu of physical quantities, the term "Materials" will be deemed to include such sequences or structures and the physical material derived therefrom.

**1.6 "Methodology Information"** shall mean any methods or processes used or developed by or for Kura in or for the provision of Services, or in any documentation, records, raw data, materials (other than Materials), specimens, work product, concepts, information, inventions, improvements, designs, programs, formulas, know-how, or writings related thereto, except those methods and/or processes, if any, disclosed or provided by the Company to Kura as specified in writing and agreed to by Kura.

### **1.7 "Services"** shall have the meaning provided in Section 2.1.

1.8 "Term" shall have the meaning provided in Section 2.6.

**1.9 "Kura Confidential Information"** shall mean (a) the Kura Work Product and (b) all data, information, technology, samples and specimens of Kura or any other person or entity with which Kura has a commercial relationship (other than the Company) or their respective products, technologies, businesses, financial, marketing, clinical or regulatory affairs, manufacturing processes and procedures, or those of any other third party from whom Kura receives information on a confidential basis, whether written, graphic or oral, furnished to or obtained by the Company, either directly or indirectly, during the course of receiving Services hereunder, including, without limitation, Methodology Information, but excluding the Company's Work Product. The Company shall be considered the receiving party with respect to all Kura Confidential Information.

### 1.10 "Kura Intellectual Property" shall have the meaning provided in Section 2.5(a).

**1.11 "Kura Key Team"** shall mean the individuals as specified on **Exhibit A** hereto as amended from time to time and such other individuals as may be agreed to between Kura and the Company from time to time.

**1.12 "Kura Work Product"** shall mean any and all results (including data) and products (interim and/or final) of any activities or services performed by Kura on behalf of itself or any third party, other than in the course of performing the Services, whether tangible or intangible, including, without limitation, each and every invention (whether or not patentable), discovery, design, drawing, protocol, process, technique, formula, trade secret, device, compound, substance, material, pharmaceutical, method, software program (including without limitation, object code, source code, flow charts, algorithms and related documentation), listing, routine, manual and specification, whether or not patentable or copyrightable, and that are made, developed, perfected, designed, conceived or first reduced to practice by Kura, either solely or jointly with others, whether before, during or after the Term, including, without limitation, the Methodology Information.

#### **ARTICLE 2**

#### SERVICES

**2.1 Services.** Subject to the terms of this Agreement, for the Term determined pursuant to Section 2.6(a) hereof, Kura shall provide or cause to be provided to the Company such services, in the nature of those described on **Exhibit A**, as may reasonably be requested by the Company and reasonably approved by Kura from time to time following the date hereof (the "*Services*").

**2.2 Charges and Payment.** As compensation for its services hereunder, Kura shall be entitled to receive from the Company, and the Company is obligated to pay fees to Kura, for the provision of the Services. The Company shall pay Kura for the Services in accordance with the provisions of **Exhibit B** attached hereto.

## 2.3 General Obligations; Standard of Care.

(a) **Performance Requirements.** Kura shall use commercially reasonable efforts to provide Services subject to the terms of this Agreement and in accordance with its policies, procedures and practices then in effect, and shall exercise substantially the same care and skill as it exercises in performing similar activities to the services for itself.

(b) Changes. The parties acknowledge that Kura may make changes from time to time in the manner of performing the Services. Such changes shall be made in consultation with the Company.

(c) Compliance. Kura agrees to perform the Services in accordance with the terms and conditions contained in this Agreement and in compliance with all applicable federal, state and local laws and regulations including without limitation, the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, *et. seq.*) as amended ("FCPA"). In furtherance of the foregoing, Kura shall conduct its activities hereunder in accordance with the guidelines set forth in Exhibit C (Compliance with Laws and the FCPA).



(d) Communication. On a regular basis during the Term, the parties shall conduct meetings, either in person or by telephone or video conference, to discuss the progress and results of the Services.

(e) Services by Kura Key Team. It is the present intention of Kura that substantially all of the Services will be provided and/or overseen by members of the Kura Key Team, as agreed from time to time.

(f) Subcontracting. Kura may subcontract Services to third parties provided that Kura will ensure that it enters into an agreement with each subcontractor that, at a minimum, provides for ownership and allocation of intellectual property rights and for obligations of confidentiality of information that are consistent with the intent and terms of this Agreement. Kura will remain liable to Company for the performance of any of its obligations hereunder that it delegates to a subcontractor.

## 2.4 Confidentiality.

(a) Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term of this Agreement and thereafter, the receiving party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other party. Each party may use the other party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, consistent with any restrictions on the use of Confidential Information received from a third party and communicated by the party disclosing such Confidential Information ("*Third Party Restrictions*"). To the extent that any Third Party Restrictions exceed the restrictions on the use of Confidential Information set forth in this Agreement, the parties each hereby agree to be bound by such Third Party Restrictions. The parties agree and acknowledge that certain Confidential Information may be required for submission to the U.S. Food and Drug Administration and/or federal or state regulatory bodies. The parties acknowledge and agree that such submissions, to the extent required by applicable law, shall not constitute a violation of the terms of this Agreement if permitted under any applicable agreement with a third party from whom the disclosing party obtained the Confidential Information. Each party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of such Confidential Information. Each party will promptly notify the other upon discovery of any unauthorized use or disclosure of such Confidential Information.

(b) Limitations. Confidential Information shall not include any information that the receiving party can prove by competent evidence: (i) was already known to the receiving party without any obligations of confidentiality prior to receipt from the other party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving party in breach of any obligation of confidentiality; (iv) was disclosed to the receiving party, other than under an obligation of confidentiality, by a third party who had no obligation not to disclose such information to others; or (v) was independently discovered or developed by the receiving party without the use of Confidential Information; *provided, however*, that any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions solely because certain individual features are published or available to the general public or in the rightful possession of a party unless the combination as a whole falls within any of the above exceptions.

(c) Authorized Disclosure. Notwithstanding Section 2.4(a), a party may disclose Confidential Information of the other party, without violating the obligations of this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body having jurisdiction, provided that such party gives reasonable prior written notice to the other party of such required disclosure and makes a reasonable effort to obtain, or to assist the other party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued.

(d) Use of Name/Publicity. Neither party shall use the other party's name in connection with any publication or promotion without the other party's written consent, except as required by federal, state or local laws, rules and

regulations. Neither party shall disclose the specific content or terms of this Agreement without the prior written consent of the other party.

#### **2.5 Intellectual Property Rights**

(a) Ownership. The Company shall own all right, title and interest in and to all Materials and Company Work Product, including, without limitation, all patent, copyright or other intellectual property rights therein, that is conceived or first reduced to practice by Kura, or its subcontractors, consultants or agents, either solely or jointly with others, in the course of performing the Services (collectively, the "*Company Intellectual Property*"), and neither this Agreement, nor the provision of the Services hereunder, shall give Kura any right, title or interest in or to any Company Intellectual Property except as provided in the following sentence. The Company hereby grants to Kura a non-exclusive, worldwide, fully-paid, royalty-free license, without the right to sublicense, under the Company Intellectual Property solely as necessary or appropriate to perform Services under this Agreement during the Term. Kura shall retain all right, title and interest in and to any and all Methodology Information and Kura Work Product, including, without limitation, all patent, copyright or other intellectual property rights therein (collectively, the "*Kura Intellectual Property*"), and neither this Agreement, nor the provision of the Services hereunder, shall give the Company any right, title or interest in or to any Kura Intellectual Property except as provided in the following sentence. In the event that in the performance of the Services, Kura utilizes Kura Intellectual Property, Kura hereby grants to the Company a non-exclusive, worldwide, fully-paid, royalty-free license, without the right to sublicense, under such Kura Intellectual Property solely as necessary for the Company or its affiliates or licensees (other than Kura) to develop, make, have made, use, sell, offer to sell and import products.

(b) Assignment; Assistance. Kura hereby assigns all of Kura's right, title and interest in and to any Company Intellectual Property to the Company without royalty or any other consideration and agrees to execute all applications, assignments or other instruments reasonably requested by the Company in order for the Company to establish its ownership of such Company Intellectual Property and to obtain whatever protection for such Company Intellectual Property, including copyright and patent rights in any and all countries designated by the Company on such Company Intellectual Property as the Company shall determine. Kura agrees to assist the Company, or its designee, in every reasonable way (but at the Company's expense) to secure the Company's rights in Company Intellectual Property and any copyrights, patents or other intellectual property rights relating to all Company Intellectual Property in any and all countries designated by the Company, including the disclosure to the Company of all pertinent information and data with respect to all Company Intellectual Property, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title and interest in and to all Company Intellectual Property. Kura also agrees that its obligation to execute or cause to be executed any such instrument or papers shall continue after the expiration or termination of this Agreement. Kura agrees that, if the Company is unable because of Kura's unavailability, dissolution, or otherwise, to secure Kura's signature for the purpose of applying for or pursuing any application for any United States or foreign patents or copyright registrations covering the Company Intellectual Property assigned to the Company herein, then, until such time Kura becomes available it hereby designates and appoints the Company and its duly authorized officers and agents as Kura's agent and attorney-in-fact, to act for and on Kura's behalf to execute and file any such applications and to do all other lawfully permitted acts only to further the prosecution and issuance of patents and copyright registrations with the same legal force and effect as if executed by Kura.

(c) Protection of Privileged Advice Shared for Common Interest. For the avoidance of doubt, any opinions or other advice of any qualified legal personnel (whether a patent attorney or other counsel) representing a party hereunder communicated to the other party or both parties, directly by such legal personnel or indirectly such as through a patent liaison for common interest purposes contemplated hereunder, shall be held in strict confidence to protect the privileged nature thereof, and not disclosed to any Third Party without the prior written consent of both parties, each under the advice of its respective legal counsel.

### 2.6 Term; Termination.

(a) Term. This Agreement shall be in effect from the Effective Date until December 31, 2015 (the "*Initial Term*") and shall be renewed automatically thereafter for additional consecutive periods of one (1) year each (each a



"*Renewal Term*") unless either party gives notice to the other party of its intention to terminate at least thirty (30) days prior to the expiration of the Initial Term or then-current Renewal Term, as applicable (the Initial Term and all Renewal Terms, collectively, the "*Term*").

(b) Election to Terminate. The Company may terminate this Agreement either with respect to all, or with respect to any one or more, of the Services provided hereunder (including, without limitation, terminating the provision of Services by any member or members of the Kura Key Team) at any time and from time to time, for any reason or no reason, by giving written notice to Kura at least thirty (30) days prior to the date of such termination. Kura may terminate this Agreement either with respect to all, or with respect to any one or more, of the Services provided hereunder at any time and from time to time, for any reason or no reason, by giving written notice to the Company at least thirty (30) days prior to the date of such termination. In addition, the parties may at any time agree in writing to terminate this Agreement with respect to some or all of the Services, effective immediately or as indicated in such writing. In the event of any termination with respect to one or more, but less than all, Services, this Agreement shall continue in full force and effect with respect to any Services not terminated hereby.

(c) Payment Upon Early Termination. In the event of termination of this Agreement or any Services hereunder, Kura shall be paid for all work completed through the date of termination in accordance with this Agreement, including reasonable and documented out-of-pocket expenses and any non-cancelable commitments incurred by Kura in accordance with this Agreement. Kura shall refund to the Company any prepaid amounts not earned by Kura prior to the date of such termination, including as set forth in Section 2.2 hereof.

(d) Survival Upon Termination. Expiration or termination of this Agreement will not relieve either party of any obligation accruing prior to such expiration or termination. Article 1, Sections 2.2, 2.4, 2.5, 2.6(c), 2.6(d), 3.4 and 3.5, and Articles 4 and 5 will survive expiration or termination of this Agreement.

## ARTICLE 3

## **REPRESENTATIONS AND WARRANTIES; DISCLAIMER; LIMITATION OF LIABILITY.**

**3.1 Mutual Representations and Warranties.** Each party represents and warrants to the other that: (a) it has full power and authority to enter into this Agreement and to perform its obligations hereunder; (b) this Agreement is legally binding upon it, enforceable against it in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and (c) such party is not under any pre-existing obligation inconsistent with the provisions of this Agreement.

3.2 Kura Representations and Warranties. Kura hereby represents and warrants to the Company that:

(a) the Services shall be performed by qualified personnel in a good, timely, efficient and professional manner;

(b) Kura shall perform the Services in compliance with all applicable laws, rules and regulations, including but not limited to the U.S. Food, Drug and Cosmetic Act and the regulations promulgated thereunder. The parties acknowledge and agree that Kura does not warrant or represent that the results of the Services will be acceptable to any regulatory agency to which they are presented nor that the Company will be able to market or otherwise exploit any Company Work Product; and

(c) neither Kura nor any Kura contractors or personnel performing Services under this Agreement have been: (i) debarred, or proposed to be debarred under Section 306(a) or 306(b) of the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the rules, regulations and guidelines promulgated thereunder, or under 42 U.S.C. Section 1320-7; (ii) sanctioned by, suspended, debarred, excluded or otherwise ineligible to participate in any federal or state health care program, including Medicare and Medicaid or in any federal procurement or non-procurement programs; or (iii) charged with or convicted of any felony or misdemeanor under 42 U.S.C. Section 1320a-7(a) or 42 U.S.C. Section 1320a-7(b)(1)-(3), or otherwise proposed for exclusion. Kura will promptly inform the Company, but in no event later than four (4) Business Days, if Kura becomes aware that its

or any of its subcontractors, or any employee of Kura or any of its subcontractors, in each case performing any Services related to development activities or in support of the marketing authorizations, is not in compliance with any of the criteria set forth in this Section 3.2(c) on or after the Effective Date.

## 3.3 Company Representations and Warranties. The Company hereby represents and warrants to Kura that:

(a) to the extent this Agreement provides for the Company to provide Kura with any Materials, the Company has the right to provide such Materials to Kura for use as contemplated by this Agreement; and

(b) to the Company's knowledge, the use of such Materials as contemplated by this Agreement will not infringe the intellectual property rights of any third party.

**3.4 Disclaimer of Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, AND EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, KURA MAKES NO REPRESENTATIONS OR WARRANTIES AS TO THE QUALITY, SUITABILITY OR ADEQUACY OF THE SERVICES FOR ANY PURPOSE OR USE.

**3.5 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT; *provided, however*, that this Section 3.5 shall not apply to any breaches of Section 2.4 or be construed to limit either party's indemnification obligations under Article 4.

#### **ARTICLE 4**

## INDEMNIFICATION.

**4.1 By the Company.** The Company hereby agrees to save, defend, indemnify and hold harmless Kura, its affiliates (other than the Company) and their respective officers, directors, employees, consultants and agents (each, a "*Kura Party*") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("*Losses*"), to which any Kura Party may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise directly or indirectly out of (a) the performance of the Services, (b) the development, manufacture, use, handling, storage, sale or other disposition of any product by the Company, or (c) the gross negligence or willful misconduct of any Company Party (as defined below) or the breach by the Company of any warranty, representation, covenant or agreement made by the Company in this Agreement, except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Warranty, representation, covenant or agreement made by Kura in this Agreement.

**4.2 By Kura.** Kura hereby agrees to save, defend, indemnify and hold harmless the Company, its affiliates and their respective officers, directors, employees, consultants and agents (each, a "*Company Party*") from and against any and all Losses to which any Company Party may become subject as a result of any claim, demand, action or other proceeding by any third party to the extent such Losses arise directly or indirectly out of the gross negligence or willful misconduct of any Kura Party or the breach by Kura of any warranty, representation, covenant or agreement made by Kura in this Agreement, except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Company Party or the breach by the Company of any warranty, representation, covenant or agreement made by the Company of any warranty, representation, covenant or agreement made by the Company in this Agreement.

**4.3 Control of Defense.** In the event a party seeks indemnification under Section 4.1 or Section 4.2, it shall inform the other party (the "*Indemnifying Party*") of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration with no admission of fault), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim.



**4.4 Liability Insurance.** Each party agrees to maintain during the Term usual and customary liability, workers compensation and errors and omissions insurance in amounts consistent with industry standards and to provide a certificate of insurance evidencing such coverage to the other party upon request.

## **ARTICLE 5**

## MISCELLANEOUS

5.1 Taxes. Kura will pay any and all taxes levied on account of any payments made to it under this Agreement.

**5.2 Relationship of Parties.** Nothing in this Agreement shall be deemed or construed by the parties or any third party as creating the relationship of principal and agent, partnership or joint venture between the parties, it being understood and agreed that no provision contained herein, and no act of the parties, shall be deemed to create any relationship between the parties other than the relationship of independent contractor nor be deemed to vest any rights, interest or claims in any third parties.

**5.3 Integration.** This Agreement (including the Exhibits hereto) contains the complete, final and exclusive agreement of the parties relating to the subject matter hereof, and supersedes all prior and contemporaneous oral and written agreements or arrangements between the parties. To the extent this Agreement conflicts with any other agreements, written or oral, between the parties, this Agreement controls.

5.4 Modification and Amendment. This Agreement may be modified or amended only by a writing signed by both parties.

**5.5 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of California as applied to contracts entered into entirely in California by California residents.

**5.6 No Implied Licenses.** No right or license is granted under this Agreement by either party to the other, either expressly or by implication, except those specifically set forth herein.

**5.7 Severability.** If any provision of this Agreement should be held invalid or unenforceable, the remaining provisions shall be unaffected and shall remain in full force and effect, to the extent consistent with the intent of the parties as evidenced by this Agreement as a whole.

**5.8** Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); *provided*, *however*, that the Company may assign this Agreement and its rights and obligations hereunder without Kura's consent in connection with the transfer or sale of all or substantially all of the Company's business to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

5.9 Headings. Section headings are for convenience of reference only and shall not be considered in the interpretation of this Agreement.

**5.10 Force Majeure.** In the event of a delay caused by inclement weather, fire, flood, strike or other labor dispute, act of God, act of governmental officials or agencies, or any other cause beyond the control of the parties, the party or parties so affected shall be excused from performance hereunder for the period of time attributable to such delay, which may extend beyond the time lost due to one or more of the causes mentioned above. In the event of any such delay, the parties may, in their sole discretion, amend this Agreement, as appropriate, by mutual written agreement.

**5.11 Notices.** Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing.



If to Kura:	Kura Oncology, Inc. 11119 N. Torrey Pines Road, Suite 125 La Jolla, CA 92037
If to the Company:	Araxes Pharma LLC 11119 N. Torrey Pines Road, Suite 125 La Jolla, CA 92037

All notices under this Agreement shall be deemed made upon receipt by the addressee as evidenced by the applicable written receipt or, in the case of a facsimile, as evidenced by the confirmation of transmission.

**5.12 Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

**5.13 Non-Waiver.** No failure or delay of one of the parties to insist upon strict performance of any of its rights or powers under this Agreement shall operate as a waiver thereof, nor shall any other single or partial exercise of such right or power preclude any other further exercise of any rights or remedies provided by law.

