UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-37620

KURA ONCOLOGY, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**61-1547851**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12730 High Bluff Drive, Suite 400, San Diego, CA	**92130**
(Address of principal executive offices)	**(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 registered
Common Stock, par value $0.0001 per share	**KURA**	**The Nasdaq Global Select Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting of common equity held by non-affiliates of the registrant was approximately $776.5 million as of June 30, 2023 based on the closing price of $10.58 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 20, 2024 was 76,136,963 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 2024 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, 2023.

Auditor Firm Id: 42 Auditor Name: Ernst & Young LLP Auditor Location: San Diego, CA USA

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "may," "plan," "potential," "predict," "project," "targets," "likely," "will," "would," "could," "should," "continue," and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 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;
- our ability to attract and retain key management, scientific or clinical personnel; and
- the impact of geopolitical events and actual or threatened public health epidemics and pandemics on our business and operations.

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. In addition, our use of the word "including" in this Annual Report is not intended to be exhaustive but instead is intended to mean "including, without limitation."

Risk Factor Summary

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

- We are highly dependent on the success of our lead product candidate, ziftomenib, which is still in clinical development, and we cannot give any assurance that ziftomenib or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- 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 may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.
- Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.
- Failure by us or our third-party collaborators to develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.
- We 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, and/or to supply materials to conduct, our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the supply of materials and/or the completion of such clinical trials.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals in some or all planned regions, we will not be able to commercialize, or may be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

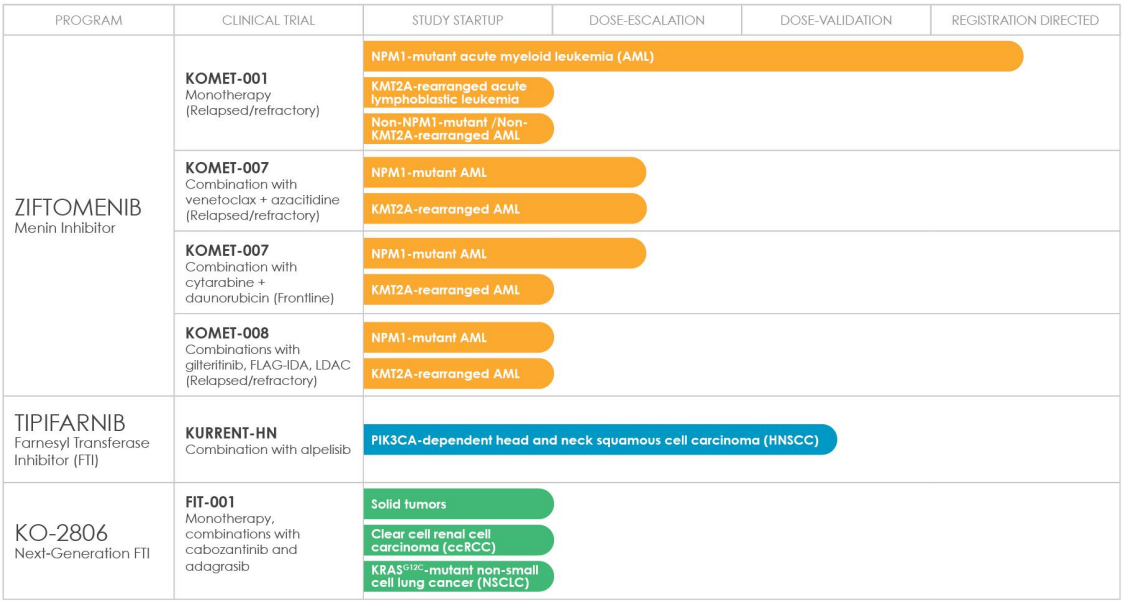
- Any product candidate for which we obtain marketing approval will be subject to extensive post-approval regulatory requirements and could be subject to post-approval restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.
- If we are unable to, or if we do not, obtain and maintain intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.
- We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.
- Patent terms may be inadequate to protect our competitive position on our product candidates for a commercially meaningful length of time.
- We may not be successful in obtaining or maintaining necessary third-party intellectual property rights for our development pipeline through acquisitions and in-licenses.
- If we are unable to maintain the confidentiality of our trade secrets or other confidential information, our business and competitive position would be harmed.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We currently have no sales personnel. If we are unable to establish effective sales 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 are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock.
- The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

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 are conducting clinical trials of three product candidates: ziftomenib, tipifarnib and KO-2806. We also have additional programs that are at a discovery stage. We own global commercial rights to all of our programs and product candidates. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

DRUG CANDIDATE PIPELINE



Ziftomenib. Our first product candidate, ziftomenib, is a potent, selective, reversible and oral small molecule inhibitor that blocks the interaction of two proteins, menin and the protein expressed by the Lysine K-specific Methyl Transferase 2A gene, or KMT2A gene (formerly referred to as the mixed-lineage leukemia 1 gene).

We received orphan drug designation for ziftomenib for the treatment of acute myeloid leukemia, or AML, from the U.S. Food and Drug Administration, or the FDA, in July 2019. We initiated our global menin-KMT2A Phase 1/2 clinical trial of ziftomenib in relapsed or refractory AML, which we call the Kura Oncology MEnin-KMT2A Trial, or KOMET-001, in September 2019. In the Phase 1a dose-escalation portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all-comer population of 30 patients with relapsed or refractory AML. A total of 53 patients were treated in the Phase 1b dose-validation and dose-expansion portions of the trial, which consisted of two randomized expansion cohorts, each comprised of nucleophosmin 1-, or NPM1-, mutant and KMT2A-rearranged AML patients. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the recommended Phase 2 dose, or RP2D.