**5.14 Waiver of Conflicts.** Each party to this Agreement acknowledges that Cooley LLP ("*Cooley*"), special counsel to Kura with respect to this Agreement, has in the past represented and is now representing and may in the future represent the Company in matters unrelated to the transactions contemplated by this Agreement (the "*Services Agreement*"), including representation of the Company in matters of a similar nature to the Services Agreement. The applicable rules of professional conduct require that Cooley inform the parties hereunder of this representation and obtain their consent. Kura and the Company hereby (a) acknowledge that they are entitled to seek independent legal advice regarding the provisions of this paragraph and the granting of the consent provided for herein, (b) acknowledge that they have had an opportunity to ask for and have obtained information relevant to such representation, including disclosure of the reasonably foreseeable adverse consequences of such representation, (c) acknowledge that with respect to the Services Agreement, Cooley has represented solely Kura and not the Company or any stockholder, director or employee of the Company and (d) give their informed consent to Cooley's representation as special counsel to Kura in connection with the Services Agreement.

**5.15 Waiver of Corporate Opportunity.** In the event that one of the parties to this Agreement or any director, officer, employee or representative of such party (the "*Primary Party*") acquires knowledge of a potential transaction or other matter (including, but not limited to, any compounds or other assets or the opportunity to acquire interests thereof) and that may be an opportunity of interest (a "*Corporate Opportunity*") for the other party to this Agreement (the "*Other Party*"), then the Other Party (i) renounces any expectancy that the Primary Party offer an opportunity to participate in such Corporate Opportunity to the Other Party and (ii) to the fullest extent permitted by law, waives any claim that such opportunity constituted a Corporate Opportunity that should have been presented by the Primary Party to the Other Party or any of its affiliates.

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

## KURA ONCOLOGY, INC.

By:	/s/ Troy Wilson
Name:	Troy Wilson
Title:	President & CEO

## ARAXES PHARMA LLC

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

## EXHIBIT A

## SERVICES

**1.** For purposes of this Agreement, the "*Kura Key Team*" shall mean the individuals listed on **Schedule 1** to this **Exhibit A**, as may be modified by Kura from time to time in consultation with the Company. Subject to the provisions of Section 2 of the Agreement, Kura shall use commercially reasonable efforts to provide, among others, the following Services as may be requested from time to time by the Company:

A. Management Services.

B.

- (i) **Executive Management Services.** Kura shall make available to the Company appropriate executive-level personnel to assume and perform substantially all of the day-to-day operational and executive management responsibilities and functions related to the Company's business, as well as provide long-term strategic planning advice and assistance to the Company.
- (ii) General Administrative Services. Kura shall provide general administrative services required in the ordinary course of the Company's business which shall include, but is not limited to: (i) bookkeeping and accounting services, including the maintenance of books and records of the Company's financial operations in accordance with U.S. generally accepted accounting principles; (ii) reasonable management information services to the Company, including coordination of network services and database management services, information technology planning services and procurement of general hardware and software; (iii) legal services and (iv) human resources management and support.
- (iii) Financial and Tax Related Services. Kura shall provide to the Company the following financial services: (i) banking services administration, including bank account administration, loan administration and arrangement of letters of credit; (ii) financial management and information services, including centralized cash management, leasing and financial analysis and (iii) tax services, including assisting the Company in the preparation of applicable income tax returns, tax research and planning and assistance on tax audits or other tax-related controversies.
- (iv) **Development of Intellectual Property.** Kura shall assist with the development of the Company's business and intellectual property including without limitation: (i) the prosecution and maintenance of intellectual property and (ii) the formulation and execution of non-clinical and clinical development plans as agreed upon from time to time between Kura and the Company, but excluding Collaboration Services (as defined below).

The Services described in clauses (i) through (iv) above are collectively referred to as "Management Services".

- Collaboration Services. Kura shall provide to the Company research and development services in support of the Collaboration, Option and License Agreement between the Company and Janssen Biotech, Inc., dated February 25, 2013, as mutually agreed between the parties ("*Collaboration Services*").
- C. Other. Kura shall provide such other Services as mutually agreed between Kura and the Company ("Other Services").

## Schedule 1

## Kura Key Team

# (as may be modified by Kura from time to time in consultation with the Company)

- Updated as of December 8, 2014 [\*\*\*]
- [\*\*\*]

•

- [\*\*\*]
- [\*\*\*]
- [\*\*\*]
- [\*\*\*]
- [\*\*\*]
- [\*\*\*]

# [\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED

## EXHIBIT B

## SERVICES FEES

- 1. In consideration for the Services provided, the Company shall pay to Kura the following, subject to adjustment pursuant to Section 2 below:
  - For Management Services, the Company shall pay a monthly fee of \$100,000. A.
  - For Collaboration Services, the Company shall pay Kura an amount equal to the number of FTEs (as defined below) actually expended by В. Kura in the course of performing Collaboration Services during the term of this Agreement, multiplied by three hundred fifty thousand U.S. dollars (\$350,000), increased annually by the percentage increase in the Consumer Price Index—Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the United States ("CPI") as of December 31 of the then most recently ended calendar year over the level of the CPI on December 31, 2013 (i.e., the first such increase would occur on January 1, 2014). For the purposes of this Agreement, "FTE" means the equivalent of [\*\*\*] over a twelve (12)-month period [\*\*\*], which equals [\*\*\*] per year of work in performing Collaboration Services. Kura will invoice the Company for Collaboration Services on a calendar quarter basis and will include with each invoice the number of FTEs engaged in performing Collaboration Services during the applicable quarter.
  - C. If the Company and Kura agree to the provision of any Other Services, the parties will mutually agree to a reasonable fee for such Services at such time.
  - D. In addition, the Company shall reimburse Kura for its actual expenses as reasonably incurred by Kura or its employees, officers, directors, agents and/or consultants in the course of performing Services. For Collaboration Services, the Company shall reimburse Kura for direct expenses paid or payable to any Third Parties by Kura that are incurred for services and materials in the course of performing Collaboration Services, and for the avoidance of doubt, do not include capital expenditures.
- 2. The fees for the Services set forth in Section 1 above shall be subject to the following:
  - The parties acknowledge that the fees payable for the Management Services set forth in Section 1 above have been set by reference to the costs A. expected to be incurred by Kura in the provision of Management Services to the Company, as calculated in accordance with generally accepted accounting principles (the "GAAP Costs"), plus a reasonable mark-up. Such charges shall be reviewed from time to time pursuant to this Section 2 to ensure they remain consistent with this
    - standard and generally reflect comparable dealings between unrelated parties as discussed in IRC Regulation §1.482.
  - В. The GAAP Costs shall include directly related salaries and expenses incurred, reasonably allocated indirect salaries and any other reasonably allocated indirect costs incurred by Kura in providing the Management Services under this Agreement.
  - The Service fees shall be payable in U.S. dollars (unless mutually agreed by the parties) and shall be subject to all applicable government С. regulations and rulings.
  - D. Kura shall provide the Company with documentation which may be required by the revenue authorities to support the fact that the Services fees represent arm's length remuneration for the benefits derived from the Services provided to the Company in that particular year.
  - Е. If at any time the amount paid under this Agreement for the Services is subsequently adjusted by a tax administration for the purposes of calculating the income tax liability of either party, the parties agree that the amount of the adjustment shall be payable and receivable by either party, as the case may be, within 90 days of the issue date of the tax assessment under which the adjustment arises.
- 3. All payments hereunder shall be made in cash or by offset against any indebtedness owing to the Company by Kura. Kura shall invoice the Company at least quarterly for services provided during the previous quarter, together with the amount of reimbursable costs and expenses incurred by Kura on behalf of the Company pursuant to Section 2.2 of the Agreement prior to such invoice. The Company agrees to pay all amounts due to Kura arising under this Agreement promptly upon receipt of any such invoice. The parties to this Agreement agree to discuss in good faith on a semi-annual basis during the term of this Agreement the necessity or desirability of adjusting the fees set forth in this Exhibit B.

[\*\*\*] = CERTAIN CONFIDENTIAL INFORMATION OMITTED



4. The Company understands and acknowledges that Kura must reasonably allocate its staff resources among all of the companies to which Kura provides services. Notwithstanding any other provision of this Agreement, Kura may at any time, without notice or liability, change or eliminate the persons who provide the Services to the Company on behalf of Kura pursuant to this Agreement, provided that the Services continue to be provided to the Company on substantially the same levels as provided prior to such change or elimination. The Company expressly acknowledges that Kura is engaged in the business of providing drug development services to multiple companies and providing management, scientific, business development, financial and other operational services to those companies and that neither Kura nor any other company to which Kura provides services shall have any exclusivity or similar obligation to the Company, including without limitation any corporate opportunity obligation or any obligation to disclose or make available to the Company any information, potential transaction or other matter of which Aura Party becomes aware otherwise than solely in the course of performing Services under this Agreement on behalf of the Company.

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#### EXHIBIT C

#### **Compliance with Laws and the FCPA**

- 1.1. Kura shall become familiar with the FCPA, its prohibitions and purposes, and shall not undertake any actions that may violate the FCPA. Accordingly, Kura hereby agrees that:
  - (i) no person shall be employed by it who is an official or employee of any government or any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government);
  - (ii) no payment or offer to pay, or the giving or offering to give, anything of value to an official or employee of any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government), or to any political party or any candidate for political office, shall be made with the purpose of influencing any decisions favorable to either Party or its Affiliates in contravention of the FCPA or the laws of the country in which it is providing work;
  - (iii) it not pay, nor offer or agree to pay, nor caused to be paid, directly or indirectly, any political contributions, fees or commissions to any governmental employee or representative (including, but not limited to, any employee of any health or medical provider owned or controlled by the government) that could cause a violation of the FCPA;
  - (iv) it will not, directly or indirectly, in connection with the Agreement and the business resulting therefrom, offer, pay, promise to pay, or authorize the giving of money or anything of value to any governmental official or representative, to any political party or official thereof, or to any candidate for political office, or to any person, while knowing or being aware of the probability that all or any portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any government official, to any political party or official thereof, or to any candidate to political office, for the purpose of:
    - a. influencing any act or decisions of such official, political party, party official, or candidate in its official capacity, including a decision to fail to perform official functions; or
    - b. inducing such official, political party, party official, or candidate to use influence with the government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist either Party in obtaining or retaining business for or with, or directing business to, any third party.
  - (v) Kura will immediately notify the Company if it becomes aware of any apparent violation of the FCPA in connection with its activities hereunder.
- 1.2. Kura shall provide the Company and its agents and representatives (collectively, "Agents"), as well as any regulatory authorities having regulatory oversight of Kura, with access to its facilities, records (financial and otherwise), and supporting documentation as may be requested by any Agents in order to document or verify compliance with the provisions of this Exhibit. Kura acknowledges that the provisions of this Exhibit granting the Company certain audit rights shall in no way relieve Kura of any of its obligations under the Agreement, nor shall such provisions require the Company to conduct any such audits.
- 1.3. Kura shall maintain true and accurate records necessary to demonstrate compliance with this Agreement (including the requirements of this Exhibit).
- 1.4. If Kura fails to comply with any of the provisions of this Exhibit (irrespective of the size, nature or materiality of such violation), such failure may be treated by the Company as a material breach.
- 1.5. Notwithstanding anything to the contrary in the Agreement, each Party may disclose its terms and conditions (including any financial terms) to any government authority that it determines in good faith has a legitimate need for access to such information (including, but not limited to, any governmental authorities in the U.S. or those in the country where research is being provided).

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### MASTER COLLABORATION AGREEMENT

This Master Collaboration Agreement (this "**Agreement**") is effective as of January 4, 2021 (the "**Effective Date**") and is made by and between Illumina, Inc., a Delaware corporation ("**Illumina**") and Kura Oncology, Inc., a Delaware corporation ("**Partner**"). Illumina and Partner may be referred to each individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Illumina develops, manufactures and sells (among other things) in vitro diagnostic products;

WHEREAS, Partner develops, manufactures and sells (among other things) pharmaceutical products; and

WHEREAS, the Parties desire to collaborate on one or more Projects (as defined below) concerning Illumina's development of in vitro diagnostic products related to one or more Partner Products (as defined below);

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, the foregoing recitals, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### 1. **DEFINITIONS**

The following capitalized terms will have the following meanings:

1.1 "**Advisors**" means, with respect to a Party, its and its Affiliates' attorneys, accountants, financial advisors, and other similar advisors.

1.2 "Affiliate" means, with respect to any Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person for so long as such other Person controls, is controlled by, or is under common Control with such first Person. For purposes of this definition, "control" means the possession, direct or indirect, of the power to direct or cause the direction of the management of a Person, whether through ownership interests, by contract, or otherwise. Without limiting the generality of the foregoing, a Person will be deemed to control any other Person in which it owns, directly or indirectly, 50% or more of the outstanding shares, stock, securities or other ownership interests of such Person.

1.3 **"Assay**" means a nucleic acid sequencing based assay utilizing an Illumina Platform Technology for detecting or analyzing one or more Biomarker(s) when used in conjunction with the Instrument and Software. An Assay may be a Background Assay developed by or for Illumina or its Affiliates outside of

this Agreement, or an IUO Assay or IVD Assay developed by or for Illumina or its Affiliates pursuant to this Agreement.

1.4 **"Assay Performance Data"** means all data, information, and reports, and results of analysis of any of the foregoing, generated from the activities under this Agreement that supports the performance of any Assay (including its ability to detect and measure one or more Biomarkers) used with the Partner Product, and with the Illumina Technology Platform (including the Instrument or Software), including limit of detection, limit of blank, and cross reactivity as well as the accuracy, reliability, reproducibility, analytical sensitivity and analytical specificity in detecting any genetic variations or alterations. Assay Performance Data constitutes Illumina Confidential Information and is solely owned by Illumina.

1.5 **"Background Assay**" means an Assay developed by or for Illumina or its Affiliate outside of this Agreement (whether before or during the Term).

1.6 **"Background IP**" means, on an individual Project basis, IP Rights that (a) are Controlled by a Party or its Affiliates as of the effective date of the respective Project Schedule, or (b) are conceived, discovered, reduced to practice or writing, generated or developed by such Party or its Affiliates, or otherwise come into the Control of a Party or its Affiliates, during the Term independently of the respective Project and otherwise outside the scope of this Agreement.

1.7 **"Biomarker"** means a defined genetic characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions, and may include one or more specific genes or genetic sequences, determinations of genomic aberrations, alterations or variations at the DNA or RNA level or expression at the RNA level.

1.8 **"Biomarker Data"** means data (or the results of analysis thereof) concerning Biomarkers that is derived from Samples in the performance of a Project using an IUO Assay, including the aggregated prevalence of such data in a particular intended use. Biomarker Data does not include any Assay Performance Data or data pertaining to the Illumina Platform Technology or Clinical Outcomes Data or other data pertaining to the Partner Product.

1.9 **"Biomarker IP**" means any and all Patents that claim Biomarkers or methods of testing or otherwise using Biomarkers.

1.10 **"BLA"** or "**Biologics License Application**" is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce pursuant to Title 21 of the United States Code of Federal Regulations, parts 600 – 680, as may be amended from time-to-time.

1.11 **"Change in Control**" means the occurrence of any of the following:

(a) the sale, transfer, assignment, or other disposition of securities of Partner (or any Affiliate of Partner that controls Partner) representing a majority of the voting power of Partner's outstanding

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voting securities (or a majority of the voting power of the outstanding voting securities of any Affiliate of Partner that controls Partner) in any one transaction or a series of related transactions;

(b) any transaction or series of related transactions in which the holders of the outstanding securities of Partner (or any Affiliate of Partner that controls Partner) immediately before such transaction(s), do not, immediately after such transaction(s), retain control of Partner (or any Affiliate of Partner that controls Partner);

(c) any direct or indirect acquisition of Partner or any Affiliate of Partner that controls Partner by means of merger, consolidation, exchange or contribution of equity, or other form of reorganization in one transaction or a series of related transactions with or into another entity;

(d) the liquidation or dissolution of Partner or any Affiliate of Partner that controls Partner; or

(e) any direct or indirect sale, transfer, or other disposition of all or substantially all of the assets of Partner to which this Agreement relates.

1.12 "Claims" is defined in Section 13.1

1.13 **"Clinical Outcomes Data**" means data (or the results of analysis thereof) from Clinical Trials of the Partner Product to the extent related to the safety and efficacy of such Partner Product.

1.14 **"Clinical Trial**" means a clinical trial involving the IUO Assay or the Partner Product that is undertaken pursuant to a Project Schedule, including an investigation involving human subjects of a Partner Product undertaken or sponsored by Partner as part of the development of such pharmaceutical product to obtain information relating to patient outcome or selection for therapy with such pharmaceutical product, which includes the use of an IUO Assay.

1.15 **"Commercialization**" (and its corollaries) means those activities directed to the selling, marketing, and promotion of a product, including pre-marketing, marketing, manufacturing, promoting, transporting, distributing, offering for sale, selling, and supporting of such product.

1.16 **"Commercialization Plan**" is defined in Section 5.5.

1.17 **"Commercially Reasonable Efforts"** means, with respect to the efforts to be expended by a Party in performing its obligations specified in this Agreement, no less than the reasonable, diligent, good faith efforts to accomplish such obligations as such Party would normally use to accomplish similar obligations under similar circumstances, taking into account issues of safety and efficacy, product profile (including lifecycle and profitability), the competitiveness of the marketplace, proprietary position, applicable Law and the regulatory structure involved, and other relevant scientific, technical, regulatory, and commercial factors. Commercially Reasonable Efforts will be determined on a case-by-case basis and the level of such effort may vary based on the applicable circumstances. Commercially Reasonable

- 3 -

Efforts requires, with respect to a Party's obligations under this Agreement, promptly and consistently making and implementing decisions and allocating resources in a manner that is reasonably designed to advance progress and carry out such obligations and achieve the objectives set forth in the applicable Project Schedule. "Commercially Reasonable" has an equivalent meaning.

1.18 **"Committee**" means the JSC, JDC, JCC, JPC or any other committee or subcommittee established by the JSC; "Committees" means two or more of the foregoing.

1.19 **"Confidential Information**" means all information and Know-How and any tangible embodiments thereof provided by or on behalf of the Disclosing Party to the Receiving Party in the course of performing under this Agreement, whether disclosed in writing, verbally, or otherwise, that is identified or marked as "Confidential" (or with similar language) or should reasonably ascertained to be confidential, either because of the circumstances of disclosure or the nature of the information itself. Confidential Information may include data, knowledge, practices, processes, ideas, research plans, formulations, manufacturing techniques, marketing and business plans, financial information, personnel information, and other information relating to the Disclosing Party or to its present or future products, sales, suppliers, customers, employees, or business; provided however that Confidential Information specifically excludes any information that:

(a) at the time of disclosure is generally available to the public;

(b) after disclosure becomes generally available to the public by publication or otherwise through no fault of the Receiving Party or its Representatives or Advisors;

(c) the Receiving Party can demonstrate was in its possession or in the possession of its Representatives before disclosure by the Disclosing Party and which was not acquired, directly or indirectly, from the Disclosing Party or its Representatives, and which is held by the Receiving Party free of any obligation of confidence to any Third Party;

(d) the Receiving Party can demonstrate was received by it after the time of disclosure by the Disclosing Party from a Third Party who had a lawful right to disclose it to the Receiving Party and who did not require the Receiving Party to hold it in confidence; or

(e) the Receiving Party can demonstrate was independently generated by or for the Receiving Party or its Representatives without any use of or reference to the Disclosing Party's Confidential Information or violation of this Agreement, as evidenced by contemporaneous written records.

1.20 **"Contract Laboratory**" is defined in Section 4.3.