On June 11, 2023, we presented updated clinical data from KOMET-001, including data from Phase 1b, during a late-breaking oral session at the 2023 European Hematology Association Annual Congress in Frankfurt, Germany, or EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a complete remission, or CR, with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after hematopoietic cell transplantation, or HCT, and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with isocitrate dehydrogenase, or IDH, co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an overall response rate, or ORR, of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The median duration of response, or DoR, for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M3271 was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of differentiation syndrome, or DS, was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed or refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024. In May 2023, we amended the KOMET-001 protocol to include a sub-study of ziftomenib in patients with acute lymphoblastic leukemia, or ALL, and two sub-studies of ziftomenib in patients with non-NPM1-mutant and non-KMT2A-rearranged AML. We dosed the first patients in the ALL sub-study in the first quarter of 2024, and we expect to dose the first patients in non-NPM1-mutant and non-KMT2A-rearranged AML by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The first of these studies, which we call KOMET-007, is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with cytarabine and daunorubicin, or 7+3, in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. We initiated dosing of patients in KOMET-007 in the third quarter of 2023.

On January 30, 2024, we announced preliminary data from the first 20 patients in the KOMET-007 study. The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk NPM1-mutant or KMT2A-rearranged AML and 15 patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. Patients are considered “adverse risk” if they are more than 60 years old and/or have treatment-related AML and/or adverse risk cytogenics per European LeukemiaNet.

Continuous daily dosing of ziftomenib at 200 mg was well tolerated and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a CR with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-mutant AML and one patient with KMT2A-rearranged AML. The ORR among relapsed or refractory patients treated with ziftomenib and venetoclax/azacitidine was 53% (8/15). Among all patients treated with ziftomenib and venetoclax/azacitidine, 40% (6/15) received prior treatment with a menin inhibitor. The rate of CRs or CRs with partial hematologic recovery, or CRh, in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-mutant AML and 50% (2/4) in patients with KMT2A-rearranged AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-mutant AML. As of the data cutoff, 80% (16/20) of patients remained on trial, including 100% (11/11) of all NPM1-mutant patients.

The 200 mg dose of ziftomenib cleared the safety threshold for dose escalation in the relapsed or refractory venetoclax/azacitidine cohorts and enrollment at the 400 mg dose is ongoing. We anticipate determining the RP2D of ziftomenib in combination with venetoclax and azacitidine by mid-2024, upon which we plan to initiate a Phase 1b dose validation/expansion of ziftomenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutant AML (without adverse risk) or KMT2A- rearranged AML. We also have escalated to the 400 mg dose of ziftomenib in the frontline NPM1-mutant 7 + 3 cohort, and we expect to determine the RP2D of ziftomenib in combination with 7 + 3 by mid-2024.

The second ziftomenib combination study, which we call KOMET-008, is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with

fludarabine, cytarabine, granulocyte-colony stimulating factor, or G-CSF, and idarubicin, or FLAG-IDA, or low-dose cytarabine, or LDAC, in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. On February 26, 2024, we announced that we dosed the first patient in KOMET-008.

We also intend to evaluate the use of ziftomenib as a maintenance therapy in patients with NPM1-mutant or KMT2A-rearranged AML who have undergone HCT. HCT represents the only potentially curative treatment for AML, yet the most common reason for long-term failure after HCT is disease relapse. We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy following HCT. We expect to initiate the post-transplant maintenance program in the first quarter of 2024.

On December 8, 2023, we announced a clinical collaboration with The Leukemia & Lymphoma Society, or LLS, to evaluate ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia. Under the terms of the collaboration agreement, LLS will serve as the coordinating sponsor of a Phase 1 study of ziftomenib in pediatric patients with acute leukemias in North America, the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands will serve as the coordinating sponsor of the study in Europe, and Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

Tipifarnib. Our second product candidate, tipifarnib, is a potent, selective and orally bioavailable farnesyl transferase inhibitor, or FTI, 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.

In February 2021, tipifarnib was granted Breakthrough Therapy Designation from the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma, or HNSCC, with variant allele frequency ≥ 20% after disease progression on platinum-based chemotherapy, or high VAF.

In July 2021, we announced a clinical collaboration with Novartis Pharma AG, or Novartis, to evaluate the combination of tipifarnib and alpelisib, a PI3 kinase alpha inhibitor, in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification. In the fourth quarter of 2021, we commenced a Phase 1/2 open-label, biomarker-defined cohort study, which we call the KURRENT-HN trial, to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of the combination for the treatment of such patients. Under the terms of our collaboration agreement with Novartis, we sponsor the KURRENT-HN trial and supply tipifarnib, and Novartis supplies alpelisib. In December 2021, we announced dose administration for the first patient in the PIK3CA cohort in KURRENT-HN. In October 2022, we reported the first demonstration of a durable clinical response with the combination of tipifarnib and alpelisib in a patient with PIK3CA-mutated squamous cell carcinoma of the tonsil. Since that time, we have continued dose escalation and have observed evidence of clinical activity, along with a manageable safety profile, at multiple doses. We continue to evaluate patients in the dose-escalation study to inform the selection of the optimal biologically active dose, or OBAD, for the combination, which we expect to determine by the end of 2024. Once we determine the OBAD, we will continue to evaluate whether the activity supports the development and commercialization of the combination in HNSCC.

KO-2806. Our newest product candidate, KO-2806, is a next-generation FTI that we believe demonstrates improved potency, pharmacokinetic and physicochemical properties relative to earlier FTI drug candidates. In January 2023, we announced the clearance by the FDA of our investigational new drug, or IND, application for KO-2806 for the treatment of advanced solid tumors.

We delivered multiple presentations of preclinical data in 2023 that we believe support the development of FTIs such as KO-2806 in combination with targeted therapies.

In April 2023, we presented preclinical data at the American Association for Cancer Research Annual Meeting highlighting the potential use of FTIs in combination with two distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic tyrosine kinase inhibitor, or TKI, axitinib in cell- and patient-derived xenograft, or PDX, models of clear cell renal cell carcinoma, or ccRCC. The second poster reported regression of multiple models of KRAS inhibitor-resistant non-small cell lung cancer, or NSCLC, by addition of tipifarnib to adagrasib or sotorasib.