1.21 **"Control"** or **"Controlled**" means, with respect to any IP Rights, Materials, item of information or other intangible right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to grant the other Party access, a license or sublicense, as provided for herein, without obtaining the consent of any Third Party or violating the terms of any written

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agreement with any Third Party. Notwithstanding the foregoing, if a Third Party becomes an Affiliate of a Party after the Effective Date as a result of a transaction in which such Third Party acquires control (as defined in Section 1.2) of such Party, whether by merger, acquisition, sale of assets or otherwise, in no event will any IP Rights of such Third Party or its Affiliates (other than such acquired Party or its Affiliates existing prior to such transaction) be deemed Controlled by the acquired Party or otherwise be deemed part of the acquired Party's Background IP.

1.22 **"De-identified**" means generally information that no longer identifies an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify or re-identify an individual, as determined in accordance with applicable Laws, including, as applicable, without limitation, (a) De-Identification of protected health information as set forth in §164.514 of the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") and (b) Anonymization of Personal Data (as those terms are defined in Article 4 of the General Data Protection Regulation ("GDPR")).

1.23 **"Deliverables**" means the Project Results or materials to be provided by either Party in connection with a particular Project, in each case, as specified in the Project Schedule.

1.24 **"Design Lock**" means when an Assay has completed Illumina design verification testing and the Parties have confirmed readiness for first patient screening.

1.25 **"Diagnostics Field**" means in vitro testing for research use, investigational use, or as a clinical diagnostic for use in the diagnosis or on-going evaluation of a disease or medical condition, including the prediction or monitoring of a response to a therapeutic agent, selection for therapy, and use as an in vitro diagnostic.

1.26 **"Disclosing Party**" means a Party who discloses its Confidential Information to the other Party.

1.27 **"Dispute**" is defined in Section 16.1.

1.28 **"Drug Development Failure**" means, with respect to a Partner Product, that Partner has discontinued or indefinitely paused development of such Partner Product in a Market for an Indication that is the subject of a Project Schedule.

1.29 **"EEA"** means the European Economic Area as its membership may be constituted from time to time, and any successor thereto, and which, as of the Effective Date, is composed of the members of the European Union together with Iceland, Liechtenstein and Norway.

1.30 **"EMA**" means the European Medicines Agency, or any successor thereto, having the administrative authority to regulate the marketing of in vitro diagnostics and other medical devices in the European Union.

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1.31 **"European Union**" means the European Union as its membership may be constituted from time to time, and any successor thereto.

1.32 **"Exploit**" means to make, have made, use, sell, offer for sale, import, and otherwise commercialize.

1.33 **"FDA"** means the United States Food and Drug Administration, or any successor thereto, having the administrative authority to regulate the marketing of in vitro diagnostics and other medical devices in the United States.

1.34 **"Force Majeure**" means any cause beyond such Party's reasonable control and without its fault or negligence, including acts of God, fire, flood, tornado, earthquake, hurricane, lightning, actual or threatened acts of war, terrorism, civil disturbance or insurrection, sabotage, embargo, acts of government (including injunctions), labor shortages or disputes, material or equipment shortages, transportation difficulties, interruption or failure of any utility service, or equipment.

1.35 **"GCP**" means the current good clinical practice applicable to the clinical development of any Partner Product, IUO Assay, or IVD Assay used in a Project under applicable Laws, including the ICH guidelines.

1.36 **"GLP**" means the current good laboratory practice applicable to the process and conditions under which nonclinical studies are performed, monitored, recorded, archived and reported established by the Organization for Economic Cooperation and Development.

1.37 "**GMP**" means current good manufacturing practices that apply to the manufacture of any Partner Product, IUO Assay, or IVD Assay used in a Project, including the United States regulations set forth under Title 21 of the United States Code of Federal Regulations, parts 210, 211, 820, as well as the requirements of ISO13485, as may be amended from time-to-time, as well as all applicable guidance published from time-to-time by the FDA and the ICH Guidelines ICHQ7A Good Manufacturing Practice Guidance for API and the principles and guidelines of Good Manufacturing Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice and DIRECTIVE 98/79/EC on in vitro diagnostic medical devices.

1.38 "**GRP**" means all applicable current good research practices including, as applicable, (a) the research quality standards defining how each Party's research laboratories conduct good science for non-regulated work as set forth in applicable Project Schedule, (b) the BARQA Guidelines for Quality in Non-regulated Scientific Research, (c) the WHO Quality Practices in Basic Biomedical Research Guidelines or, (d) the equivalent applicable Laws if any, in any relevant country, each as may be amended and applicable from time to time.

1.39 **"Government Official**" means: (a) any officer or employee of: (i) a government, or any department or agency thereof; (ii) a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; or (iii) a public international organization

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(such as the United Nations, the International Monetary Fund, the International Committee of the Red Cross, and the World Health Organization), or any department or agency thereof; (b) any political party or party official or candidate for public or political party office; and (c) any person acting in an official capacity on behalf of any of the foregoing.

- 1.40 **"ICH**" means the International Conference on Harmonisation.
- 1.41 **"Illumina Indemnitee**" is defined in Section 13.1.
- 1.42 **"Illumina Inventions**" is defined in Section 8.4.

1.43 **"Illumina Platform Technology**" means Illumina's and its Affiliates' proprietary products and systems that do not relate specifically to an Assay and are used for testing of samples or other biological materials to identify genetic sequences, or alterations and variations, including Illumina instruments (including the Instrument), software (including the Software), consumables, reagents, analytical methods, algorithms, procedures, techniques, software or platforms intended for use in genetic analysis, and related technologies and any improvements to the foregoing.

1.44 **"Illumina Project Results**" is defined in Section 8.2.

1.45 **"Indication**" means the disease(s) or condition(s) for which a Partner Product can be used to treat or prevent, which use is the subject of a Regulatory Approval, as specified in the applicable Project Schedule.

1.46 **"Instrument**" means the Illumina instrument on which an Assay will be run as further described in the applicable Project Schedule or any improvements thereto or any successor instrument thereof.

1.47 **"Intended Use**" means the statement of the intended use of an IVD Assay to be included in the Labeling for such IVD Assay.

1.48 **"Invention**" means any invention or discovery, whether or not patentable, that is first conceived or reduced to practice by or on behalf of employees or agents of either Party or its Affiliates or jointly by or on behalf of employees or agents of both Parties or their Affiliates and that is generated in the course of performance of the Project, together with all Patents (including applications) claiming or covering such invention or discovery and all other IP Rights therein.

1.49 **"IP Rights**" means all intellectual property rights, including rights to Patents, Know-How, trademarks, utility models, registered designs, design rights, copyrights, copyright registrations, trade secrets, and similar intellectual property rights of any kind, whether registered or not, and including all applications or rights to apply therefor and registrations thereto.

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1.50 **"IRB**" means an Institutional Review Board, independent ethics committee, or any equivalent authority.

1.51 **"IUO Assay**" means an Assay (which may be based on a Background Assay) that is developed by Illumina or its Affiliates pursuant to this Agreement for investigational use only with the Partner Product.

1.52 "**IVD**" or "in vitro diagnostic" means: (a) in the United States, an Assay intended for use in disease identification, monitoring, prognosis or treatment selection, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae, as more fully defined in 21 C.F.R. § 800 et seq., including so-called complementary diagnostics (e.g., those used to identify patients whose Biomarker status is associated with a changed therapeutic response) and companion diagnostics for a pharmaceutical product as defined in FDA's "Draft Guidance for Industry and Food and Drug Administration Staff - In Vitro Companion Diagnostic Devices", (b) in the European Union, an in vitro diagnostic medical device as defined in the European directive 98/79/EC, and (c) any similar definitions set by Regulatory Authorities in Markets outside of the United States and the European Union or as may be updated by Regulatory Authorities in the United States and the European Union in the future.

1.53 **"IVD Assay**" means an Assay (which may be based on a Background Assay) that is developed by or for Illumina or its Affiliates pursuant to this Agreement as an IVD, and has received Regulatory Approval for use as an IVD with the Partner Product.

1.54 **"Joint Invention**" is defined in Section 8.4.

1.55 **"Joint Patents**" is defined in Section 8.7.

1.56 "Joint Project Results" is defined in Section 8.2.

1.57 **"JSC"**, **"JDC"**, **"JCC"**, and **"JPC"** or **"Joint Steering Committee"**, **"Joint Development Committee"**, **"Joint Commercialization Committee"** and **"Joint Patent Committee"** have their respective meanings set forth in Section 10.

1.58 **"Know-How**" means any information, improvements, practices, formula, trade secrets, techniques, procedures, knowledge, skill, experience, results, and any information regarding marketing, pricing, distribution, cost, sales or manufacturing; provided, however, that Know-How does not include Patents.

1.59 **"Labeling**" means all labels and other written, printed, or graphic matter (a) upon the IVD Assay or Partner Product, or (b) on any of their respective containers or wrappers, or (c) otherwise accompanying the IVD Assay or Partner Product, in each case, that may include the statement of the Intended Use for the IVD Assay, and the Indication for the Partner Product.

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1.60 "**Law**" means: (a) all statutes, regulations, ordinances, and directives and applicable policies, rules, or orders made or given by a governmental authority or Regulatory Authority that are binding on a Party as a matter of law; (b) common law and the law of equity as applicable to a Party; (c) court orders, judgments, or decrees that are binding a Party; and (d) industry codes of practice, policies, or standards in each case to the extent enforceable against a Party by a governmental authority or Regulatory Authority as law.

1.61 **"Losses**" is defined in Section 13.1.

1.62 **"MHRA**" means the Medicines and Healthcare Products Regulatory Agency, or any successor thereto, having the administrative authority to regulate the marketing of in vitro diagnostics and other medical devices in the United Kingdom.

1.63 **"Markets**" means the countries designated for each Project in a Project Schedule.

1.64 **"Materials**" means Samples, biological materials, compounds, reagents, supplies and other goods, other than Deliverables, that one Party delivers or causes to be delivered to the other Party in connection with a Project, as set forth in the applicable Project Schedule.

1.65 **"Milestone**" means a milestone event specified in a Project Schedule.

1.66 **"Non-Participating Party**" is defined in Section 8.7.

1.67 **"Notice of Dispute**" is defined in Section 16.2(a).

1.68 **"Package Instructions**" means instructions or restrictions placed on Materials or products, including, as applicable, Labeling on products that have received Regulatory Approval.

1.69 **"Partner Assay Background IP**" means Background IP Controlled by Partner or its Affiliate (as of the Effective Date or during the Term) that would, but for the licenses granted to Illumina and its Affiliates in this Agreement, be infringed by the development or Commercialization of an IUO Assay or IVD Assay (including Biomarker IP).

1.70 **"Partner Indemnitee**" is defined in Section 13.2.

1.71 **"Partner Inventions**" is defined in Section 8.4.

1.72 **"Partner Product**" means any pharmaceutical product of Partner or its Affiliate that is identified as the subject of a Project Schedule.

1.73 **"Partner Project Results**" is defined in Section 8.2.

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1.74 **"Party**" means Partner or Illumina as the context requires and "Parties" means both Partner and Illumina.

1.75 **"Patent**" means any existing or future: (a) national, regional or international patent or patent application in any jurisdiction (including any provisional, divisional, continuation, continuation-in-part, non-provisional, converted provisional, or continued prosecution application, any utility model, petty patent, design patent, or certificate of invention), (b) any extension, restoration, revalidation, reissue, re-examination and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications, and (c) any ex-U.S. equivalents corresponding to any of the foregoing.

1.76 **"Person**" means an individual or firm, trust, corporation, partnership, joint venture (whether entity-based or by contract), limited liability company, association, unincorporated organization, or other legal or governmental entity.

1.77 **"Pharmaceutical Field**" means the discovery, development, manufacture, use, and sale of biological or chemical substances for the medical cure, treatment, palliation or prevention of diseases of human beings.

1.78 **"PMA**" means: (a) a U.S. pre-market approval application for a Class III medical device, including all information submitted with or incorporated by reference, or (b) any analogous application to those set forth in (a) that is filed with the relevant Regulatory Authority in a country or region in the Markets, including any supplemental applications.

1.79 **"PMDA**" means the Pharmaceuticals and Medical Devices Agency, or any successor thereto, having the administrative authority to regulate the marketing of in vitro diagnostics and other medical devices in Japan.

1.80 **"Project**" means a project in one or more of the following areas as set forth in the applicable Project Schedule: (a) Biomarker identification and validation, (b) development of an IUO Assay, (c) IVD Assay proof of concept, (d) development of an IVD Assay, (e) pivotal trial support, or (f) submission for Regulatory Approval; which project ultimately may result in the development or Regulatory Approval of an IVD Assay under this Agreement.

1.81 **"Project Results**" means, other than Inventions, all information, data, and reports developed or produced as a result of a Project.

1.82 **"Project Schedule**" means an attachment to this Agreement containing a list of activities, Deliverables and other terms applicable to the development of an IVD Assay pursuant to this Agreement. Each Project Schedule may include: (a) Project description, including Intended Use of the IVD Assay and Indication of the Partner Product, target user population and a general overview; (b) Assay specifications or description, including the Background Assay upon which the IUO Assay and IVD Assay will be based; (c) the development objectives to be obtained by the Parties in performing such Project; (d) the roles

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and responsibilities of each Party in conducting such Project, including identification of key personnel, including principal investigators, and other Third Parties required by the Parties to conduct the Project; (e) any written reports, data, results and materials (including any Materials) with respect to the Project, and the form thereof, that are to be delivered to one or more of the Parties; (f) the timeline and term of the Project Schedule, Milestones and any deadlines for the performance of such activities and the delivery of any Deliverables in accordance with such plan; (g) any indicators or measurements to be used by the Parties to evaluate the quality or performance of such activities and the related Deliverables; (h) performance characteristics to be used by the Parties to determine the progression of an IUO Assay or a Project generally; (i) JDC members; (j) JCC members; (k) the addresses at which each Party will perform the Project (the "**Facility(ies)**"); (l) any other roles, responsibilities or procedures required by the applicable Partner standards and protocols; (m) a budget and Milestones; (n) Markets; (o) Materials; (p) licenses and permits required to conduct the Project; (q) targeted Regulatory Approvals; (r) Partner GMP, GCP and GRP, if applicable; and/or (s) a Commercialization Plan.

1.83 **"Receiving Party**" means a Party who receives Confidential Information from the other Party or its Representatives or Advisors.

1.84 **"Recipient**" means a Party who receives Materials from the other Party under this Agreement.

1.85 **"Regulatory Approval**" means with regard to an IVD, FDA approval of a PMA (or PMA supplement, as applicable), FDA clearance of a 510(k) notification, or FDA grant of a de novo petition for reclassification in the U.S., the issuance of a CE marking declaration of conformity by or on behalf of the manufacturer of the device in the EEA, and similar approvals of Regulatory Authorities in other jurisdictions in the Markets; and with regard to the Partner Product, NDA or BLA approval granted by the FDA in the U.S., and similar approvals of Regulatory Authorities in other jurisdictions.

1.86 **"Regulatory Authority**" means any national, supranational, regional, state or local regulatory agency, administration, department, bureau, commission, council or other governmental entity including the FDA, the EMA, the PMDA, the MHRA and any notified body or other equivalent entity, involved in the granting or receipt of Regulatory Approvals for in vitro diagnostic devices and other medical devices.

1.87 **"Regulatory Submission**" means, with respect to a regulatory jurisdiction, any submission to a Regulatory Authority that is necessary to obtain or maintain (as context requires) a Regulatory Approval in that jurisdiction.

1.88 **"Replacement Diagnostic Solution**" is defined in Section 5.10.

1.89 **"Representatives**" means, with respect to a Party, its Affiliates, and such Party's and its Affiliates' respective directors, officers, employees, contractors, consultants, subcontractors and agents.

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1.90 **"Samples**" means, to the extent that a Party delivers or causes it to be delivered to the other Party hereunder for the performance of a Project: (a) human tissue samples, whether in blocks, slides, fresh or otherwise, (b) human blood samples, clinical isolates, bodily fluids, cells, organs, and human-derived waste or other similar specimen samples, and (c) any data or information concerning the origin or collection of such Samples or phenotypic information concerning such Samples; provided, however that neither Party will include any personally identifiable information in the data or information that is part of such Samples without the other Party's prior written consent.

1.91 **"Sample Requirements**" is defined in Section 3.2(a).

1.92 **"Software**" means software designed or created by or on behalf of Illumina for use in conjunction with any Assay and Instrument to detect, identify, analyze and report genetic alterations, variations or relationships, including that which is designed to be capable of analyzing or processing a subset of the sequences or data related to the Biomarkers.

- 1.93 **"Standard Terms**" is defined in Section 5.13(a).
- 1.94 **"Supplier**" means a Party who provided Materials to the other Party under this Agreement.

1.95 **"Tax"** or "**Taxes**" means any federal, state, local, or non-U.S. tax, fee, charge, license, duty, levy, required deposit or other tax of any kind whatsoever, including imposed on or with respect to income, gross receipts, payroll, employment, social security (or similar), unemployment, excise, severance, stamp, occupation, premium, gains, windfall profits, environmental (including taxes under Code Section 59A), customs duties, capital stock, franchise, gross or net profits, withholding, disability, real property, personal property, sales, use, transfer, registration, value added, ad valorem, escheat or unclaimed property, alternative or add on minimum or estimated, whether computed on a separate or consolidated, unitary or combined basis (including under Treasury Regulation § 1.1502-6) or in any other manner, including any interest, penalty, or addition thereto, whether disputed or not.

1.96 **"Term**" is defined in Section 15.1.

1.97 **"Third Party"** means any Person other than: (a) Partner or any of its Affiliates; or (b) Illumina or any of its Affiliates.

## 2. **PROJECTS**

### 2.1 <u>Projects, Generally</u>.

(a) <u>General</u>. This Agreement governs all Projects undertaken pursuant to a Project Schedule. Generally speaking, the ultimate goal of each Project is to enable Illumina to develop and receive Regulatory Approval for an IVD Assay for use as an IVD with a Partner Product. It is anticipated that each IVD Assay will be based upon a Background Assay, and such development work will generally involve (i)

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Illumina adding bioinformatic analysis capability to the Background Assay to create an IUO Assay for clinical testing in connection with a Partner Product, and (ii) performing the necessary testing using the IUO Assay to generate data necessary to pursue Regulatory Approval for the Assay to function as an IVD for the Partner Product, and (iii) receiving Regulatory Approval for the resulting IVD Assay as an IVD for the Partner Product. The Background Assay for each IUO Assay and IVD Assay will be set forth in the Project Schedule.

(b) <u>Efforts</u>. Illumina will use Commercially Reasonable Efforts to perform the Projects and provide the Deliverables set forth in the relevant Project Schedule in accordance with the timelines set forth in the Project Schedule. In performing the Projects, Illumina will use the standards of care and skill to be reasonably expected in the Diagnostics Field and will adhere to applicable laws including and GLP, GCP and GMP practices. Partner will use Commercially Reasonable Efforts to perform the Projects and provide the Deliverables set forth in the relevant Project Schedule in accordance with the timelines set forth in the Project Schedule. In performing the Projects, Partner will use the standards of care and skill to be reasonably expected in the Deliverables set forth in the relevant Project Schedule in accordance with the timelines set forth in the Project Schedule. In performing the Projects, Partner will use the standards of care and skill to be reasonably expected in the Pharmaceutical Field and will adhere to applicable laws and GLP, GCP and GMP practices.

(c) <u>Projects are Experimental</u>. The Parties acknowledge and agree that the Projects are experimental in nature and that there are uncertainties with respect to technical feasibility and regulatory requirements. As such, outcomes cannot be guaranteed and there is no certainty that the efforts undertaken will result in appropriate IUO Assays or IVD Assays or that any Regulatory Approvals will be obtained. Illumina will not be responsible for any failure or delay in performing its obligations under a Project Schedule to the extent such failure or delay is caused by a failure or delay on the part of Partner.

(d) Drug Development Failures. Partner will notify Illumina within 30 days of any Drug Development failure.

2.2 <u>Negotiation of Project Schedules</u>. The Parties will negotiate the specific details of each Project conducted by the Parties under this Agreement separately, which will be set forth in a written Project Schedule to be agreed upon and executed by both Parties. Once executed by both Parties, each Project Schedule will automatically be incorporated in its entirety into this Agreement. Nothing herein will create an express or implied obligation on the part of either Party to execute any Project Schedule.

2.3 <u>Amendments to Project Schedules</u>. Each time that the Parties agree that changes should be made to a Project Schedule, the Parties will amend the Project Schedule for such Project in accordance with Section 16.8. Upon request of either Party, the Parties will discuss and negotiate in good faith potential changes to a Project Schedule. Nothing herein will create an express or implied obligation on the part of either Party to execute any amendment to a Project Schedule.

2.4 <u>Agreement Precedence</u>. Terms or conditions on a Project Schedule that differ from those in this Agreement take precedence over the terms and conditions in the Agreement only with respect to that

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particular Project Schedule, and only to the extent the Project Schedule specifically identifies the terms and conditions in this Agreement that are intended to be superseded or modified.

2.5 <u>Responsibility</u>. As further specified in this Agreement and each Project Schedule, Partner or its Affiliate will have final responsibility and decision making authority with respect to all matters regarding the Partner Product to the extent set forth in the applicable Project Schedule, and Illumina or its Affiliate will have final responsibility and decision making authority with respect to all matters regarding the IUO Assay, IVD Assay, and Illumina Platform Technology. The Parties will coordinate their respective development activities through the Joint Steering Committee, or the Joint Development Committee, as applicable.

### 3. MATERIALS AND RECORDS

3.1 <u>Materials Delivery</u>. Each Party will provide the other Party with the Materials in the quantities, and on the timing, as more specifically provided in each Project Schedule. If Materials provided by either Party do not conform to the specifications set forth in the Project Schedule at the time of delivery or are otherwise not suitable for the Project, then the providing Party will provide new or replacement Materials or, if that is not possible, propose and discuss with the other Party in good faith an alternative. Illumina will not be responsible for any delays to any Project caused by Partner's failure to timely provide Materials conforming to the applicable Project Schedule and suitable for the Project.

### 3.2 <u>Samples</u>.

(a) <u>Sample Requirements</u>. Each Party acknowledges that certain of the Materials transferred hereunder may consist of Samples that are derived or collected from human subjects. Each Party further acknowledges that the transfer of Samples is a highly sensitive matter, and therefore, each Party will ensure that all Samples transferred under this Agreement are collected, processed, De-identified (to the extent possible bearing in mind the minimum amount of data that the Parties agree, through the JDC, must be associated with the Materials in order to perform the Project and bearing in mind the implementation of new applicable Laws that may determine such data to be personal information), tracked, stored, transported, manipulated and destroyed in a manner appropriate to ensure compliance with: (i) the terms and conditions of this Agreement and the applicable Project Schedule (which may set forth specific requirements), (ii) all applicable requirements of an IRB/IEC, and (iii) all applicable Laws (collectively, (i), (ii) and (iii) are referred to as "Sample Requirements").

(b) <u>Treatment of Samples</u>. Each Party will develop and follow all of its documented policies and procedures to ensure the protection of the autonomy and confidentiality of the human subjects from whom the Samples were collected in compliance with the Sample Requirements. If collection of the Samples is subject to informed consent or required authorization, the Supplier will ensure that the scope of such informed consent or authorization is consistent with the transfer of the Samples hereunder and that each Party may use the Samples for the Project. All Samples delivered under this Agreement will be labelled clearly in accordance with the Sample Requirements.

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### 3.3 <u>Use Restrictions</u>.

(a) <u>Permissible Uses</u>. Each Recipient will handle, store and use the Materials in accordance with applicable Laws, the relevant informed consent, any applicable documentation, reasonable handling procedures, applicable common scientific standards of care, and the Supplier's reasonable written instructions. Unless otherwise agreed in the Project Schedule, each Recipient may use the Materials of the Supplier only in connection with performing the Project described in the applicable Project Schedule and for no other purpose.

Restrictions; Respect for Labeling. The Recipient may not modify, analyze, sequence, derivatize, nor (b) attempt to determine the structure of any Material except to the extent described in the applicable Project Schedule. The Supplier will retain ownership of the Materials at all times. This Agreement may not be construed as granting any rights to the Supplier's interests in the Materials, or their manufacture, commercialization, or any other uses thereof except to the extent described in the applicable Project Schedule. A Recipient may not transfer any of the Materials to any Third Parties except to Contract Laboratories and subcontractors as permitted under this Agreement. The Recipient may not use the Materials of the Supplier for testing in or treatment of human subjects except to the extent described in the applicable Project Schedule. To the extent that the Supplier includes with any Materials specific Package Instructions (including, for example, package inserts or legends reading "For Research Use Only. Not for use in diagnostic procedures." or "For Investigational Use Only"), the Recipient may only use such Materials in accordance with its accompanying Package Instructions. All such Package Instructions must be reasonable and may not unreasonably limit or delay the Recipient's ability to perform the Project or increase the cost of Recipient's use of such Materials (unless a corresponding amendment to the Project Schedule with appropriate financial consideration is agreed to). EXCEPT AS SET FORTH IN THIS AGREEMENT OR THE APPLICABLE PROJECT SCHEDULE, THE RECIPIENT ACKNOWLEDGES THAT THE MATERIALS ARE BEING SUPPLIED AS-IS WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE, MISAPPROPRIATE OR OTHERWISE VIOLATE ANY PATENT OR PROPRIETARY RIGHTS OF ANY THIRD PARTY.

(c) <u>Documents</u>. Each Party will, upon request, timely provide the other Party with reasonable access to Project Results or other documentation (or portions thereof) in its Control related to the IVD Assay or Partner Product that are reasonably necessary for the other Party's performance of each Project under this Agreement or the exercise of the rights expressly granted to the other Party under this Agreement. This will include: (i) Partner providing Illumina with reasonable access to its Clinical Trial protocols (including template forms of patient consents), statistical analysis plan, and other Partner Confidential Information and documentation relating to the Partner Product if and to the extent reasonably necessary to enable Illumina to perform the Project, and (ii) Illumina providing Partner with reasonable access to its Clinical Trial protocols, statistical analysis plan, IUO Assay specifications, and other Illumina Confidential Information and documentation relating to the IVD Assay if and to the extent reasonably necessary to enable Partner to perform the Project.

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### 4. THIRD PARTY INTERACTIONS

4.1 <u>Subcontractors</u>. Except as specified in a Project Schedule, any involvement of Third Party contractors by either Party for a material portion of the Project will require the prior written consent of the other Party, which consent may not be unreasonably withheld. The foregoing may not be construed as requiring either Party to obtain consent from the other Party before using individual consultants, subcontracting those minor portions of the Project that it would customarily subcontract in the ordinary course of business, or subcontracting to Affiliates. To the extent that a Party utilizes Third Party contractors or Affiliates to perform tasks within the scope of a Project, such Party will ensure all such Third Party contractors and Affiliates are obligated to: (a) treat the other Party's Confidential Information in accordance with the provisions of Section 7, (b) assign rights to any Inventions and Project Results so that such rights can be conveyed in accordance with the terms and conditions of Section 8 and (c) comply with all other terms of this Agreement applicable to the performance of such subcontracted task. Each Party will be solely responsible for the acts, performance and compensation of its respective Third Party contractors.

### 4.2 <u>Third Party IP</u>.

(a) <u>Responsibility</u>. Unless the Project Schedule specifically provides otherwise, Illumina will be responsible, at its own expense, for obtaining and maintaining any licenses or other rights to access or use any IP Rights owned or controlled by a Third Party ("**Third Party IP**") (other than as described in this Section 4.2) that, in the absence of a license, would be infringed by Illumina or its Affiliates' development, manufacture, use or Commercialization of such IVD Assay pursuant to this Agreement (a "**Third Party License**").

(b) <u>Biomarker IP</u>. If, in Illumina's reasonable determination, a Third Party License to any Biomarker IP is reasonably necessary with respect to a particular Biomarker for the purpose of Exploiting any IUO Assay or IVD Assay intended to be Commercialized pursuant to this Agreement, then Illumina will notify Partner and, at Partner's request, will consult with Partner via the JSC (i) concerning the determination of whether a Third Party License is reasonably necessary for Illumina to Exploit such IUO Assay or IVD Assay and (ii) regarding reasonable risk mitigation strategies, including reasonable alternatives to termination if such Third Party License is necessary for a single or small number of Biomarkers. If, following such reasonable consultation, Illumina determines that such Third Party License is not reasonably obtainable, Illumina will have the right to modify the IUO Assay at any time prior to Design Lock so that the particular Biomarkers are not reported. If the applicable Biomarkers are critical to the IUO Assay for use with the Partner Product, the Parties via the JSC will in good faith discuss and negotiate modification (if possible) of the Assay or other remedial alternatives, including termination of the specific Project Schedule.

(c) <u>Third Party IP with respect to Partner Product</u>. For the avoidance of doubt, Partner will be solely responsible, at its own expense, for obtaining and maintaining any licenses or other rights to access or use any Third Party IP (other than as described in this Section 4.2) that is necessary for the development, manufacture, use, or Commercialization of any Partner Product.

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(d) <u>Cooperation</u>. Each Party agrees to cooperate reasonably with the other Party to assist the other Party's acquisition of any licenses that it is obligated to obtain pursuant to this Section 4.2; <u>provided</u>, <u>however</u>, that such cooperation will not include any requirement that such Party undertake any financial obligations such as the payment of royalties, fees, milestones, or the like.

4.3 <u>Contract Laboratories</u>. Notwithstanding anything to the contrary in this Agreement, each Party may use Third Party contract laboratories for the performance of certain Project activities (such as Sample testing) as mutually agreed in the Project Schedule (each a "**Contract Laboratory**").

### 4.4 <u>Regulatory Approvals</u>.

(a) Subject to each applicable Project Schedule, Illumina will be responsible for interacting with Regulatory Authorities and for seeking, obtaining and maintaining Regulatory Approvals for the IVD Assay in each Market set forth in the applicable Project Schedule; Partner will be responsible for interacting with Regulatory Authorities and for seeking, obtaining and maintaining Regulatory Approvals for the Partner Product in each Market set forth in the applicable Project Schedule. Illumina will use Commercially Reasonable Efforts to ensure that the IVD Assay developed in a Project complies with all applicable Laws and fulfills all applicable statutory requirements in the Markets for use as an IVD in connection with the Partner Product in the Indication(s) specified in the applicable Project Schedule, including the CE-marking in the European Union, and requirements for comparable approvals in other countries. Illumina will use Commercially Reasonable Efforts to ensure that the IVD Assay receives such Regulatory Approval in the Markets in the time specified in the applicable Project Schedule.

(b) The Parties will cooperate and assist each other reasonably in the Regulatory Approval process and reasonably coordinate and align their Regulatory Approval filings. For the avoidance of doubt, each Party acknowledges that Illumina will not be obligated to seek Regulatory Approvals in jurisdictions other than the Markets identified in a Project Schedule, and if Illumina agrees to amend any Project Schedule to add additional Markets such amendment will be subject to additional costs such as regulatory filing fees, preparation of regulatory filings and, if necessary, Clinical Trials to be negotiated in good faith pursuant to Section 2.3. If Partner requests the addition of one or more additional markets to be added as Market(s) for a particular Project Schedule but the Parties do not agree on amendment to the Project Schedule to add such additional market(s) as Market(s) within sixty (60) days after such request, then, upon Partner's request, the Parties will negotiate a potential Replacement Diagnostic Solution for such additional market(s) pursuant to Section 5.10.

(c) If Illumina is unwilling to seek, obtain, or maintain Regulatory Approvals for the IVD Assay in any country in the Markets then Illumina will provide Partner with written notice to that effect. In such circumstance or in the event Illumina otherwise breaches its obligations under Section (a) above to seek, obtain, or maintain Regulatory Approvals for the IVD Assay in any country in the Markets, Partner may provide written notice to Illumina, and if Illumina fails to adequately address such situation and, if applicable, cure such breach within sixty (60) days after receipt of such notice then, upon Partner's

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request, the Parties will negotiate a potential Replacement Diagnostic Solution for such Market pursuant to Section 5.10.

(d) All (a) applications, registrations, dossiers, licenses, authorizations and approvals (including Regulatory Approvals); and (b) correspondence, reports and other submissions submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority and any drug master files or device master files, as applicable to Partner or Illumina) and all supporting documents with respect thereto, including all adverse event files and complaint files, in each case ((a) and (b)), (i) relating to an IUO Assay or IVD Assay will be owned by Illumina or its Affiliate, and (ii) relating to a Partner Product will be owned by Partner or its Affiliate, respectively. Each Party will provide the other Party with copies of such documents and information described in (a) and (b) above promptly after reasonable request by the other Party, provided that the first Party may redact Confidential Information (including confidential or proprietary information of Third Parties).

## 5. COMMERCIALIZATION

General Principles. The Parties agree that the ultimate goal of each Project conducted under this Agreement is the 5.1 Commercialization of an IVD Assay that may be used in connection with the Partner Product in the Market(s) and for the Indication(s) specified in the applicable Project Schedule, and Illumina acknowledges that availability of such IVD Assay might be a condition for obtaining a Regulatory Approval for a Partner Product. The following general principles will govern Commercialization activities: (a) determining whether and to what extent and in what countries the Partner Product will be Commercialized will be within Partner's sole discretion, (b) in Markets where Partner desires to Commercialize the Partner Product and in which Illumina determines that the Commercialization of such IVD Assay is not or is not likely to be commercially reasonable, the Parties will negotiate in good faith a potential alternative plan for the Commercialization of such IVD Assay in such Markets under the following principles: (i) neither Party will be obligated to undertake any action that it believes in good faith is unlawful, or which exposes it to regulatory or legal risks (e.g., infringement of Third Party IP, noncompliance with export or corruption laws, etc.) in excess of those which it customarily assumes, and (ii) subject to clause (i), a goal of the Parties will be to ensure that after Regulatory Approval such IVD Assay can be sold in each such Market by Illumina or its Affiliates through the use of Commercially Reasonable Efforts. If a commercially reasonable plan for Commercializing an IVD Assay in a given Market is not possible, then Partner may provide written notice to Illumina, and if Illumina fails to adequately address such situation within sixty (60) days after receipt of such notice then, upon Partner's request, the Parties will negotiate a potential a Replacement Diagnostic Solution for such Market pursuant to Section 5.10.

5.2 <u>Illumina Obligations</u>. Upon Regulatory Approval of the IVD Assay in each Market, Illumina (or its Affiliates, as applicable) will use Commercially Reasonable Efforts, at its sole expense (except for Partner payments agreed-upon in the Project Schedule) and discretion, to Commercialize the IVD Assay in each such Market. In the event Illumina decides (whether such decision is consistent with its exercise of Commercially Reasonable Efforts or not and whether or not such decision is caused by a force majeure event) to materially limit or cease Commercialization of the IVD Assay in any Market, then Illumina shall

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provide prompt written notice thereof to Partner. If Partner reasonably determines that such limitation or cessation of Commercialization of the IVD Assay will have an adverse impact on Partner's or its Affiliate's Commercialization of the Partner Product in such Market, then Partner shall have the right to provide notice thereof to Illumina and if Illumina does not adequately address such situation within sixty (60) days of receipt of such notice then, upon Partner's request, the Parties will negotiate a potential Replacement Diagnostic Solution for such Market pursuant to Section 5.10.

5.3 <u>Partner Obligations</u>. Upon Regulatory Approval of the Partner Product in each Market that Illumina is actively Commercializing the IVD Assay, Partner (or its Affiliates, or any sublicensee of a Partner Product in any Market, as applicable) will use Commercially Reasonable Efforts, at its sole expense and discretion, to: (a) Commercialize the Partner Product, in each such Market in accordance with the applicable Project Schedule; and (b) as permitted by applicable Laws, reference testing with the IVD Assay to the Partner Product target customer segment.

5.4 <u>Coordination</u>. Solely as permitted by applicable Laws, each of the Parties, under the direction and oversight of the JCC and at their own respective costs (except as set forth in the applicable Project Schedule), will in good faith discuss potential scientific support, marketing strategies, sales force initiatives, and a coordinated approach for the marketing of the IVD Assay and the respective Partner Product, including identification of Markets, alignment of package inserts, instructions for use, data sheets, marketing collateral and materials, publications, training reimbursement strategies, support of investigator initiated studies, sharing of market research information, use of advisory boards, or engagement of key opinion leaders. As it becomes available or known to Partner, Partner will provide Illumina with information concerning its launch plans and its anticipated release timelines for the Partner Product and such information will be treated as Confidential Information of Partner.

5.5 <u>Commercialization Plan</u>. Under the direction and oversight of the JCC, the Parties may work cooperatively to develop one or more commercialization plans for each IVD Assay (each being a "**Commercialization Plan**"). Each Commercialization Plan is part of the Project Schedule for the IVD Assay and will include a description of those Commercialization activities to be conducted by each Party in support of the launch of and the Commercialization of the IVD Assay pursuant to and subject to this Agreement, including a budget for costs and expenses to be paid by Partner. The Commercialization Plan may be regional or country specific depending on the market or diagnostic landscape needs.

5.6 <u>Quality Assurance</u>. Illumina will adhere to the applicable Quality System Regulations as found in 21CFR820 or 21CFR11 and ISO13485, or their successor, applicable regulatory guidance and specifications for the manufacture and performance of the IVD Assay developed under a Project Schedule as may be necessary to meet applicable regulatory requirements or applicable Law for the development and manufacture thereof in accordance with the Project Schedule. Illumina will furnish Partner with certificates of conformance in the format reasonably agreed to by the Parties.

5.7 <u>Trademarks and Labeling</u>. Illumina will ensure that its, and its Affiliates', references to Partner (and any product, trademark, logo, or trade name of Partner or any of its Affiliates) in connection with the IVD Assay (including any use in any Labeling, the IVD Assay description, technical information,

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instructions for use, promotional material, advertising and other information and messaging to be included with the IVD Assay or otherwise to be provided by Illumina to potential purchasers or users of the IVD Assay) will only be as approved in advance in writing by Partner and only to the extent as specifically agreed to in advance in writing by Partner, provided that such approval or agreement may not be unreasonably withheld, delayed, or conditioned. Likewise, Partner will ensure that its, and its Affiliates', references to Illumina (and any product, trademark, logo, or trade name of Illumina or any of its Affiliates) in connection with the Partner Product (including any use in any Labeling, the Partner Product description, technical information, instructions for use, promotional material, advertising and other information and messaging to be included with the Partner Product or otherwise to be provided by Partner to potential purchasers or users of the Partner Product) will only be as approved in advance in writing by Illumina and only to the extent as specifically agreed to in advance in writing by Illumina, provided that such approval or agreement may not be unreasonably withheld, delayed, or conditioned. The Parties will in good faith negotiate and include any necessary trademark licenses in the applicable Project Schedule.