On September 28, 2023, we presented preclinical data in an oral session at the 5th RAS-Targeted Drug Development Summit supporting the development of KO-2806 in combination with KRAS^{G12C} inhibitors to drive tumor regressions and durable responses in KRAS^{G12C}-mutant NSCLC. KRAS^{G12C} inhibitors have previously been shown to activate receptor tyrosine

kinase signaling, leading to ERK-RSK and/or mTOR-S6 pathway reactivation. Our preclinical data show that co-treatment of preclinical models of $KRAS^{G12C}$-mutant NSCLC with KO-2806 and adagrasib deepens signaling inhibition at multiple nodes, including the mitogen-activated protein kinase and mTOR pathways, while decreasing cell proliferation. In both cell-derived xenograft, or CDX, and PDX models originating from NSCLC tumors, the combination of KO-2806 with adagrasib induced tumor regressions. In addition, the CDX and PDX models demonstrated enhanced duration and depth of antitumor response compared to adagrasib as a single-agent therapy.

On October 13, 2023, we presented preclinical data at the AACR-NCI-EORTC International Conference supporting the development of KO-2806 with targeted therapies, including TKIs, $KRAS^{G12C}$ inhibitors and $KRAS^{G12D}$ inhibitors. The first of three posters illustrated that KO-2806 potentiates the antitumor activity of cabozantinib in ccRCC models. The second poster illustrated that KO-2806 blocks oncogenetic signaling at multiple nodes to enhance the antitumor activity of $KRAS^{G12C}$ inhibitor adagrasib in $KRAS^{G12C}$ NSCLC. The third poster illustrated that KO-2806 constrains compensatory signaling reactivation to deepen responses to $KRAS^{G12D}$ inhibition.

We believe these data support our rationale to combine KO-2806 with TKIs in ccRCC and with $KRAS^{G12C}$ inhibitors in NSCLC.

We are evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of KO-2806 as a monotherapy and in combination with other targeted therapies in a Phase 1 first-in-human study, which we call the FIT-001 trial. On October 19, 2023, we announced that we dosed the first patient in the monotherapy portion of the FIT-001 trial. We anticipate dosing the first patients with KO-2806 in combination with cabozantinib in ccRCC by mid-2024. On November 2, 2023, we announced a clinical collaboration with Mirati Therapeutics, Inc., or Mirati, to evaluate the combination of KO-2806 and adagrasib in patients with NSCLC whose tumors have a $KRAS^{G12C}$ mutation. Under the terms of the agreement, Mirati will supply us with adagrasib for the NSCLC combination cohort of the FIT-001 trial, and we sponsor the trial. We anticipate initiation of the $KRAS^{G12C}$-mutant NSCLC cohort by mid-2024.

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 of patients more likely to benefit from our product candidates;
- Leverage clinical and pathology trends towards comprehensive tumor profiling and the use of companion diagnostics;
- Pursue opportunities to enhance clinical activity, minimize toxicity and address innate and adaptive resistance to standard of care therapies through rational combinations;
- Build a sustainable product pipeline and advance our programs through a combination of internal discovery and development and external sources, including strategic partnerships, collaborations, in-licenses and acquisitions;
- Maintain significant development and commercial rights to our product candidates; and
- Invest in pre-commercial activities to maximize the value of our pipeline assets.

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 area of 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 or drug resistance 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 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 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; expedited clinical development in areas of high unmet need and improved safety relative to standard chemotherapy. 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 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 molecular assays (next-generation sequencing, or NGS, and/or qualitative polymerase chain reaction of DNA and/or RNA), or tissue-based assays such as protein expression by immunohistochemistry 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

Ziftomenib – A Selective Inhibitor of the Menin-KMT2A Interaction

Overview

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

Acute Leukemias and Genetic Alterations

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 NPM1, 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-rearranged 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. 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.

NPM1-mutations are among the most common genetic alterations, representing approximately 30% of AML. NPM1 mutations drive leukemogenesis in AML via cytoplasmic dislocation of NPM1 protein, resulting in transcription of disease-associated genes and inhibition of normal differentiation programs. NPM1-mutant AML is highly sensitive to disruption of the menin-KMT2A complex, which leads to decreased expression of essential leukemic genes, reduction of leukemic self-renewal capacity and promotion of differentiation. While patients with NPM1-mutant AML have high response rates to frontline therapy, relapse rates are high and survival outcomes are poor. Median overall survival is only six months following relapse for NPM1-mutant patients.

KMT2A-rearrangements represent approximately 5-10% of AML. Patients with KMT2A-rearranged AML have a poor prognosis with high rates of resistance and relapse following standard of care therapies. Currently, there are no approved therapies indicated for NPM1-mutant or KMT2A-rearranged leukemias. In the pediatric population, KMT2A-rearranged leukemias make up approximately 10% of acute leukemias. 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 a significant unmet medical need given the lack of curative therapeutic options.

In adults, AML is the most common acute leukemia worldwide. Despite the many available treatments for AML, prognosis for patients remains poor. Approximately 50% of patients with AML who achieve a CR after induction therapy relapse, and 40% of patients relapse after undergoing HCT. By preventing the interaction of menin and KMT2A/MLL, we believe ziftomenib has the potential to address up to 50% of AML cases, including NPM1-mutant AML and KMT2A-rearranged AML.

Preclinical Data Supporting Ziftomenib as a Monotherapy and in Combination with Other Therapies

We have generated preclinical data that support the potential anti-tumor activity of ziftomenib 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 NPM1. Our preclinical data support the hypothesis that ziftomenib targets epigenetic dysregulation and removes a key block to cellular differentiation to drive anti-tumor activity.