5.8 <u>Manufacture and Supply</u>. Illumina will be solely responsible for the manufacture of the IVD Assay. Until commercial launch of an IVD Assay, Illumina will ensure that supplies of the IVD Assays (or prototypes) in the amounts provided in the Project Schedule, are available to support Partner Clinical Trial requirements in accordance with Illumina generally applicable commercial terms and any forecast, order, payment, quality, delivery, and shipment terms mutually agreed between the Parties in good faith negotiations unless already set forth in the Project Schedule. Illumina's responsibilities with respect to the performance of any Clinical Trials will be set forth in the applicable Project Schedule.

5.9 <u>Supply Failures</u>. After Regulatory Approval of an IVD Assay, if Illumina fails to reasonably meet commercial demand for the IVD Assay in a Market, unless such failure is caused in whole or in part by Partner or one or more persons acting on Partner's behalf, then Partner may provide written notice to Illumina, and if Illumina fails to cure such situation within sixty (60) days after receipt of such notice then, upon Partner's request, the Parties will negotiate a potential a Replacement Diagnostic Solution for such Market pursuant to Section 5.10.

5.10 <u>Replacement Diagnostic Solutions</u>. If Illumina is required to negotiate a Replacement Diagnostic Solution with respect to an IVD Assay for a Market (or a proposed market, as applicable) in accordance with the terms of this Agreement, then the Parties will negotiate in good faith a potential Replacement Diagnostic Solution for such IVD Assay in the applicable Market(s) pursuant to this Section 5.10. A "**Replacement Diagnostic Solution**" means an alternative arrangement on commercially reasonable terms to ensure the continuing development, supply and Commercialization of the applicable IVD Assay in connection with the applicable Partner Product in the applicable Market(s) and for the Indication(s) specified in the Project Schedule, such as:: (a) the exclusive right for Partner to distribute the IVD Assay in such Market (or proposed market, as applicable), (b) the right for one or more Third Party(ies) agreed to by the Parties to distribute the IVD Assay in such Market (or proposed market, as applicable), (c) an arrangement to transport blood or tissue samples to Markets where the IVD Assay is available, (d) a licensing arrangement (provided, however, that Illumina will in no event be required to license any Illumina Platform Technology to any Third Party or to license IP to any Third Party who (or

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whose Affiliate) develops or sells, or who has announced an intention to develop or sell, instruments for nucleic acid sequencing), or (e) such other mutually agreeable arrangement to help support sales of the Partner Product, with the ultimate goal of ensuring that diagnostic testing using the IVD Assay in connection with the Partner Product for the Indication is (or remains) available in the relevant Markets (or proposed markets, as applicable) without interruption. The Parties will negotiate for up to ninety (90) days commercially reasonable terms and conditions for such arrangement. If a Replacement Diagnostic Solution is not feasible, or after a reasonable period of negotiation the Parties are not able to agree on a proposed Replacement Diagnostic Solution, then, without limiting any other rights or remedies available to Partner, Illumina will transfer to Partner all residuals of Samples used in performance of a Project Schedule and any data reasonably required by Partner to conduct bridging studies in connection with the transfer of development or commercialization activities for an alternative companion diagnostic to Partner or one or more Third Parties designated by Partner.

5.11 <u>Access</u>. Authorized Representatives of Partner will have the right to perform a quality management system audit of Illumina Facilities and to inspect the Facilities and records that relate to the performance of the Project Schedules and compliance under this Agreement. Such audit by Partner will be: (a) on at least sixty (60) days prior written notice, (b) during Illumina regular business hours, (c) not unreasonably disruptive to Illumina business operations, (d) reasonable in duration, (e) not unduly burdensome to Illumina's personnel, (f) not more than once per year except as required by applicable Law, and (g) subject to Illumina's generally applicable confidentiality, security and safety procedures, as well as quality management system procedures for Third Party auditors. All information learned in the course of any such audit will be Illumina's Confidential Information.

## 5.12 <u>Life Cycle</u>

(a) <u>Change Period</u>. The Parties anticipate that the initial IVD Assays will be for use on Illumina's NextSeq 550Dx Instrument ("**NextSeqDx**"). The period of time commencing on the Effective Date and ending, is the "**Change Period**" for the NextSeqDx Instrument and related core sequencing consumables. If the Parties agree to any Project Schedule concerning an IVD Assay for use on another Instrument, the Parties will set forth the Change Period for such Instrument in that Project Schedule.

(b) <u>Change Notice</u>. Illumina will notify Partner at least ninety (90) days in advance of any planned changes to the Illumina technical environment recommendations, including instrumentation and test or data protocols and analysis or a new, upgraded version or release of such related to a IVD Assay during the Change Period (each a "**Life Cycle Change**") that would result in material changes or updates to the data package submitted to Regulatory Authorities related to the IVD Assay to allow continued use of the IVD Assay with such Life Cycle Change.

(c) <u>Life Cycle Management</u>. The IVD Assay will be compatible with the Illumina technical environment recommendations, including instrumentation and test or data protocols and analysis by Illumina in the applicable Project Schedule, during the Change Period. Within ninety (90) days after Illumina makes a Life Cycle Change generally available to its customers, Illumina will, at Illumina's sole cost, deliver to Partner an update to the IVD Assay to ensure its compatibility with such Life Cycle

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Changes, or if no update is necessary, Illumina will so state to Partner in writing within such ninety (90) days. Illumina warrants that, unless otherwise mutually agreed in writing by the Parties, any voluntary (e.g. not made to satisfy a requirement of applicable Law) Life Cycle Changes to the IVD Assay will not materially adversely impact the ability to obtain Regulatory Approval in any Market.

(d) <u>Innovation</u>. Partner acknowledges that Illumina is constantly innovating and developing new products and new versions of products. Notwithstanding anything to the contrary, Illumina makes no covenant, representation, or guarantee that any Instrument or related core sequencing consumables specified in the applicable Project Schedule will be manufactured or sold following the Change Period. Except as expressly stated in this Section 5.12, Illumina is under no obligation to notify Partner of any changes to products or development of new products.

## 5.13 <u>Supply and Purchase of Instruments and Associated Consumables</u>.

(a) Instruments and associated consumables required for performance of any Project will be purchased from Illumina at commercially reasonable prices to be negotiated in good faith, and the terms of such purchases will be governed by Illumina's standard terms and conditions of sale applicable to such Instruments and associated consumables, as applicable, as such standard terms and conditions may be updated from time to time pursuant to Illumina's prevailing practices (the "**Standard Terms**"). The Standard Terms as of the Effective Date are available at the following website: https://www.illumina.com/company/legal/terms-and-conditions.html.

(b) This Agreement, including the Standard Terms as incorporated herein, exclusively governs Partner's ordering, purchase, supply, and use of Instruments and associated consumables in connection with any Project, and overrides any conflicting, amending, or additional terms or conditions contained in any purchase orders or similar documents, all of which are hereby rejected and are null and void. Illumina's failure to object to any such terms or conditions will not constitute a waiver by Illumina, nor constitute acceptance by Illumina of such terms or conditions. In interpreting the Standard Terms, Partner's use of a product in any manner not permitted by this Agreement will be deemed a use of the product not in accordance with the Standard Terms and a breach of the Standard Terms. Notwithstanding anything to the contrary in the Standard Terms, to the extent any provision of the Standard Terms conflicts with a provision in this Agreement, the provision in this Agreement will control. Without limiting the foregoing, to the extent any provision of the Standard Terms would prevent Partner's exercise of the rights expressly granted to Partner in this Agreement, or to the extent any provision of the Standard Terms would allow Partner to act in a manner prohibited by this Agreement, such provision will not apply to Partner or this Agreement.

## 6. PAYMENT

### 6.1 <u>Payments and Invoices</u>.

(a) Partner will pay the non-refundable, non-creditable, milestone payments to Illumina set forth in the Project Schedule upon achievement of the Milestones set forth therein. The Parties hereby

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agree that all Projects shall be performed on the basis of a milestone-based fee structure, unless agreed otherwise in a Project Schedule. Payments by Partner shall be made in United States Dollars by wire transfer or ACH transfer to a bank account specified by Illumina in the invoice (or if not specified in the invoice, specified in the Project Schedule). Upon achievement of each Milestone, Illumina will document achievement via the JDC or JCC (as applicable) together with reasonable supporting documentation to evidence such achievement. Illumina may issue an invoice for the applicable Milestone payment only upon receipt of confirmation from the JDC or JCC (as applicable) that the applicable Milestone has been achieved. In the event of any dispute with respect to the achievement of any Milestone, such dispute shall be escalated from the JDC or JCC (as applicable) to the JSC for resolution. Each calendar month, via JDC meetings, Illumina will provide Partner an estimate of percent completion of in-progress activities as outlined in the relevant Project Schedule. Partner will make all undisputed payment no later than 45 days after receiving an invoice. Illumina invoices and related documentation may come from an Illumina Affiliate, which Partner shall honor as if they came directly from Illumina so long as Illumina has given written instruction to Partner as to the use of such Illumina Affiliate.

(b) Upon the date that is ninety (90) days after the consummation of a Change in Control of Partner (the "**CIC Payment Date**"), unless (i) Illumina terminates this Agreement pursuant to Sections 15.2 or 15.4 prior to such CIC Payment Date, (ii) Partner (or its acquiror or successor) has given notice of termination of this Agreement pursuant to Sections 15.2 or 15.3 prior to the CIC Payment Date, or (iii) Partner's acquirer or successor (including any Affiliate thereof) is, as of the time of the consummation of such Change In Control, already party to an agreement with Illumina concerning Illumina's development of an in vitro diagnostic assay pursuant to which such acquirer or successor has an active development program (which program is evidenced by an active project schedule, statement of work, or similar documentation appended to the agreement), Partner (or its acquirer or successor) will pay Illumina \$\*\*\* due within 30 days of the CIC Payment Date upon Illumina issuing an invoice therefor.

6.2 <u>Disputes; Late Payments</u>. In the event that Partner does not make a payment of an undisputed amount within forty-five (45) days after the date of the applicable invoice, Illumina will send a payment reminder to Partner, and may apply interest on the outstanding amount owed to Illumina for the period that commences on the date Partner receives Illumina's payment reminder (inclusive) and ends on the payment date (exclusive). Interest for such undisputed late payments shall be calculated based on the actual number of days in the interest period divided by 360 at the annual rate of the Bank Prime Loan rate (as quoted in Federal Reserve Bulletin H.15 or a successor bulletin thereto) plus one percent (1%).

6.3 <u>Sunshine Act</u>. Illumina and Partner acknowledge that they both may be "Applicable Manufacturers" pursuant to the Physician Payment Sunshine Act and may have certain duties to track and report payments and transfers of value to "Covered Recipients", as those terms are defined by the Centers for Medicare & Medicaid Services, or a successor entity thereto. To the extent either Party has reporting obligations under the Physician Payment Sunshine Act, upon the reasonable request of the reporting Party the other Party will provide such reporting Party with complete and accurate information about payments or transfers of value in relation to the activities under this Agreement that are reportable thereunder.

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6.4 <u>Taxes</u>. All amounts payable by Partner to Illumina pursuant to this Agreement will be paid free and clear of any and all taxes, except for any withholding taxes required by applicable Law. Except as provided in this Section 6.4, Illumina will be solely responsible for paying any and all taxes (other than withholding taxes required by applicable Law to be deducted from such payments and remitted by Partner) levied on account of, or measured in whole or in part by reference to, any payments it receives. Partner will deduct or withhold from payments to Illumina any taxes that it is required by applicable Law to deduct or withhold. Notwithstanding the foregoing, if Illumina is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it will deliver to Partner or the appropriate governmental authority (with the assistance of Partner to the extent reasonably requested in writing by Illumina) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Partner of its obligation to withhold such tax and Partner will apply the reduced rate of withholding or dispense with withholding, as the case may be. If, in accordance with the foregoing, Partner withholds any amount, it will pay to Illumina the remaining balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Illumina proof of such payment within ten (10) days following such payment.

### 6.5 <u>Books and Records</u>.

(a) For a period of 8 years from the date of their creation, Illumina will maintain complete and accurate books and records regarding the amounts invoiced to Partner pursuant to this Agreement. During such period, an independent certified public accounting firm of nationally recognized standing, selected by Partner and reasonably acceptable to Illumina, at Partner's expense, will have the right to inspect and audit such books, records of Illumina as may be reasonably necessary to verify the accuracy of the invoices submitted by Illumina under this Agreement for any year ending not more than twenty-four (24) months prior to the date of Partner exercising such right. Partner may exercise such right once per calendar year (provided that the foregoing limit will not apply if the immediately prior inspection and audit revealed any non-compliance or incorrect invoicing). Any such inspection and audit will be conducted during regular business hours and in a manner that minimizes interference with Illumina's normal business activities. The accounting firm will be subject to Illumina's standard confidentiality obligations and will disclose to Partner only whether the invoices are correct or not and the specific details concerning any discrepancies. No other information will be shared.

(b) If such an inspection and audit reveals an overpayment of any amounts payable by Partner, then Illumina will promptly remit the full amount of such overpayment to Partner, including interest calculated in accordance with Section 6.2. If the overpaid amount exceeds seven percent (7%) of the amounts properly payable by Partner for the period audited, then Illumina will also pay Partner's reasonable costs of conducting the inspection and audit. If an inspection and audit reveals that additional amounts were owed during the audited period, Partner will pay such additional amounts within thirty (30) days of the date Partner receives the accounting firm's written report so concluding.

(c) Partner will treat all financial and other information subject to review under this Section 6.5 as Illumina's Confidential Information.

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### 7. CONFIDENTIAL INFORMATION

### 7.1 <u>Disclosure and Use Restriction</u>.

(a) <u>Confidentiality</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Receiving Party will keep confidential and may not publish or otherwise disclose or transfer the Disclosing Party's Confidential Information to any Third Party. The Receiving Party may disclose the Disclosing Party's Confidential Information only to its Advisors and Representatives who are bound by professional confidentiality and non-use restrictions or written confidentiality and non-use restrictions at least as restrictive as those set forth in this Agreement and who have a specific need to know in order for the Receiving Party to be able to perform its obligations and exercise its express rights under this Agreement, and only to the extent necessary for such purpose. Each Party will be responsible for any conduct by its respective Advisors and Representatives a breach of this Section 7 or that would be a breach of this Agreement by such Party had such Party engaged in such conduct itself. Such conduct will be deemed and is a breach of this Agreement by such Party. The Receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than a reasonable standard of care) to ensure that it and its Advisors and Representatives do not disclose or make any unauthorized use of the Disclosing Party's Confidential Information. The Receiving Party will promptly notify the Disclosing Party upon discovery of any unauthorized disclosure or use of the Disclosing Party's Confidential Information.

(b) <u>Term</u>. The confidentiality and non-use obligations in this Agreement with respect to the Disclosing Party's Confidential Information will continue throughout the Term and for seven (7) years thereafter.

7.2 <u>Authorized Disclosure</u>. The Receiving Party may disclose the Disclosing Party's Confidential Information to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other governmental authority; provided, however, that the Receiving Party will, to the extent permitted by Law, give written notice to the Disclosing Party within five (5) business days of receipt of such order and give the Disclosing Party a reasonable opportunity to quash or limit the scope of such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental authority or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or limited in scope, or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental authority;

(b) otherwise required by Law; provided, that the Receiving Party: (i) promptly notifies the Disclosing Party of the specifics of such requirement (providing a copy of the Confidential Information to be disclosed) at least thirty (30) days before the actual disclosure (or as soon as reasonably possible

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before the actual disclosure if such thirty (30) day prior notice is impractical under the circumstances) or promptly after actual disclosure if prior disclosure is impractical under the circumstances; (ii) discloses only the minimal information necessary to satisfy such requirement; (iii) reasonably cooperates with the Disclosing Party to prevent or limit such disclosure; and (iv) provides the Disclosing Party with a copy of Confidential Information actually disclosed; or

(c) made by the Receiving Party with the prior written consent of the Disclosing Party; or

(d) to bona fide actual or potential investors, acquirors, or licensees of a Receiving Party (i) in the case of Partner as the Receiving Party, consists of the terms of this Agreement and any Project Schedule, Illumina Project Results or Joint Project Results or (ii) in the case of Illumina as the Receiving Party, consists of the terms of this Agreement and any Project Schedule, Partner Project Results or Joint Project Results; provided that, in each case, (a) such Person is bound by professional confidentiality and non-use restrictions or written confidentiality and non-use restrictive as those set forth in this Agreement; (b) such Confidential Information may only be used by such Person for purposes of evaluating an existing or potential investment, acquisition, or license with the Receiving Party (which, in the case of the license, relates to the Parties' activities under this Agreement); and (c) the Receiving Party will be responsible for any conduct by any such Person that constitutes a breach of this Section 7 or that would be a breach of this Section 7 by the Receiving Party had the Receiving Party engaged in such conduct itself, and such conduct will be deemed and is a breach of this Agreement by such Party.

7.3 <u>Authorized Use</u>. The Receiving Party may use the Disclosing Party's Confidential Information solely to the extent necessary for the Receiving Party to perform its obligations and exercise its express rights under this Agreement, and such use will be otherwise subject to all restrictions and limitations set forth in this Agreement.

7.4 <u>Agreement; Publicity</u>. The existence and terms of this Agreement are both Parties' Confidential Information. Subject to Section 7.2 and Section 7.5, each Party must obtain the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed) on all press releases or other public announcements or disclosures relating to this Agreement, provided that a Party is not required to obtain prior written consent of the other Party for press releases or public disclosures that repeat information that has been previously publicly disclosed pursuant to this Section 7.4.

7.5 <u>SEC Filings and Other Disclosures</u>. Either Party may disclose the terms of this Agreement and make any other public written disclosure regarding the existence of, or performance under, this Agreement, to the extent required to comply with applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental authority, securities exchange or securities regulator in any applicable country. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 7.5, the Parties shall consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the disclosing Party providing as much advance notice as is feasible under the circumstances, and giving consideration to the timely comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 7.5, such Party shall, at its own expense, seek such

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confidential treatment of confidential portions of this Agreement and such other terms as it reasonably determines, giving consideration to the comments of the other Party pursuant to the preceding sentence.