In November 2017, we reported preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing robust and durable activity 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 December 2021, we reported the presentation of preclinical data for ziftomenib and its potential for synergistic activity in combination with the BCL2 inhibitor venetoclax, a current standard of care in the treatment of patients with AML. These data confirm that treatment with ziftomenib drives dose-dependent induction of growth inhibition, differentiation and loss of viability of AML cells with KMT2A rearrangements or NPM1 mutations, while also reducing key protein levels such as MEIS1, FLT3 and BCL2 and menin itself. In addition, the findings demonstrated that co-treatment with ziftomenib and venetoclax induces synergistic activity in patient-derived AML cells expressing KMT2A rearrangements or NPM1 mutations, with or without mutant FLT3 expression, and prolongs survival in an aggressive disseminated model of KMT2A-rearranged, FLT3-mutant AML.

Clinical Development of Ziftomenib in AML

In September 2019, we initiated the KOMET-001 trial, a Phase 1/2 clinical trial of ziftomenib in patients with relapsed or refractory AML to investigate the safety and tolerability of ziftomenib in humans, determine a RP2D, characterize pharmacokinetics of ziftomenib and assess any early evidence of clinical activity.

In December 2020, we announced preliminary results from our KOMET-001 trial at an oral presentation at the 2020 American Society of Hematology Annual Meeting, 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 CR, 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, ziftomenib was well tolerated with a manageable safety profile. 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 ≥ 3) were reported to include pancreatitis, increased lipase, decreased neutrophil count, tumor lysis syndrome and deep venous thrombosis.

In May 2021, we reported that we amended the KOMET-001 trial protocol to include two Phase 1b expansion cohorts at doses that cleared the safety threshold in dose escalation. The Phase 1b portion of the study was designed to determine the lowest dose of ziftomenib that provides maximum biologic and clinical effect, consistent with guidance from the FDA relating to targeted oncology therapies, known as Project Optimus.

In June 2021, we reported that we dosed our first patient in the Phase 1b expansion cohorts. Each cohort – a lower dose (200 mg) and a higher dose (600 mg) – was comprised of NPM1-mutant and KMT2A-rearranged relapsed or refractory AML patients. Both doses demonstrated preliminary evidence of activity and safety and were determined to be well tolerated in the Phase 1a portion of the study.

In November 2021, we reported that the FDA had placed the KOMET-001 trial on a partial clinical hold. The partial clinical hold was initiated following our report to the FDA of a Grade 5 serious adverse event potentially associated with DS, a known adverse event related to differentiating agents in the treatment of AML. Patients who were enrolled in the Phase 1b expansion cohort at the time of the partial clinical hold were permitted to continue to receive ziftomenib, although no additional patients were to be enrolled until the partial clinical hold was lifted. In January 2022, we announced that the FDA had lifted the partial clinical hold on the KOMET-001 trial following agreement on our mitigation strategy for DS, and that the study would resume screening and enrollment of new patients.

In August 2022, we announced that we completed enrollment in the Phase 1b expansion cohorts of the KOMET-001 trial.

In December 2022, we announced updated clinical data from Phase 1a of the KOMET-001 trial that were presented during an oral presentation session at ASH. In the Phase 1a portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all comer population of 30 patients with relapsed or refractory AML.

On June 11, 2023, we presented updated clinical data from KOMET-001, including data from Phase 1b, during a late-breaking oral session at EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML. A total of 53 patients were treated in the Phase 1b dose-validation and dose-expansion portions of the study. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the RP2D.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a CR with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after HCT and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with IDH co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an ORR of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The median DoR for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M3271 was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of DS was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed or refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024. In May 2023, we amended the KOMET-001 protocol to include a sub-study of ziftomenib in patients with ALL, and two sub-studies of ziftomenib in patients with non-NPM1-mutant and non-KMT2A-rearranged AML. We dosed the first patients in the ALL sub-study in the first quarter of 2024, and we expect to dose the first patients in non-NPM1-mutant and non-KMT2A-rearranged AML by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The first of these studies, which we call KOMET-007, is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with 7+3 in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. We initiated dosing of patients in KOMET-007 in the third quarter of 2023.

On January 30, 2024, we announced preliminary data from the first 20 patients in the KOMET-007 study. The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk NPM1-mutant or KMT2A-rearranged AML and 15 patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. Patients are considered “adverse risk” if they are more than 60 years old and/or have treatment-related AML and/or adverse risk cytogenics per European LeukemiaNet.

Continuous daily dosing of ziftomenib at 200 mg was well tolerated and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a CR with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-mutant AML and one patient with KMT2A-rearranged AML. The ORR among relapsed or refractory patients treated with ziftomenib and venetoclax/azacitidine was 53% (8/15). Among all patients treated with ziftomenib and venetoclax/azacitidine, 40% (6/15) received prior treatment with a menin inhibitor. The rate of CRs or CRhs in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-mutant AML and 50% (2/4) in patients with KMT2A-rearranged AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-mutant AML. As of the data cutoff, 80% (16/20) of patients remained on trial, including 100% (11/11) of all NPM1-mutant patients.

The 200 mg dose of ziftomenib cleared the safety threshold for dose escalation in the relapsed or refractory venetoclax/azacitidine cohorts and enrollment at the 400 mg dose is ongoing. We anticipate determining the RP2D of ziftomenib in combination with venetoclax and azacitidine by mid-2024, upon which we plan to initiate a Phase 1b dose validation/expansion of ziftomenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutant AML (without adverse risk) or KMT2A- rearranged AML. We also have escalated to the 400 mg dose of ziftomenib in the frontline NPM1-mutant 7 + 3 cohort, and we expect to determine the RP2D of ziftomenib in combination with 7 + 3 by mid-2024.

The second ziftomenib combination study, which we call KOMET-008, is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with FLAG-IDA or LDAC in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. On February 26, 2024, we announced that we dosed the first patient in KOMET-008.

Registration Strategy for Ziftomenib. Our immediate strategy for ziftomenib in AML is to generate a data package to support an application for marketing approval in relapsed or refractory NPM1-mutant AML. Our comprehensive clinical development plan for ziftomenib also includes the evaluation of ziftomenib in combination with standards of care for NPM1-mutant and KMT2A-rearranged AML in the frontline and relapsed or refractory settings, as described above. We also are evaluating ziftomenib in other indications, beginning with ALL, and plan to evaluate ziftomenib as a maintenance therapy.

We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy to patients with NPM1-mutant or KMT2A-rearranged AML following HCT.

Our clinical development plan also includes a pediatric development strategy. On December 8, 2023, we announced a clinical collaboration with LLS to evaluate ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia. Under the terms of the collaboration agreement, LLS will serve as the coordinating sponsor of a Phase 1 study of ziftomenib in pediatric patients with acute leukemias in North America, the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands will serve as the coordinating sponsor of the study in Europe, and Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

Finally, several investigator-sponsored clinical trials of ziftomenib are either open for enrollment or in development, in addition to the clinical trials described above.

Farnesyl Transferase Inhibitors

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

Rat sarcoma virus, or RAS, oncogenes are translated into a family of membrane-associated proteins that are involved in regulating cell division in response to growth factor stimulation. The RAS gene family is comprised of three oncogenes: HRAS, KRAS and NRAS. Collectively, the three RAS genes constitute one of the most frequently mutated families of oncogenes in human cancers. Although HRAS mutations are less common overall relative to KRAS and NRAS mutations, they have a higher prevalence in cancers of the thyroid and urinary bladder and in head and neck squamous cell carcinomas.

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 solid 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 our FTI product candidates have 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 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®), nivolumab (Opdivo®) and pembrolizumab (Keytruda®), are in the range of 13-16% in unselected populations, with a median progression-free survival of approximately two months and a median overall survival of less than eight months. Data in the literature along with our own clinical data suggest response rates to these second-line agents 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.

Tipifarnib – An Oral Farnesyl Transferase Inhibitor

Overview

Tipifarnib is a potent, selective and orally bioavailable FTI. 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.

Tipifarnib as a Monotherapy

We conducted a global Phase 2, multi-center, open-label, non-comparative registration-directed clinical trial of tipifarnib in patients with recurrent/metastatic, or R/M, HRAS mutant HNSCC, which we called AIM-HN. On October 21, 2023, we presented the results of the AIM-HN study in a late-breaking oral session at the 2023 European Society for Medical Oncology Congress. As of the data cutoff on June 15, 2023, 59 patients with R/M HRAS mutant HNSCC were enrolled in the AIM-HN study, of whom 50 had high VAF and 38 were evaluable for efficacy. Responses were assessed by the investigators and an independent review facility, or IRF, in the modified intent to treat high VAF population. Both assessments by investigators and IRF observed one patient achieving a CR on treatment. Patients had a median of two prior lines of therapy (range 0-6) in the R/M setting and robust activity was seen in second line treatment and beyond with greater activity observed in the second line versus the third line and subsequent treatments. The objective response rate in second line treatment was 29% [0.13, 0.51] in the IRF assessment. The objective response rate for three FDA-approved therapies for the treatment of HNSCC in the second line range from 13-16%. Tipifarnib was generally well-tolerated with a manageable safety profile. The most common grade 3 or 4 treatment-related adverse events, or TRAEs, seen in at least 10% of patients were cytopenias and TRAEs led to discontinuation of treatment in 7% of patients. We believe the positive results from AIM-HN validate the therapeutic value of farnesyl transferase inhibition.

While the AIM-HN study generated compelling clinical data, in an ongoing effort to prioritize those programs with the highest potential to create value for patients, health care providers and shareholders, we have decided to discontinue development of tipifarnib as a monotherapy.

Tipifarnib in Combinations

In July 2021, we announced a clinical collaboration with Novartis to evaluate the combination of tipifarnib and alpelisib, a PI3 kinase alpha inhibitor, in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification. In the fourth quarter of 2021, we commenced a Phase 1/2 open-label, biomarker-defined cohort study, which we call the KURRENT-HN trial, to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of the combination for the treatment of such patients. Under the terms of our collaboration agreement with Novartis, we sponsor the KURRENT-HN trial and supply tipifarnib, and Novartis supplies alpelisib. In December 2021, we announced dose administration for the first patient in the PIK3CA cohort in KURRENT-HN.

In October 2022, we reported the first demonstration that the combination of tipifarnib and alpelisib can induce a durable clinical response in PIK3CA-dependent HNSCC at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium, or the Triple Meeting. In a poster presented at the Triple Meeting, we highlighted a patient with stage III squamous cell carcinoma of the tonsil with a PIK3CA mutation who had achieved a durable partial response in the KURRENT-HN trial and continued on-study for more than 27 weeks as of the September 14th data cutoff. Since the Triple Meeting, we have continued dose escalation and have observed evidence of clinical activity at multiple doses. Treatment-related adverse events in KURRENT-HN are consistent with the known safety profiles of each drug and are mostly low-grade and manageable with appropriate standard of care treatment. We continue to evaluate patients in the dose-escalation study to inform the selection of the OBAD for the combination, which we expect to determine by the end of 2024. Once we determine the OBAD, we will continue to evaluate whether the activity supports the development and commercialization of the combination in HNSCC.

We have also evaluated the use of FTIs in combination with EGFR-targeted therapies to prevent emergence of resistance to EGFR-targeted therapies. In November 2022, we announced the initiation of a Phase 1 clinical trial, which we called the KURRENT-LUNG trial, of tipifarnib in combination with osimertinib in treatment-naïve locally advanced or metastatic EGFR mutated NSCLC. In February 2023, we announced that in an ongoing effort to prioritize those programs with the highest potential to create value for patients, health care providers and shareholders, we decided to close our KURRENT-LUNG trial and discontinue further development of tipifarnib in combination with osimertinib, despite compelling preclinical data.