Publications. Each of Illumina and Partner (each, a "Submitting Party") shall have the right to publish or present 7.6 Project Results, subject to the prior review and written approval of the other Party (the "**Reviewing Party**"), which approval shall not be unreasonably withheld, conditioned or delayed. The Submitting Party will provide the Reviewing Party with the opportunity to review any proposed abstract, manuscript, or presentation which discloses the Project Results. The Submitting Party will provide the Reviewing Party with the opportunity to review any proposed abstract, manuscript or presentation which discloses the Project Results by delivering a copy thereof to the Reviewing Party not less than forty five (45) days before its intended submission for publication or presentation. The Reviewing Party will have thirty (30) days from its receipt of any such abstract, manuscript or presentation in which to notify the Submitting Party in writing of any specific objections to the disclosure, including objections based on either the need to seek patent protection or concern regarding the specific disclosure of the Confidential Information of the Reviewing Party. In the event the Reviewing Party objects to the disclosure on such grounds, the Submitting Party agrees not to submit the publication or abstract or make the presentation containing the objected-to information until the Reviewing Party is given a reasonable additional period of time (not to exceed an additional ninety (90) days) to seek patent protection for any material in the disclosure which the Reviewing Party believes is patentable or, in the case of Confidential Information, to allow the Submitting Party to delete any Confidential Information of the Reviewing Party from the proposed disclosure. The Submitting Party agrees to delete from the proposed disclosure any Confidential Information of the Reviewing Party upon request.

7.7 <u>Post-Termination</u>. Following expiration or termination of this Agreement for any reason, upon the request of the Disclosing Party, the Receiving Party will, at the Disclosing Party's option: (a) return all materials containing the Disclosing Party's Confidential Information to the Disclosing Party; or (b) destroy all materials containing the Disclosing Party's Confidential Information and certify such destruction in writing to the Disclosing Party; provided that the Receiving Party will be authorized to retain one copy in its legal department for the purpose of determining any continuing obligation with respect thereto. Notwithstanding the foregoing, the Receiving Party will not be required to destroy or delete electronic copies (including emails) that have become embedded in its electronic storage systems through routine backup processes. Any Confidential Information so retained will continue to be held pursuant to all of the confidentiality, non-use, and other terms of this Agreement.

### 8. INTELLECTUAL PROPERTY OWNERSHIP

8.1 <u>Ownership of Background IP</u>. Each Party (and its respective Affiliates) will own all right, title and interest in and to its (and their) respective Background IP. Each Party acknowledges and agrees that, except for the licenses expressly granted in Section 9 below, in a Project Schedule, or as part of a Replacement Diagnostic Solution, neither Party (nor their respective Affiliates) will have any rights to, or licenses under, the other Party's Background IP.

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Ownership of Project Results. Ownership of Project Results will be determined as follows: (a) Partner will own 8.2 (i) all Project Results that relate directly to the Partner Product, including Clinical Outcomes Data, and that do not relate to an Assay, the Assay Performance Data or the Illumina Platform Technology ("Partner Product Results"), and (ii) any Project Results that are not Partner Product Results, Illumina Platform Results or Joint Product-Platform Results and are made, invented, conceived, created, authored, or developed solely by employees or contractors of Partner (or its Affiliates) ((a)(i) and (ii) collectively, "Partner Project Results"), (b) Illumina will own (i) all Project Results that relate directly to an Assay or the Illumina Platform Technology, including Assay Performance Data, and that do not relate to the Partner Product (collectively, "Illumina Platform Results"), and (ii) any Project Results that are not Partner Product Results, Illumina Platform Results or Joint Product-Platform Results and are made, invented, conceived, created, authored, or developed solely by employees or contractors of Illumina (or its Affiliates) ((b)(i) and (ii) collectively, "Illumina Project Results"), and (c) the Parties will jointly own (i) all Project Results that relate to both (A) the Partner Product and (B) an Assay, the Assay Performance Data or the Illumina Platform Technology ("Joint Product-Platform Results") and (ii) all other Project Results that are not Partner Project Results, Illumina Project Results or Joint Product-Platform Results and are made, invented, conceived, created, authored, or developed jointly by the employees or contractors of Illumina (or its Affiliates) and Partner (or its Affiliates) ((c)(i) and (ii) collectively, "Joint Project Results"), with each Party having an undivided one-half interest in and to such Project Results, with the right to use, practice, license and otherwise Exploit, and assign its interest in, such Joint Project Results without the consent of or a duty of accounting to the other Party. Partner Project Results will be Partner Confidential Information. Illumina Project Results will be Illumina Confidential Information. The Joint Project Results will be each Party's Confidential Information: provided, however, that a Party may disclose Joint Project Results to an actual or potential licensee of such Joint Project Results in accordance with Section 7.2(d). Each Party will be responsible for any conduct by its sublicensee that constitutes a breach of Section 7 or that otherwise would cause such Party to be in breach of Section 7 had it performed such acts itself, and such conduct will be a breach of this Agreement by such Party.

8.3 <u>Transfer of Project Results</u>. Acting under the oversight of the JDC or JSC as applicable, each Party will promptly disclose all Project Results to the other Party. Illumina will promptly provide all Partner Project Results to Partner and hereby assigns and agrees to assign all of its right, title, and interest in such Partner Project Results, to Partner. Partner will promptly provide all Illumina Project Results to Illumina and hereby assigns and agrees to assign all of its right, title, and interest in such Illumina Project Results to Illumina. Acting under the oversight of the JDC or JSC as applicable, each Party will promptly provide to the other Party all Joint Project Results (and to the extent necessary to effect joint ownership thereof, hereby assigns an undivided one-half interest in and to such Project Results to the other Party). Each Party will, upon the reasonable request by the other Party and at the other Party's cost and expense, promptly execute any and all documents deemed necessary or appropriate by the other Party to memorialize, effect or perfect the assignments under this Section 8.3 throughout the world.

8.4 <u>Ownership of Inventions</u>. Acting under the oversight of the JPC or JSC as applicable, the Parties will promptly notify each other in confidence of any Inventions. Inventorship will be determined according to US patent law (without reference to any conflict of law principles). Ownership of Inventions will be determined by the following provisions: (a) Partner will own (i) all Inventions (regardless of

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inventorship) that relate directly to the Partner Product or the Clinical Outcomes Data and that do not relate to an Assay, the Assay Performance Data or the Illumina Platform Technology ("**Partner Product Inventions**") and (ii) any Inventions that are not Partner Product Inventions, Illumina Platform Inventions or Joint Product-Platform Inventions and are made, invented, conceived, created, authored, or developed solely by employees or contractors of Partner (or its Affiliates) ((a)(i) and (ii) collectively, "**Partner Inventions**"), (b) Illumina will own (i) all Inventions (regardless of inventorship) that relate directly to an Assay, Assay Performance Data, or the Illumina Platform Technology and that do not relate to the Partner Product or the Clinical Outcomes Data and (ii) any Inventions that are not Partner Product Inventions, Illumina Platform Inventions and are made, invented, conceived, created, authored, or developed solely by employees or contractors of Illumina (or its Affiliates) ((b)(i) and (ii) collectively, "**Illumina Inventions**"); and (c) the Parties will jointly own (i) all Inventions that relate to both (A) the Partner Product and (B) an Assay, the Assay Performance Data or the Illumina Platform **Technology** ("**Joint Product-Platform Inventions**") and (ii) all other Inventions made, invented, conceived, created, authored, or developed jointly by the employees or contractors of Illumina (or its Affiliates) and that are not Partner Inventions, Illumina Inventions, invented, conceived, created, authored, or developed jointly by the employees or contractors of Illumina (or its Affiliates) and Partner (or its Affiliates) and that are not Partner Inventions, Illumina Inventions or Joint Product-Platform Inventions ((c)(i) and (ii) "**Joint Inventions**"), with each Party having an undivided one-half interest in and to such Joint Inventions, with the right to use, practice, license and otherwise Exploit, and assign its interest in such Joint Inventions without the consent of or a duty of accounting t

8.5 <u>Transfer of Inventions</u>. Where applicable under Section 8.4, each Party agrees to and does hereby assign any and all (or an undivided one-half interest in) right, title, and interest in such Inventions to the other Party to the extent necessary to effect the ownership provisions of Section 8.4. Each Party agrees, upon request by the other Party, to promptly execute any and all documents deemed necessary or appropriate by the other Party to memorialize, effect, or perfect the assignments under this Section 8.5 throughout the world.

8.6 <u>Background IP and Patents Claiming Inventions</u>. As between the Parties, Illumina will have the right, but no obligation, to prosecute, maintain, control, license, enforce, and defend worldwide, at its own expense, Background IP Controlled by Illumina and any Patents claiming Illumina Inventions. As between the Parties, Partner will have the right, but no obligation, to prosecute, maintain, control, license, enforce, and defend worldwide, at its own expense, Background IP Controlled by Partner and any Patents claiming Partner Inventions.

8.7 <u>Prosecution and Maintenance of Joint Patents</u>. In accordance with Section 10.5, the JPC will be responsible for planning and coordinating the prosecution and maintenance of any Patents claiming or covering any Joint Inventions (the "**Joint Patents**"). In the event that one of the Parties does not wish to prosecute or maintain a Joint Patent ("**Non-Participating Party**"), the Non-Participating Party may choose to either (a) share the costs of the prosecution and maintenance of the Joint Patent as agreed to by the JPC; or (b) assign the Non-Participating Party's interest in the Joint Patent to the other Party, subject to a fully paid, royalty-free, non-exclusive, non-transferable, worldwide, irrevocable, perpetual, license under the rights in such Joint Patent to Exploit products and services. The non-exclusive license to the Non-Participating Party under this Section 8.7 may not be sub-licensed by the Non-Participating

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Party, except to (y) Affiliates of the Non-Participating Party and (z) any Third Party engaged in the development, manufacture, or Commercialization of a Partner Product (in the case of Partner) or an Assay (in the case of Illumina). Each Party agrees, upon the reasonable request of the other Party, to cooperate with such other Party in connection with such other Party's rights and obligations under this Section 8.7, including by executing papers and providing affidavits and declarations that cannot be prepared by such other Party alone.

## 9. LICENSES

# 9.1 <u>Research and Development Licenses</u>.

(a) <u>Partner Generic Assay License to Illumina</u>. Subject to the terms of this Agreement, Partner hereby grants Illumina a paid-up, royalty-free, non-exclusive license under Partner's Background IP, for the sole purpose of researching and developing each IUO Assay and IVD Assay and otherwise performing its activities, in each case, under and in accordance with each Project Schedule during the term thereof. The license granted in this Section 9.1(a) is not sublicensable, except to Illumina's Affiliates and any Third Party engaged in the research and development of each IUO Assay and IVD Assay and otherwise in performing Illumina's activities, in each case, under and in accordance with each Project Schedule.

(b) Partner Product Specific License to Illumina. Subject to the terms of this Agreement, Partner hereby grants Illumina a paid-up, royalty-free, non-exclusive license under the Partner Inventions and Partner Project Results for the sole purpose of researching and developing each IUO Assay and IVD Assay and otherwise performing its activities, in each case, under and in accordance with each specific Project Schedule during the term thereof. The license granted in this Section 9.1(b) is not sublicensable, except to Illumina's Affiliates and any Third Party engaged in the development, manufacture or Commercialization and other Exploitation of each IUO Assay and IVD Assay and otherwise performing Illumina's activities, in each case, under and in accordance with each Project Schedule.

## 9.2 <u>Commercialization Licenses</u>.

(a) <u>Project Invention License to Partner</u>. In the event that Illumina or its Affiliate files a Patent (or has filed a Patent), arising from Inventions generated in the performance of a Project that would prevent Partner from Exploiting the Partner Product for use solely with the applicable IVD Assay, Illumina hereby grants to Partner a worldwide, perpetual, fully-paid, royalty-free, non-exclusive license, with right to sub-license, solely to Exploit the Partner Product for use with the applicable IVD Assay.

(b) <u>Project Invention License to Illumina</u>. In the event that Partner or its Affiliate files a Patent (or has filed a Patent), arising from Inventions generated in the performance of a Project that would prevent Illumina from Exploiting any Assay, then Partner hereby grants to Illumina a worldwide, perpetual, fully-paid, royalty-free, non-exclusive license, with the right to sub-license, under the rights in such Patent to Exploit (i) the IUO Assays or IVD Assays solely with the applicable Partner Product, or (ii) any other Assay solely for research or investigational use.

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(c) <u>Partner Assay Background IP License to Illumina</u>. Partner hereby grants to Illumina a worldwide, perpetual, fully paid, royalty-free, irrevocable, non-exclusive license or sublicense, under any Partner Assay Background IP, to Exploit the IUO Assays or IVD Assays developed under this Agreement for use with a Partner Product.

9.3 <u>No Other Rights; No Implied Licenses</u>. Only the licenses and other rights expressly granted by one Party to the other Party under terms of this Agreement (including any Project Schedule) are of any legal force or effect. No other licenses or other rights are granted, conveyed or created (whether by implication, estoppel or otherwise).

## **10. MANAGEMENT**

## 10.1 <u>Committees; Generally</u>.

(a) <u>Membership and Decisions</u>. Each Party will only appoint as representatives to a Committee those of its employees who have appropriate experience, knowledge, and ongoing familiarity with the Projects in their then current phases. Each Party will be free to replace such representatives upon prior written notice to the other Party. Unless set forth to the contrary by the Parties, decisions of (including approval by) each Committee will be by consensus, with each Party having one (1) vote.

(b) <u>Meetings</u>. The JSC will meet (either in person, telephonically, or via video conference) not less than twice per year or at such other frequency as agreed by the JSC; other Committees will meet as directed by the JSC. Additional representatives of the Parties may from time to time be invited to attend Committee meetings, subject to the other Party's prior consent (email acceptable) which may not be unreasonably withheld. On a meeting by meeting basis, choice of the meeting location will alternate between the Parties, and the chair of each Committee will alternate between a representative of Partner and a representative of Illumina. Each Party will bear its own expenses related to the attendance of meetings by its representatives on each of the committees.

(c) <u>Management and Administration</u>. Illumina shall record minutes of the meetings and draft minutes of the meetings of each Committee, which will be generated and circulated to its members within two (2) weeks following each meeting and finalized by the applicable Committee promptly thereafter.

## 10.2 <u>Joint Steering Committee</u>.

(a) <u>Membership and Powers</u>. Within thirty (30) days after the Effective Date, the Parties will form a joint steering committee ("**Joint Steering Committee**" or "**JSC**") comprised of three representatives of each Party (to be designated by each Party in its sole discretion). At this time the Parties will designate the initial members of the JSC. The Joint Steering Committee may form a sub-committee Joint Steering Committee for each Project.

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(b) <u>Responsibilities</u>. The role of the JSC is to manage and optimize the collaboration between the Parties on Projects in accordance with this Agreement and each applicable Project Schedule. The JSC's responsibilities and decision-making authority will include the following functions: (i) facilitating the transfer of information and data related to development, Commercialization, and Regulatory Approval processes, (ii) facilitating the cooperation of the Parties, when requested, to provide information and support, (iii) facilitating coordinated interpretation of Clinical Trial data, (iv) discussing freedom to operate aspects (subject to the Parties entering into a common interest agreement), (v) coordinating planned marketing activities, (vi) forming additional committees, (vii) resolving disputes escalated by any other Committees, and (viii) taking such other actions as may be specifically allocated to the JSC by the Parties from time to time. In the event that the JSC is unable to resolve a dispute arising hereunder (including any dispute escalated from another Committee) within 15 days, then such dispute will be escalated to senior executives of the Parties pursuant to Section 16.2.

### 10.3 <u>Joint Development Committee</u>.

(a) <u>General</u>. Upon the request of either Party, the JSC will form a joint development committee (a "**Joint Development Committee**" or "**JDC**") for each Project. The JDC will have the role and responsibilities and decision-making authority as set forth below.

(b) <u>Responsibilities</u>. The JDC will be responsible for reviewing and reporting on the progress of each Project and ensuring that each Project proceeds according to the timelines set forth in the applicable Project Schedule. The JDC will be informed of, and each Party will reasonably and in good faith consider the other Party's views on, the following decisions prior to submission of the relevant documents to Regulatory Authorities or finalization of such decisions: (i) approval of the requirements for the IVD Assay; (ii) approval of the Labeling (including the "Intended Use" statement to be submitted in a PMA) to be submitted in a Regulatory Submission or otherwise to be presented to a Regulatory Authority for the IVD Assay; and (iii) the decision regarding the type of approval application to be developed and filed for Regulatory Approval for the IVD Assay (e.g., in the U.S., the decision whether the IVD Assay will be developed for Regulatory Approval under a PMA or a 510(k)). In the event that the JDC is unable to resolve a dispute arising hereunder within 15 days, then such dispute will be escalated to the JSC for resolution.

### 10.4 Joint Commercialization Committee.

(a) <u>General</u>. Upon request by either Party, the Parties will form a joint commercialization committee (the "Joint Commercialization Committee" or "JCC"). The JCC will have at least one representative responsible for marketing from each Party. The JCC will be responsible for planning and coordinating the activities of the Parties with respect to the marketing and distribution of the IVD Assay with the objective of assuring that: (i) the IVD Assay is supplied, marketed, promoted, distributed and otherwise Commercialized in a manner that supports diagnostic testing for the Partner Product, and (ii) the IVD Assay is commercially available in all countries of the applicable Markets in reasonably sufficient quantities.

(b) <u>Responsibilities</u>. Unless otherwise agreed to in writing by the Parties, the responsibilities of the JCC will include the following activities, to the extent that they involve both the IVD Assay and the Partner Product: (i) discuss, coordinate and align the launch, marketing and Commercialization of the IVD Assay and the Partner Product, including the exchange of information on the objectives, methodology, expected demand, and other considerations; (ii) discuss and coordinate Illumina's activities supporting the marketing, promotion, distribution and sale of the IVD Assay, such as sales training (including, at Illumina's discretion, training for Partner sales representatives), promotion, customer service, support, and education activities; (iii) discuss and coordinate possible activities with respect to quality assurance plans (including training and monitoring programs); (iv) discuss and resolve issues concerning shelf-supply and emergency stocks of IVD Assay; (v) review and approve any additional Commercialization activities and associated payments in accordance with the provisions of this Agreement relating to such activities and payments; and (vi) such other activities as mutually agreed between the Parties from time to time. In the event that the JCC is unable to resolve a dispute arising hereunder within 15 days, then such dispute will be escalated to the JSC for resolution.

### 10.5 <u>Joint Patent Committee</u>.

(a) <u>General</u>. Upon request by either Party, the Parties will form a joint patent committee for a Project (the "**Joint Patent Committee**" or "**JPC**") comprised of one or more representatives of each Party, to be designated by each Party in its sole discretion; <u>provided</u>, that at least one representative is a licensed patent attorney with relevant technology expertise. Upon request by either Party, the Parties will in good faith negotiate a common interest agreement with respect to the activities of the JPC.

(b) <u>Responsibilities</u>. The JPC will be responsible for planning and coordinating the activities of the Parties with respect to matters involving Joint Inventions and Joint Patents as follows: (i) allocating responsibility for prosecution of applications for Joint Patents, (ii) providing the Parties with copies of material communications submitted to, and received from, any Patent authority regarding Joint Inventions and Joint Patents, (iii) providing drafts of any material filings or responses to be made to such Patent authorities a reasonable amount of time in advance of submitting such filings or responses so that the Parties may have an opportunity to review and comment, (iv) ensuring that Joint Patents, misappropriation or misuse of any Know-How that is subject to this Agreement, or Third Party Claims contesting the validity or enforceability of any Joint Patents, (vi) enforcing Joint Patents. In the event that the Parties cannot agree on the responsibilities set forth in this Section 10.5(b) or are otherwise unable to resolve a dispute arising hereunder, in each case, within 15 days, such Dispute will be escalated to the JSC for resolution.