KO-2806- Next-Generation Farnesyl Transferase Inhibitor

Over the past several years, we have pioneered the development of FTIs as combination agents to prevent or delay emergence of resistance to certain classes of targeted therapy in large solid tumor indications. Our preclinical data is supportive of FTIs in combination with a growing number of targeted therapies, including EGFR inhibitors and PI3 kinase alpha inhibitors, as well as TKIs in renal cell carcinoma and $KRAS^{G12C}$ inhibitors in lung cancer. Our next-generation FTI, KO-2806, was developed with these applications in mind, and was designed to improve upon the potency, pharmacokinetic and physicochemical properties relative to earlier FTI drug candidates.

We delivered multiple presentations of preclinical data in 2023 that we believe support the development of FTIs such as KO-2806 in combination with targeted therapies.

In April 2023, we presented preclinical data at the American Association for Cancer Research Annual Meeting highlighting the potential use of FTIs in combination with two distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic TKI axitinib in cell- and PDX models of ccRCC. The second poster reported regression of multiple models of KRAS inhibitor-resistant NSCLC by addition of tipifarnib to adagrasib or sotorasib.

On September 28, 2023, we presented preclinical data in an oral session at the 5th RAS-Targeted Drug Development Summit supporting the development of KO-2806 in combination with $KRAS^{G12C}$ inhibitors to drive tumor regressions and durable responses in $KRAS^{G12C}$-mutant NSCLC. $KRAS^{G12C}$ inhibitors have previously been shown to activate receptor tyrosine kinase signaling, leading to ERK-RSK and/or mTOR-S6 pathway reactivation. Our preclinical data show that co-treatment of preclinical models of $KRAS^{G12C}$-mutant NSCLC with KO-2806 and adagrasib deepens signaling inhibition at multiple nodes, including the mitogen-activated protein kinase and mTOR pathways, while decreasing cell proliferation. In both CDX and PDX models originating from NSCLC tumors, the combination of KO-2806 with adagrasib induced tumor regressions. In addition, the CDX and PDX models demonstrated enhanced duration and depth of antitumor response compared to adagrasib as a single-agent therapy.

On October 13, 2023, we presented preclinical data at the AACR-NCI-EORTC International Conference supporting the development of KO-2806 with targeted therapies, including TKIs, $KRAS^{G12C}$ inhibitors and $KRAS^{G12D}$ inhibitors. The first of three posters illustrated that KO-2806 potentiates the antitumor activity of cabozantinib in ccRCC models. The second poster illustrated that KO-2806 blocks oncogenetic signaling at multiple nodes to enhance the antitumor activity of $KRAS^{G12C}$ inhibitor adagrasib in $KRAS^{G12C}$ NSCLC. The third poster illustrated that KO-2806 constrains compensatory signaling reactivation to deepen responses to $KRAS^{G12D}$ inhibition.

We believe these data support our rationale to combine KO-2806 with TKIs in ccRCC and with $KRAS^{G12C}$ inhibitors in NSCLC.

In January 2023, we announced the clearance by the FDA of our IND application for KO-2806 for the treatment of advanced solid tumors. We are now evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of KO-2806 when administered as a monotherapy and in combination with other targeted therapies in a Phase 1 first-in-human study, which we call the FIT-001 trial. We anticipate dosing the first patients with KO-2806 in combination with cabozantinib in ccRCC by mid-2024. On November 2, 2023, we announced a clinical collaboration with Mirati to evaluate the combination of KO-2806 and adagrasib, a $KRAS^{G12C}$ inhibitor, in patients with NSCLC whose tumors have a $KRAS^{G12C}$ mutation. Under the terms of the agreement, Mirati will supply us with adagrasib for the NSCLC combination cohort of the FIT-001 trial, and we sponsor the trial. We anticipate initiation of the $KRAS^{G12C}$-mutant NSCLC cohort by mid-2024.

License Agreements

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, that 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 retains the right to use the licensed compounds for non-commercial research, internal and/or educational purposes, with the right to grant the same limited rights to other non-profit research institutions. Under the agreement, as a result of our March 2015 private placement, we issued to the University of Michigan 79,113 shares of our common stock at a fair value of $0.5 million. The 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.

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 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.

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.

Menin 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, Biomea Fusion, Janssen, Sumitomo Dainippon and Daiichi Sankyo. If ziftomenib 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. There are several therapies approved for the treatment of AML, including Abbvie's/Genentech's venetoclax (VENCLEXTA®), Novartis's midostaurin (RYDAPT®), Astellas's gilteritinib (XOSPATA®), Bristol-Myers Squibb's, or BMS's, enasidenib (IDHIFA®), Servier's ivosidenib (TIBSOVO®), Rigel's olutasidenib (REZLIDHIA®) and Daiichi-Sankyo's quizartinib (VANFLYTA®).

FTI 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, BMS'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 farnesyl transferase inhibitor 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. There are several therapies approved for the treatment of NSCLC, including BMS's nivolumab (Opdivo®) and ipilimumab (Yervoy®), Merck's pembrolizumab (Keytruda®), AstraZeneca's durvalumab (Imfinzi®), Roche's atezolizumab (Tencentriq®), Regeneron's cemiplimab-rwlc (Libtayo®), Amgen's sotorasib (Lumakras®) and Mirati's/BMS's adagrasib (Krazati®); RCC, including Keytruda®, Opdivo®, Yervoy®, Exelixis's cabozantinib (Cabomeyx®), Merck's axitinib (Inlyta®) and Eisai's lenvatinib (Lenvima®); and HNSCC, including Opdivo®, Keytruda® and Eli Lilly's/Merck KGaA's cetuximab (Erbitux®).

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 presently are in the planning stages of shaping our commercial capabilities and infrastructure. 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 and that, if and when appropriate, we will seek to access the North American oncology markets through a focused, specialized, internal sales force. 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.

Subject to receiving marketing approvals, we expect to commence commercialization activities through 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 have begun building 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 a new drug application, or 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.

We monitor and manage our supply chain network for potential changes that could impact our global or regulatory manufacturing supply strategy. We regularly review with our third-party manufacturers and supply chain suppliers their business continuity initiatives and programs.

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-licensed patents or patent applications into our patent portfolio that now includes issued U.S. and foreign patents, 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 the University of Michigan or co-own multiple families of patent applications pertaining to our menin-KMT2A program. The U.S. Patent and Trademark Office, or U.S. PTO, has issued the University of Michigan and us patents covering the composition of matter of ziftomenib and certain structurally related compounds, and methods of using the compounds for the treatment of cancers, and related patents have been granted in foreign jurisdictions such as Europe, China, and Japan. We are pursuing additional U.S. and foreign patents related to ziftomenib development.

We have exclusively licensed from Janssen a portfolio of approximately 20 patent families related to tipifarnib. The in-licensed Janssen composition-of-matter family for tipifarnib expired in the United States and Europe in 2016. We have secured several U.S. and foreign method of treatment patents specifically directed to tipifarnib, as well as several U.S. and foreign patents pertaining to methods of treatment for FTIs more broadly. We have also exclusively licensed from Memorial Sloan Kettering Cancer Center a patent family pertaining to a method of use of tipifarnib, in which the U.S. PTO issued a patent. 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 related to our FTI program.

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 inventions that arise from our research and development programs, including dosage forms, methods of treatment and additional compounds that inhibit our oncology molecular targets. Specifically, we have filed patent applications and we anticipate that we will continue to 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 a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that the FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. 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 for one patent. The allowable patent term extension is calculated as up to half of the drug's testing phase—the time between IND effective date 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, or 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.

Project Optimus

In 2021, the FDA's Oncology Center of Excellence launched Project Optimus, an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose that maximizes not only the efficacy of a drug but also its safety and tolerability. Project Optimus was driven by the FDA's concerns that the historical approach to dose selection, which generally determined the maximum tolerated dose, may have resulted in doses and schedules of molecularly targeted therapies that were inadequately characterized before the initiation of pivotal trials.

Project Optimus requires the implementation of strategies for dose finding and dose optimization that leverage nonclinical and clinical data in dose selection, including randomized evaluations of a range of doses in trials. This initiative emphasizes the performance of dose finding and dose optimization studies as early and efficiently as possible in development programs. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval.

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 life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new product candidate may request that 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 for which the sponsor is seeking orphan designation, the sponsor must present a plausible hypothesis of clinical superiority to obtain orphan designation. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the FDA discloses the identity of the therapeutic agent and its potential orphan use.

Orphan designation may provide manufacturers with benefits such as research grants, tax credits, Prescription Drug User Fee Act application fee waivers, and eligibility for orphan drug exclusivity. If a product that has orphan designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or 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 post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. 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 post-approval 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 cGMP 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 cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP. 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.

Laboratory developed tests that are subject to Clinical Laboratory Improvement Amendments regulations and 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 investigational device exemption, or 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. For a clinical trial where the IVD result directs the therapeutic care of patients with cancer, we believe that the FDA may consider use of the IVD as part of the clinical 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 data to sell or market products, including the General Data Protection Regulation (EU) 2016/679, or GDPR, which imposes privacy and security obligations on any entity that collects and/or processes personal 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 laws, health information privacy and security statutes and regulations 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), certain other healthcare professionals (such as physician assistants and nurse practitioners), 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.

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 and impose additional health policy reforms. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed 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 Medicaid or the ACA. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, or IRA, which, among other reforms, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

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. Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform

measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act of 1980, or Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2032. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures. Further, Congress is considering additional health reform measures. 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.

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.

Human Capital

As of December 31, 2023, we employed 142 full-time employees. Our employees were comprised of 89 in research, development and supply chain and 53 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 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 what is now called the Diversity, Equity and Inclusion Committee, or DE&I Committee, an employee-led committee consisting of members from across the organization that focuses on matters related to our corporate culture, specifically related to diversity, equity, inclusion, and social justice. The DE&I Committee's initiatives include internal education, women's professional development, community outreach, external mentoring and clinical trial equity.

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 and lab space in San Diego, California. 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 & 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, trade dress or product owners.

Item 1A. Risk Factors.

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

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

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

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

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote any product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals. Although the scope of regulatory approval is similar in other countries, in some countries there are additional regulatory requirements and potential regulatory risks and we cannot predict success in these jurisdictions.

There is no guarantee that our clinical trials will be completed on time or at all. Prior to receiving approval, if any, to commercialize a product candidate in the United States or internationally, we must demonstrate to the satisfaction of the FDA and other regulatory authorities, that such product candidate is safe and effective for its intended use. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of a product candidate may not be replicated in subsequent clinical trials. Even if we believe the preclinical or clinical data are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. We maintain frequent, ongoing dialogue with the FDA and other regulatory bodies regarding our clinical trial designs, including the patient selection criteria, dosing 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 there may be potential to pursue a path to approval for ziftomenib for the treatment of patients with particular subtypes of relapsed or refractory AML, we cannot guarantee that ziftomenib will demonstrate sufficient safety and tolerability and clinical activity in that subtype to support an application for approval. Even if ziftomenib demonstrates sufficient activity in one patient subtype, such as patients with NPM1-mutant AML, to support an application in that subset, there can be no assurance it will demonstrate sufficient activity to support an application for approval in other patient subsets. Even if the trial results from ziftomenib demonstrate a compelling clinical benefit, the FDA has substantial discretion in the approval process and may not grant approval based on data generated by us.

If the results of our trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant additional resources to conduct additional trials in support of potential approval of ziftomenib, tipifarnib, KO-2806 or our other product candidates.