10.6 <u>Committee Restrictions</u>. As further specified in this Agreement and each Project Schedule, Partner will be responsible for development and Commercialization of the Partner Product and Illumina will be responsible for development and Commercialization of the IVD Assay. No Committee will have the power or authority to amend the terms and conditions of this Agreement. Without limiting the foregoing, each Party acknowledges and agrees that the Committees do not have authority to assume,

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create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, either Party or waive any right on behalf of either Party.

## 11. NON-EXCLUSIVITY

The Parties' relationship under this Agreement is non-exclusive. Each Party may enter into similar arrangements with Third Parties. Nothing in this Agreement will be construed as restricting either Party's ability to acquire, license, develop, manufacture, or distribute for itself, or have others acquire, license, develop, manufacture, or distribute for such Party, similar technology and products performing the same or similar functions as the technology and products subject to this Agreement, or to market and distribute such similar technology and products in addition to, or in lieu of, the technology and products subject to this Agreement; provided that such Party complies with all terms and conditions of this Agreement. For the avoidance of doubt, this Agreement does not restrict Illumina's rights, as they exist as of the Effective Date, to develop, Commercialize, and otherwise Exploit any Assay(s) (other than any IUO Assay or IVD Assay developed under a Project which shall be subject to the terms of this Agreement) or Illumina Platform Technology to any Third Parties.

### 12. **REPRESENTATIONS AND WARRANTIES**

12.1 <u>Mutual representations, warranties and covenants</u>. Each Party hereby represents and warrants as of the Effective Date and, to the extent applicable, covenants to the other Party that:

(a) it is a corporation duly incorporated, validly existing, and in good standing;

(b) it has taken all necessary actions on its part to authorize the execution, delivery, and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto;

(c) it is not a party to any agreement or understanding and knows of no law or regulation that would prohibit it from entering into and performing this Agreement;

(d) when executed and delivered by it, this Agreement will constitute a legal, valid, and binding obligation of it, enforceable against it in accordance with this Agreement's terms;

(e) it is duly licensed, authorized, or qualified to do business and is in good standing in every jurisdiction in which a license, authorization, or qualification is required for it to perform its obligations under this Agreement;

(f) it has, and throughout the Term, will retain the unconditional and irrevocable right, power, and authority to grant the applicable rights and licenses provided for under this Agreement;

(g) all Samples that it provides to the other Party hereunder will comply with the applicable Sample Requirements.

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12.2 <u>No Debarment</u>. Each Party certifies that it will not and has not employed or otherwise used in any capacity the services of any person debarred under Title 21 United States Code Section 335a in performing under this Agreement.

# 12.3 <u>Compliance.</u>

(a) <u>Compliance with Anti-Corruption Laws</u>. In connection with this Agreement, each Party has complied and will comply with all applicable Laws and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, and any laws enacted to implement the Organization of Economic Cooperation and Development ("OECD") Convention on Combating Bribery of Foreign Officials in International Business Transactions.

(b) <u>Prohibited Conduct</u>. In connection with this Agreement, each Party has not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment, or transfer of anything of value, directly or indirectly, to any person or to any Government Official for the purpose of: (i) improperly influencing any act or decision of the person or Government Official; (ii) inducing the person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (iii) securing any improper advantage; or (iv) inducing the person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist either Party in obtaining or retaining business.

(c) <u>Notice of Inspections</u>. Each Party will provide the other Party with prompt notice of any governmental or regulatory review, audit, or inspection of its facility, processes, or products relating to the subject matter of this Agreement. Each Party will provide the other Party with the results of any such review, audit or inspection to the extent relating to the subject matter of this Agreement. Each Party will be given the reasonable opportunity to provide assistance to the other Party in responding to any such review, audit, or inspection.

(d) <u>Compliance</u>. Each Party will comply with all applicable Laws in performing under this Agreement.

(e) <u>Requests for Information</u>. Each Party will use reasonable efforts to comply with requests for disclosure of information, including answering questionnaires and narrowly tailored inquiries, to enable the other Party to ensure compliance with all applicable Laws.

THE REPRESENTATIONS AND WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ANY AND ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, OR STATUTORY, AND, EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES OR REPRESENTATIONS, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR FOR NON-INFRINGEMENT OF A

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PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, (I) IN THE CASE OF BOTH PARTIES, THAT THE OBJECTIVES OF ANY PROJECT OR ANY RESEARCH OR DEVELOPMENT OBJECTIVE HEREUNDER CAN OR WILL BE ACHIEVED, OR AS TO THE TIMING OR COST AND EXPENSE ASSOCIATED WITH THE ACHIEVEMENT OF ANY SUCH OBJECTIVE, (II) IN THE CASE OF PARTNER, WITH RESPECT TO WHETHER ANY PARTNER PRODUCT WILL BE APPROVED FOR COMMERCIAL SALE BY THE APPLICABLE REGULATORY AUTHORITIES OR AS TO THE COMMERCIAL POTENTIAL OR SUCCESS OF ANY PARTNER PRODUCT, AND (III) IN THE CASE OF ILLUMINA, WITH RESPECT TO WHETHER ANY ASSAY WILL BE APPROVED OR CLEARED FOR INVESTIGATIONAL, DIAGNOSTIC, OR COMMERCIAL SALE OR USE BY THE APPLICABLE REGULATORY AUTHORITIES OR AS TO THE COMMERCIAL POTENTIAL OR SUCCESS OF ANY IUO ASSAY OR IVD ASSAY.

# 13. ALLOCATION OF RISKS

13.1 <u>Partner's Indemnification Obligations</u>. Partner will defend, indemnify, and hold harmless Illumina, its Affiliates, and their respective officers, directors, representatives, employees, successors, and assigns ("**Illumina Indemnitees**"), from and against any and all losses, liabilities, damages, fines, and penalties of any and every kind, including legal expenses and reasonable attorneys' fees ("**Losses**") to the extent resulting from any claims, causes of action, or proceedings brought or asserted by a Third Party ("**Claims**") resulting from or arising out of any Partner Indemnitee's: (a) breach of this Agreement; (b) gross negligence or intentional misconduct in performing or failing to perform under this Agreement; (c) violation of applicable Law; and (d) development or Commercialization of a Partner Product, including any claims that such infringe any Third Party IP; in each case except to the extent resulting from, relating to, or arising out of matters for which Illumina is obligated to defend, indemnify, and hold harmless Partner Indemnitees pursuant to Section 13.2.

13.2 <u>Illumina's Indemnification Obligations</u>. Illumina will defend, indemnify, and hold harmless Partner, its Affiliates, and their respective officers, directors, representatives, employees, successors, and assigns ("**Partner Indemnitees**"), from and against any and all Losses to the extent resulting from Claims resulting from or arising out of any Illumina Indemnitee's: (a) breach of this Agreement; (b) gross negligence or intentional misconduct in performing or failing to perform under this Agreement; (c) violation of applicable Law; (d) development or Commercialization of an IUO Assay or IVD Assay, including any claims that such infringe any Third Party IP; or (e) any claims that the Illumina Platform Technology infringe any Third Party IP; in each case except to the extent resulting from, relating to, or arising out of matters for which Partner is obligated to defend, indemnify, and hold harmless Illumina Indemnitees pursuant to Section 13.1.

13.3 <u>Indemnification Procedures</u>. Each Party's obligations under Sections 13.1 and 13.2 are conditioned on the Party seeking indemnification: (a) giving the indemnifying Party prompt written notice of the Claim; provided, however, that failure to provide such notice will not relieve the indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperating with the indemnifying Party, at the indemnifying Party's expense, in connection with the defense and settlement of the Claim, including

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providing accurate and complete information reasonably requested by the indemnifying Party; and (c) permitting the indemnifying Party to solely control the defense and settlement of the Claim; provided, however, that the indemnifying Party may not settle the Claim, enter into or otherwise consent to an adverse judgment or order, or make any admission as to liability or fault that would adversely affect the indemnified Party, without the indemnified Party's prior written consent, which will not be unreasonably withheld or delayed. Further, the indemnified Party will have the right to participate (but not control) and be represented in any suit or action by counsel of its selection at its own cost.

13.4 <u>Product-related Indemnification</u>. Notwithstanding anything in this Agreement to the contrary, Illumina's defense, indemnification, and hold harmless obligations with respect to Instruments and associated consumables, and Partner's purchase and use of such products, are limited solely to those obligations expressly provided in the Standard Terms for such products, and such terms will supersede and control over any other indemnification obligations of Illumina provided in this Agreement. Furthermore, neither Party will be entitled to any duplicative recovery under this Agreement and the Standard Terms.

## 14. LIMITATIONS ON LIABILITIES

14.1 EXCEPT AS STATED IN SECTION 14.3, AND EXCEPT WITH RESPECT TO DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN SECTION 7 OR TO THE EXTENT ANY AMOUNTS ARE REQUIRED TO BE PAID FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER SECTION 13, BUT OTHERWISE TO THE FULLEST EXTENT PERMITTED BY LAW, IN NO EVENT WILL A PARTY BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE PRODUCTS OR SERVICES, LOST PROFITS, DATA OR BUSINESS, OR FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY, CONSEQUENTIAL, OR PUNITIVE DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER ARISING OR CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, MISREPRESENTATION, BREACH OF STATUTORY DUTY, OR OTHERWISE).

14.2 EXCEPT AS STATED IN SECTION 14.3 BELOW, AND EXCEPT TO THE EXTENT ARISING FROM A PARTY'S DEFENSE AND INDEMNIFICATION OBLIGATIONS UNDER SECTION 13, BUT OTHERWISE TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY'S CUMULATIVE LIABILITY UNDER OR ARISING OUT OF THIS AGREEMENT, INCLUDING ANY CAUSE OF ACTION IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, MISREPRESENTATION, BREACH OF STATUTORY DUTY, OR OTHERWISE, WILL NOT EXCEED (\$\*\*\* USD).

14.3 NOTWITHSTANDING SECTION 14.1 AND 14.2 AND ANYTHING TO THE CONTRARY, THIS AGREEMENT DOES NOT LIMIT LIABILITY OF EITHER PARTY FOR ANY INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY OR SUCH PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT, FRAUD, OR BREACH OF SECTION 7.

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14.4 THE LIMITATIONS OF LIABILITY IN THIS SECTION 14 APPLY EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LIABILITY, AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

## 15. TERM AND TERMINATION

15.1 <u>Term</u>. The term of this Agreement will begin on the Effective Date and continue until December 31, 2026 (the "**Initial Term**"), and thereafter will renew automatically for one (1) year terms (each such renewal term, a "**Renewal Term**", and collectively, and together with the Initial Term, the "**Term**"), unless terminated earlier in accordance with this Section 15 or by either Party upon written notice to the other Party not less than ninety (90) days before the end of the Initial Term or then-current Renewal Term (as applicable).

## 15.2 <u>Termination for Cause</u>.

(a) <u>Mutual Termination for Cause Rights</u>. Either Partner or Illumina may terminate this Agreement and all Project Schedules by written notice to the other Party, in the event that the other Party has failed to cure its breach of a material provision of this Agreement (or a Project Schedule) within sixty (60) days of its receipt of written notice of such breach. Either Partner or Illumina also may terminate this Agreement (and all Project Schedules) by written notice to the other Party, if the other Party becomes Insolvent (as defined below), makes or has made an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against it (except for involuntary bankruptcies which are dismissed within one hundred twenty (120) days) or has a receiver or trustee appointed for substantially all of its property. For purposes of this Agreement, "**Insolvent**" with respect to a Party means that such Party fails generally to pay its debts as they become due (unless those debts are subject to a good-faith dispute as to liability or amount) or acknowledges in writing that it is unable to do so. Regardless of which Party terminates under this Section 15.2(a), Illumina may cease performing all work not necessary for the orderly close-out of the Project and for fulfillment of any regulatory requirements required by applicable Law to terminate the Project.

(b) <u>Effect of Termination by Partner for Cause</u>. If Partner terminates this Agreement for cause pursuant to Section 15.2(a), upon Partner's request in addition to any other remedies Partner may have under applicable Laws, the Parties will promptly meet to negotiate in good faith a close-out Project Schedule. Partner will pay Illumina any amounts due for Project activities performed prior to or in connection with such termination.

(c) <u>Effect of Termination by Illumina for Cause</u>. If Illumina terminates this Agreement for cause pursuant to Section 15.2(a), in addition to any other remedies Illumina may have under applicable Laws, Partner will pay Illumina all amounts due for Project activities performed prior to or in connection with such termination, reasonable amounts related to wind-down of the Project(s) (including non-cancellable expenses already incurred and inventory costs that cannot be reallocated to other projects),

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the amount budgeted for Project activities planned for three (3) months after the date of the termination notice up to \$\*\*\*, and any applicable termination fees specified in the Project Schedule(s).

# 15.3 <u>Termination by Partner Other Than for Cause</u>.

(a) <u>Termination Rights</u>. Partner may terminate any individual Project Schedule (i) for convenience upon ninety (90) days prior written notice to Illumina or (ii) upon thirty (30) days prior written notice to Illumina in the event of (A) a Drug Development Failure; or (B) the further development or Regulatory Approval of the IVD Assay under the respective Project becomes impractical.

(b) Effect of Partner Termination. In the event of a termination by Partner under Section 15.3(a), with regard to the terminated Project(s): (i) Illumina will cease performing all work not necessary for the orderly close-out of the applicable Project, (ii) Illumina will wind down such Project(s) in accordance with all regulatory requirements required by applicable Law to terminate the Project, and (iii) Partner will pay Illumina all amounts due for Project activities performed prior to or in connection with the termination of such Project, reasonable amounts related to wind-down of the Project (including non-cancellable expenses already incurred and inventory costs that cannot be reallocated to other projects), the amount budgeted for Project activities planned for three (3) months after the date of the termination notice up to \$\*\*\* (including portions of Milestone payments corresponding to Milestones planned to be achieved during such period), and any applicable termination fees specified in the Project Schedule(s).

# 15.4 <u>Termination by Illumina Other Than for Cause</u>.

(a) <u>Termination Rights</u>. Any Project hereunder may be terminated by Illumina upon sixty (60) days written notice if: (i) Partner either does not provide reasonable assurance that it intends that the Labeling proposed for the IVD Assay will reference the Partner Product, or if Partner files for Regulatory Approval of the Partner Product without requesting that Illumina also file for Regulatory Approval of the IVD Assay with Labeling that references the Partner Product, (ii) prior to Design Lock for the IVD Assay, proceeding with the Project would require alterations to the Illumina Platform Technology not agreed to in the Project Schedule, (iii) a Drug Development Failure occurs; (iv) using Commercially Reasonable Efforts Illumina is not able to obtain a Third Party License for the respective Project that is reasonably required in order for Illumina to conduct the Project on commercially reasonable terms and Illumina has complied with the terms of Section 4.2(b) with respect thereto, (v) the further development of the IUO Assay or IVD Assay under the respective Project becomes impractical for technical reasons despite the use of Illumina's Commercially Reasonable Efforts, or (vi) there are regulatory barriers that preclude commercially reasonable development of the IUO Assay or IVD Assay.

(b) <u>Termination for Change in Control</u>. Partner will notify Illumina in writing within 5 business days of the consummation of a Change in Control of Partner and will provide Illumina with the name of any parties to the transaction. If Illumina reasonably determines that the acquiring Person (or any of its Affiliates) in such Change in Control sells, or has announced an intention to sell, instruments for nucleic acid sequencing, Illumina may, in its sole discretion, terminate this Agreement or any Project Schedule

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by written notice to Partner (or its acquirer or successor) within the 45 day period commencing on the date Illumina receives such notice, or if Partner does not so notify Illumina (without limiting Partner's obligation to notify Illumina) within 90 days of Illumina's senior executives otherwise receiving credible written notice of such Change in Control. At any time during the 45 day or 90 day period, respectively, after the consummation of a Partner Change in Control, Partner will promptly (in any event within 3 business days) provide Illumina with either (1) such information concerning the Change in Control as Illumina may reasonably request to enable Illumina to determine if the Change in Control involves any Third Party who (or whose affiliate) sells, or who has announced an intention to sell, instruments for nucleic acid sequencing or (2) an explanation that such information cannot be provided.. Partner, for itself and for the benefit of any acquiror or successor in a Partner Change in Control, shall have the right to claim a Dispute under this Agreement (as provided for under Sections 16.1 and 16.2 hereof) in connection with Illumina's determination that an acquiring Person sells, or has announced its intention to sell, instruments for nucleic acid sequencing.

(c) <u>Effect of Illumina Termination</u>. In the event of a termination by Illumina under Section 15.4(a) or (b), with regard to the terminated Project(s): (i) the Parties will promptly meet to negotiate in good faith a close-out Project Schedule, (ii) Illumina will cease performing all work not necessary for the orderly close-out of the applicable Project or for the fulfillment of any regulatory requirements required by applicable Law to terminate the Project, and (iii) Partner will pay Illumina any amounts due for Project activities performed prior to or in connection with such termination.

15.5 <u>Bankruptcy</u>. All licenses granted under or pursuant to this Agreement by Partner or Illumina are and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

15.6 <u>Return of Materials and Confidential Information</u>. At the earlier of completion or termination of a particular Project (or this Agreement as a whole), and except as otherwise permitted herein or in a Project Schedule, each Party will destroy, or return at the other Party's expense and election, Project-related Materials and Confidential Information of the other Party. A Party may retain in its legal department copies of the Confidential Information of the other Party for the purpose of determining its rights and obligations hereunder. The provisions of this Section 15.6 will not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup or to Confidential Information or copies thereof which must be stored by the Receiving Party according to provisions of applicable Laws.

15.7 <u>Surviving Obligations</u>. The following provisions will survive any termination or expiration of this Agreement: Sections 1, 5.10, 6, 7, 8, 9.2, 9.3, 13, 14, 15.6, 15.7, 15.8, 16. The following provisions will survive expiration but not termination of this Agreement: Sections 5.2, 5.7, and 5.9. Termination or expiration of this Agreement will not relieve the Parties of any liability or obligation that accrued under

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this Agreement before the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have under this Agreement, at Law, or in equity with respect to any breach of this Agreement.

15.8 <u>No Damages for Termination or Expiration</u>. NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR DAMAGES OF ANY KIND (INCLUDING WITHOUT LIMITATION DAMAGES ON ACCOUNT OF PRESENT OR PROSPECTIVE PROFITS, OR ON ACCOUNT OF EXPENDITURES, INVESTMENTS, OR COMMITMENTS MADE IN CONNECTION WITH THIS AGREEMENT, OR IN CONNECTION WITH THE DEVELOPMENT OR MAINTENANCE OF THE BUSINESS OR GOODWILL OF THE OTHER PARTY) BY REASON OF EXPIRATION OF THIS AGREEMENT OR PROPER EXERCISE OF ITS RIGHT TO TERMINATE THIS AGREEMENT IN ACCORDANCE WITH THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT, AND EACH PARTY EXPRESSLY WAIVES ANY RIGHT IT MAY HAVE TO RECEIVE ANY SUCH DAMAGES.

# 16. GENERAL

16.1 <u>Governing Law</u>. This Agreement and any dispute, controversy, or claim arising out of, or relating to, this Agreement (each, a "**Dispute**") will be governed and construed in accordance with the laws of the State of California, without regard to provisions on the conflicts of laws. Any legal process to resolve a Dispute will take place in San Diego, California. The Parties agree that the United Nations Convention on Contracts for the International Sale of goods does not apply to this Agreement.

# 16.2 <u>Dispute Resolution</u>.

(a) <u>Executives</u>. If the Parties have a Dispute, except as otherwise set forth in Section 10.2, Section 10.3, Section 10.4 or Section 10.5, the Parties will first try to amicably settle such Dispute by delivering a written notice to the other Party with reasonable details of such Dispute ("**Notice of Dispute**"). Within five (5) business says of a Notice of Dispute provided to a Party in accordance with Section 16.2, senior executives of each Party will meet in person, or by teleconference, at a mutually agreeable time and place, and thereafter as often as they reasonably deem necessary, to attempt in good faith to resolve the Dispute.

(b) <u>Jurisdiction</u>. If the senior executives are unable to resolve the Dispute within thirty (30) days of the Notice of Dispute, then such Dispute shall be resolved by the federal courts in San Diego, California (collectively, the "**Courts**"). Each Party (a) irrevocably submits to the exclusive jurisdiction in the Courts for purposes of any action, suit or other proceeding relating to or arising out of this Agreement and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party; provided that either Party may enforce a judgement against the other Party in any applicable jurisdiction.

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16.3 <u>Injunctive Relief; Cumulative Remedies</u>. Each Party acknowledges that its breach of Section 7, 8, or 9 may cause irreparable injury to the other Party for which monetary damages would not be an adequate remedy, and the other Party will therefore be entitled to seek injunctive relief (including specific performance) with respect to any breach or threatened breach without posting a bond or other security as a condition for obtaining any such relief. The rights and remedies provided to each Party in this Agreement are cumulative and in addition to any other rights and remedies available to each Party under this Agreement, at Law, or in equity.

16.4 <u>Severability; No Waiver</u>. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability will not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction, subject to the remainder of this Section 16.4. Upon a determination by a court or arbitrator having jurisdiction that any term or provision of this Agreement is invalid, illegal, or unenforceable, the Parties will negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible. The failure or delay of either Party to exercise any right or remedy provided in this Agreement or to require any performance of any term of this Agreement may not be construed as a waiver, and no single or partial exercise of any right or remedy provided in this Agreement, or the waiver by either Party of any breach of this Agreement, will prevent a subsequent exercise or enforcement of, or be deemed a waiver of any subsequent breach of, the same or any other term of this Agreement. No waiver of any right, condition, or breach of this Agreement will be effective unless in writing and signed by both Parties.

16.5 Assignment; Third Party Beneficiaries. Neither Party may assign or transfer, in whole or in part, this Agreement (including any assignment or transfer by operation of law (including by vesting)) without the prior written consent of the other Party, which consent may not be unreasonably withheld; provided, that either Party may assign or transfer any right or obligation hereunder, in whole or in part, to any of its Affiliates or to its successor to all or substantially all of the business of such Party to which this Agreement relates, whether through a merger, consolidation, sale of stock, sale of assets or other transaction (subject to Sections 6.1(b) and 15.4). Any assignment or transfer of this Agreement made in contravention of the terms hereof will be null and void. Subject to the foregoing, this Agreement will be binding on and inure to the benefit of the Parties' respective successors and permitted assigns. Each Party may delegate, sublicense, and subcontract any or all of its rights and obligations under this Agreement to an Affiliate and, to the extent expressly permitted in this Agreement, to a Third Party; provided that in each case (a) the Party will remain ultimately responsible for the performance of this Agreement, and (b) the Party will be responsible for any conduct by such Affiliate or Third Party that constitutes a breach of this Agreement or that otherwise would cause such Party to be in breach of this Agreement had it engaged in such conduct itself, and such conduct will be a breach of this Agreement by such Party. There are no Third Party beneficiaries to this Agreement and no term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person or entity who is not a Party to this Agreement. The Parties may rescind or terminate this Agreement or vary any of its terms in accordance with their rights under this Agreement and by Law, without the consent of any Third Party.

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16.6 <u>Notices</u>. All notices required or permitted under this Agreement will be in writing, in English, and will be deemed received only when: (a) delivered personally; or (b) one day after deposit with a commercial express courier specifying next day delivery or, for international courier packages, two (2) days after deposit with a commercial express courier specifying two-day delivery, with written verification of receipt. All notices will be sent to the following or any other address designated by a Party using the procedures set forth in this Section:

If to Illumina:	If to Partner:
Illumina, Inc. 5200 Illumina Way San Diego, CA 92122 Attn: VP, Corporate and Business Development	Kura Oncology, Inc. 12730 High Bluff Drive, Suite 400, San Diego, CA 92130 Attn: Head of Diagnostics

## With a copy to: <a href="mailto:Legalnotices@illumina.com">Legalnotices@illumina.com</a>

With a copy to: Legal@kuraoncology.com

16.7 <u>Force Majeure</u>. Neither Party will be in breach of this Agreement nor liable for any failure to perform or delay in the performance of this Agreement attributable in whole or in part to any Force Majeure; provided, however, that in each such case the affected Party will use reasonable efforts to avoid such occurrence and to remedy it promptly. The affected Party will give prompt notice of any such cause to the other Party. The affected Party will be excused from such of its obligations as it is disabled from performing for a period of up to ninety (90) days; provided, however, that such affected Party commences and continues to take reasonable actions to cure such cause. Partner's payment obligations are not affected by this provision except to the extent the Force Majeure affects financial institutions and, as a result, the financial institutions cannot complete the transaction necessary for Partner to satisfy its payment obligations.

16.8 Entire Agreement; Amendment. This Agreement (including all Project Schedules), together with the Standard Terms, represents the entire agreement between the Parties regarding the subject matter hereof and supersedes all prior discussions, communications, agreements, and understandings of any kind and nature between the Parties with respect to the subject matter of this Agreement. The Parties acknowledge and agree that by entering into this Agreement, they do not rely on any statement, representation, assurance, or warranty of any Person other than as expressly set out in this Agreement. Each Party agrees that it will have no right or remedy (other than for breach of contract) in respect of any statement, representation, assurance, or warranty (whether made negligently or innocently) other than as expressly set forth in this Agreement. Nothing in this Section 16.8 will exclude or limit liability for fraud. No amendment to this Agreement (including changes to any Project Schedule) will be effective unless in writing and signed by both Parties.

16.9 <u>Relationship of the Parties</u>. The Parties are independent contractors under this Agreement and nothing in this Agreement may be construed as creating a partnership, joint venture, or agency relationship between the Parties, or as granting either Party the authority to bind or contract any

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obligation in the name of the other Party or to make any statements, representations, warranties, or commitments on behalf of the other Party.

Headings; Interpretation. Sections, titles, and headings in this Agreement are for convenience only and are not 16.10 intended to affect the meaning or interpretation hereof. Whenever required by the context, the singular term includes the plural, the plural term includes the singular, and the gender of any pronoun includes all genders. As used in this Agreement except as the context may otherwise require, the words "include," "includes," "including," and "such as" are deemed to be followed by "without limitation" or "but not limited to," whether or not they are in fact followed by such words or similar words, and "will" and "shall" are used synonymously. Except as expressly stated, any reference to "days" will be to calendar days, and "business day" means all days other than Saturdays, Sundays, or a national or local holiday recognized in the United States, any reference to "calendar month" will be to the month and not a 30 day period, and any reference to "calendar quarter" will mean the first three calendar months of the year, the fourth through sixth calendar months of the year, the seventh through ninth calendar months of the year, and the last three calendar months of the year. Whenever the last day for the exercise of any right or the discharge of any obligation hereunder falls on, or any notice is deemed to be given on, a Saturday, Sunday, or national holiday, the Party having such right or obligation will have until 5:00 pm PST on the next succeeding business day to exercise such right or to discharge such obligation or the Party giving notice will be deemed to have given notice on the next succeeding business day. No usage of trade, course of performance, or other regular practice between the Parties may be used to alter the terms and conditions of this Agreement. Unless otherwise expressly provided in this Agreement, any agreement, instrument, or statute defined or referred to means such agreement, instrument, or statute as from time to time amended, modified, or supplemented, including (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein. The Parties have participated jointly in the negotiation and drafting of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party because of the authorship of any provision of this Agreement.

16.11 <u>Legal Compliance</u>. Nothing in this Agreement is intended, or should be interpreted, to prevent either Party from complying with, or to require a Party to violate, any applicable Law. Should either Party reasonably conclude that any portion of this Agreement is or may be in violation of a change in a Law made after the Effective Date, the Parties agree to negotiate in good faith written modifications to this Agreement as may be necessary to establish compliance with such changes, with any mutually agreed upon modifications added to this Agreement by written amendment in accordance with Section 16.8 of this Agreement.

16.12 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, and all of which will constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement by PDF, facsimile, or other electronic transmission will be effective as delivery of a manually executed original counterpart of this Agreement.

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16.13 <u>Costs</u>. Except as expressly provided in this Agreement, each Party will pay its own costs incurred in connection with the negotiation, preparation, and execution of this Agreement and any documents referred to in it.

16.14 <u>Further Assurances</u>. Each Party will execute and deliver such further documents and take such further actions as the other Party may reasonably request to evidence and implement the provisions and intent of this Agreement.

# [SIGNATURES ON NEXT PAGE]

## SIGNATURE PAGE TO MASTER COLLABORATION AGREEMENT

ILLUM	INA	PARTNER	
Illumina	, Inc.	Kura Or	icology, Inc.
By:	/s/ Joydeep Goswami	By:	/s/ Troy Wilson
Name:	Joydeep Goswami	Name:	Troy Wilson
Title:	SVP, Corp. Dev. & Str. Planning	Title:	President and Chief Executive Officer
Date:	04-Jan-2021	Date:	04-Jan-2021

## **PROJECT SCHEDULE #1**

This Project Schedule #1 is effective as of January 4, 2021 (the "**PS Effective Date**") and is made between Illumina, Inc., a Delaware corporation ("**Illumina**") and Kura Oncology, Inc., a Delaware corporation ("**Partner**"). Illumina and Partner may be referred to each individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, the Parties have entered into a Master Collaboration Agreement, effective as of January 4, 2021 (the "Agreement");

WHEREAS, this is the first Project Schedule under the Agreement. The terms in this Project Schedule with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth herein, and if not defined herein, the meaning set forth in the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, the foregoing recitals, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

## Project Schedule Summary:

Development, Regulatory Approval, and Commercialization of a companion diagnostic using Illumina's TruSight Oncology 500 tissue assay (as the Background Assay) for tipifarnib, a farnesyl transferase inhibitor (as the Partner Product) for use in the treatment of HRAS mutated Head and neck squamous cell carcinoma.

## **Table of Contents**

- 1. Overview
- 2. Project Description
- 3. IUO Assay Specifications
- 4. Project Activities and Deliverables
- 5. Timeline
- 6. Project Budget
- 7. Commercialization Plan

## 1. <u>Overview</u>

This Project Schedule describes the activities and Deliverables in connection with development of an IVD Assay for use with the Partner Product. All activities will be performed using Commercially Reasonable Efforts.

Under this Project Schedule:

- The Background Assay will be Illumina's TruSight Oncology 500 tissue assay available as of the PS Effective Date;
- The IUO Assay will be for use with the Partner Product, tipifarnib, a farnesyltransferase inhibitor for use in the treatment of HRAS mutated Head and neck squamous cell carcinoma (HNSCC).

Upon Regulatory Approval within a particular Market, the IUO Assay will become the IVD Assay in such Market.

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(remainder of page intentionally blank)

# SIGNATURE PAGE TO PROJECT SCHEDULE # 1

Illumina, Inc.		Kura Oncology, Inc.	
By:	/s/ Joydeep Goswami	By:	/s/ Troy Wilson
Name:	Joydeep Goswami	Name:	Troy Wilson
Title:	SVP, Corp. Dev. & Str. Planning	Title:	President and Chief Executive Officer
Date:	04-Jan-2021	Date:	04-Jan-2021

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### KURA ONCOLOGY, INC. Amendment to Amended and Restated Executive Employment Agreement for

# TROY E. WILSON, PH.D., J.D.

This Amendment to Amended and Restated Executive Employment Agreement (the "*Agreement*"), entered into between Kura Oncology, Inc. (the "*Company*") and Troy E. Wilson, Ph.D., J.D. (the "*Executive*") (collectively, the "*Parties*"), is effective as of February 19, 2021 (the "*Effective Date*").

**W**HEREAS, the Company and Executive entered into an Amended and Restated Executive Employment Agreement dated as of January 29, 2016 (the *"Original Agreement"*); and

WHEREAS, Executive and Company wish to amend the Original Agreement.

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

Section 1.2 of the Original Agreement is hereby amended, and as so amended, shall read in its entirety as follows:

**"1.2 Duties and Location.** Executive will perform such duties as are required by the Company's Board of Directors (the "*Board*"), to whom Executive will report. Executive's primary office location will be his home office in Salt Lake City, Utah. The Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, including the Company's offices in Boston, Massachusetts, and San Diego, California and to require reasonable business travel. The Company may modify Executive's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time."

IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first written above.

## KURA ONCOLOGY, INC.

By:	/s/ James Basta
Name	James Basta
Title:	Chief Legal Officer

Executive

/s/ Troy E. Wilson, Ph.D., J.D. TROY E. WILSON, PH.D., J.D.

### KURA ONCOLOGY, INC. RSU Award Grant Notice (Amended and Restated 2014 Equity Incentive Plan)

Kura Oncology, Inc. (the *"Company"*) has awarded to you (the *"Participant"*) the number of restricted stock units specified and on the terms set forth below in consideration of your services (the *"RSU Award"*). Your RSU Award is subject to all of the terms and conditions as set forth herein and in the Company's Amended and Restated 2014 Equity Incentive Plan (the *"Plan"*) and the Award Agreement (the *"Agreement"*), which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Agreement shall have the meanings set forth in the Plan or the Agreement.

Number of Restricted St	tock Units/Shares:	
Number of Restricted S	tock Units/Shares:	 
Vesting Schedule:	[	].

Notwithstanding the foregoing, vesting shall terminate upon the Participant's termination of Continuous Service.

**Issuance Schedule:** One share of Common Stock will be issued for each restricted stock unit which vests at the time set forth in Section 6 of the Agreement.

**Participant Acknowledgements:** By your signature below or by electronic acceptance or authentication in a form authorized by the Company, you understand and agree that:

- The RSU Award is governed by this RSU Award Grant Notice (the "Grant Notice"), and the provisions of the Plan and the Agreement, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement (together, the "RSU Award Agreement") may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.
- You have read and are familiar with the provisions of the Plan, the RSU Award Agreement and the Prospectus. In the event of any conflict between the provisions in the RSU Award Agreement, or the Prospectus and the terms of the Plan, the terms of the Plan shall control.
- The RSU Award Agreement sets forth the entire understanding between you and the Company regarding the acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of: (i) other equity awards previously granted to you, (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and you in each case that specifies the terms that should govern this RSU Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

Kura	Oncolo	ogy, Inc.
------	--------	-----------

Participant:

By:			
-	Signature		Signature
Title:		Date:	
Date:			
Аттаснме	NTS: RSU Award Agreement, Amended and	Restated 2014 Equity Incentive Plan	

#### Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan Award Agreement (RSU Award)

Pursuant to the Restricted Stock Unit Grant Notice (the "*Grant Notice*") and this Restricted Stock Unit Award Agreement (the "Agreement"), Kura Oncology, Inc. (the "*Company*") has awarded you ("*Participant*") a Restricted Stock Unit Award (the "*Award*") pursuant to the Company's Amended and Restated 2014 Equity Incentive Plan (the "*Plan*") for the number of Restricted Stock Units/shares of Common Stock ("*Shares*") indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. **GRANT OF THE AWARD.** This Award represents the right to be issued on a future date one (1) Ordinary Share for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "Account") the number of Restricted Stock Units/Shares subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of the Shares, in part or in full satisfaction of the delivery of Shares in connection with the vesting of the Restricted Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Shares issuable in connection with your Restricted Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.

2. **VESTING.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service and the Restricted Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the Shares to be issued in respect of such portion of the Award.

3. NUMBER OF SHARES. The number of Restricted Stock Units subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional Shares shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You may not be issued any Shares under your Award unless the Shares underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. **TRANSFER RESTRICTIONS.** Prior to the time that Shares have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) **Death.** Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Shares or other consideration that vested but was not issued before your death.

(b) **Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Shares or other consideration

hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

#### 6. DATE OF ISSUANCE.

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the withholding obligations set forth in this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above). The issuance date determined by this paragraph is referred to as the "*Original Issuance Date*".

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, *and* 

(ii) either (1) Withholding Taxes do not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Taxes by withholding shares of Common Stock from the Shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to pay your Withholding Taxes in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, <u>if and only if</u> permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the Shares under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

Company.

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the

7. **DIVIDENDS.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; *provided, however*, that this sentence will not apply with respect to any Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

8. **RESTRICTIVE LEGENDS.** The Shares issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.

9. EXECUTION OF DOCUMENTS. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

#### 10. Award not a Service Contract.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "*reorganization*"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

#### 11. WITHHOLDING OBLIGATION.

On each vesting date, and on or before the time you receive a distribution of the shares underlying your Restricted (a) Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "Withholding Taxes"). Additionally, the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "FINRA Dealer") whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the Shares issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued to pursuant to Section 6) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and provided further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's

withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. TAX CONSEQUENCES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

**13. UNSECURED OBLIGATION.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. Notices. Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**15. HEADINGS.** The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

## 16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any

clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

**18.** EFFECT ON **OTHER EMPLOYEE BENEFIT PLANS.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

**19. SEVERABILITY.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**20. OTHER DOCUMENTS.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

**21. AMENDMENT.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

22. COMPLIANCE WITH SECTION 409A OF THE CODE. This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

### 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 Nos. 333-228172, 333-232947, 333-241663 and 333-251172) of Kura Oncology, Inc.,
- 2. Registration Statement (Form S-8 Nos. 333-203504 and 333-210260) pertaining to the Amended and Restated 2014 Equity Incentive Plan and the 2015 Employee Stock Purchase Plan of Kura Oncology, Inc., and
- 3. Registration Statement (Form S-8 Nos. 333-216683, 333-223591, 333-230075 and 333-236621) pertaining to the Amended and Restated 2014 Equity Incentive Plan of Kura Oncology, Inc.;

of our reports dated February 24, 2021, with respect to the financial statements of Kura Oncology, Inc. and the effectiveness of internal control over financial reporting of Kura Oncology, Inc. included in this Annual Report (Form 10-K) of Kura Oncology, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Diego, California February 24, 2021

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

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

- 1. I have reviewed this Form 10-K of Kura Oncology, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2021

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

President and Chief Executive Officer

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

I, Marc Grasso, M.D., certify that:

- 1. I have reviewed this Form 10-K of Kura Oncology, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2021

By: /s/ Marc Grasso, M.D.

Marc Grasso, M.D. Chief Financial Officer and Chief Business Officer

#### 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, 2020 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 Marc Grasso, M.D. as Chief Financial Officer and Chief Business Officer, 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, as amended; 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/ Marc Grasso, M.D. Marc Grasso, M.D. Chief Financial Officer and Chief Business Officer

Date: February 24, 2021

Date: February 24, 2021

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