We have not previously submitted an 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 any of our product candidates 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 a product candidate for any other indications. If we do not receive regulatory approvals for and successfully commercialize any of our product candidates on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one of our product candidates, our revenues 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 NPM1-mutant AML, KMT2A-rearranged AML, PIK3CA-dependent HNSCC 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 our product candidates, 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 Phase 1 and/or proof-of-concept Phase 2 clinical trials, to show early and statistically significant evidence of clinical efficacy. Potential molecular biomarkers we have identified in retrospective analyses of data from clinical trials of ziftomenib or tipifarnib in certain cancer indications may not be prospectively validated as biomarkers of ziftomenib or tipifarnib activity in future clinical trials that we may conduct in these indications. If we are unable to identify molecular or genetic alterations, or biomarkers, that are predictive of response to our product candidates, or we are unable to include patients who harbor the applicable genetic alterations or expression levels in our clinical trials, or if our product candidates fail to work as we expect, our ability to assess the therapeutic effect, seek participation in FDA expedited review and approval programs, including Breakthrough Therapy Designation, Fast Track Designation, Priority Review and Accelerated Approval, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised, resulting in longer development times, larger clinical trials and a reduced likelihood of obtaining regulatory approval.

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

Identifying and qualifying patients to participate in clinical 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, certain genetic alterations are not included in existing diagnostic panels, have unknown prognostic significance and/or are not targeted by any FDA-approved treatment, and as a result, biomarker testing for such alterations is not routinely performed. To seek to address these limitations, we have contracted with third-party laboratories to facilitate the genetic screening of patients for our clinical sites. However, there is no guarantee that these efforts will be effective.

We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical 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. Further, if patients do not comply with clinical trial process and procedure and, for example, drop out, miss scheduled doses or follow-up visits, or fail to follow trial protocols, then the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities.

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

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

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

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

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

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

Results from clinical trials conducted at a single clinical site or a small number of clinical sites may not be predictive of results from additional clinical sites or from subsequent clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, the FDA previously issued a non-approval letter to Janssen for tipifarnib as a treatment for elderly, untreated AML patients 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, comparable foreign regulatory authorities or IRBs have comments on our study plans for our clinical trials 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. For example, on November 24, 2021, we reported that the FDA had placed the KOMET-001 trial on a partial clinical hold. The partial clinical hold was initiated following our report to the FDA of a Grade 5 serious adverse event potentially associated with DS, a known adverse event related to differentiating agents in the treatment of AML. Patients who were enrolled in the Phase 1b expansion cohorts at the time of the partial clinical hold were permitted to continue to receive ziftomenib, although no additional patients were to be enrolled until the partial clinical hold was lifted. On January 20, 2022, we announced that the FDA had lifted the partial clinical hold on the KOMET-001 trial following agreement on our mitigation strategy for DS, and that the study would resume screening and enrollment of new patients. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

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

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

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

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

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

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

We licensed the rights to develop 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 may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

We are currently developing our product candidates, and may develop future product candidates, for use in combination with one or more other cancer therapies, such as venetoclax, azacitidine, cytarabine, daunorubicin, gilteritinib, fludarabine, G-CSF, and idarubicin in the case of ziftomenib, alpelisib in the case of tipifarnib, and cabozantinib and adagrasib in the case of KO-2806, or other drugs, both approved and unapproved. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with another drug or biologic will depend on our ability, or the ability of third-party clinical trial sites on which we rely, to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that we, or third-party clinical trial sites on which we rely, will be able to secure a steady supply of such drugs or biologics on commercially reasonable terms or at all.

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

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

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

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

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

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

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

Continuous daily dosing of ziftomenib was well tolerated in the Phase 1b portion of our KOMET-001 trial, with no evidence of drug-induced QTc prolongation. The on-target effect of DS was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event. Grade ≥3 treatment-emergent adverse events were reported in 17 patients (85%), and included anemia (25%) and thrombocytopenia (20%). Grade ≥3 treatment-related adverse events were reported in six patients (30%). As of the January 11, 2024 data cutoff for the initial data read-out for the KOMET-007 trial, no differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed.

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 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.

Our FIT-001 trial represents the first time our KO-2806 compound has been tested in humans. While we can anticipate potential side effects based upon the safety profiles of tipifarnib and other FTIs, we cannot predict the type, frequency or severity of side effects that we will observe in patients treated with KO-2806.

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 develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.

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

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

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 approved companion diagnostics will be required in order to obtain approval for ziftomenib in NPM1-mutant AML and KMT2A-rearranged AML and for tipifarnib in PIK3CA-dependent HNSCC. We and our third-party collaborators may encounter difficulties in developing, validating and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop, validate or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

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

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

- continue research and development of our product candidates;
- initiate new clinical trials for our product candidates;
- seek marketing approvals for our product candidates;
- enter into collaboration arrangements for combination drugs or biologics for our product candidates;
- enter into collaboration arrangements for companion diagnostics for our product candidates;
- 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, and the manufacturing, marketing and selling of these products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or even sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

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

- the success of our clinical trials through all phases of clinical development;
- delays in the commencement, enrollment and 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, debt financings, collaborations, strategic partnerships or licensing arrangements. Additional capital may not be available on reasonable terms, if at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of our stockholders as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, 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. As a result of the COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive.

On November 2, 2023, we entered into a Sales Agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., or the ATM Facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We have not sold any shares of our common stock under the ATM Facility.

In November 2022, we entered into a loan and security agreement, or the Loan Agreement, with several banks and other financial institutions or entities party thereto, or collectively the Lenders, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, providing for up to $125.0 million in a series of term loans, or Term Loans. Upon entering into the Loan Agreement, we borrowed $10.0 million of an initial $25.0 million tranche of Term Loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining $15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to $35.0 million at any time until March 15, 2024. Thereafter, we may borrow (i) an additional tranche of Term Loans in the amount of up to $40.0 million which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of term loans in the amount of up to $25.0 million, subject to the Lenders' investment committee approval in its sole discretion. Other than our term loan facility, 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, transactions with affiliates and a minimum cash covenant, among other customary covenants. If we default under our term loan facility, the Lenders may accelerate our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the Lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could accelerate our obligations under the Loan Agreement upon the occurrence of an event of default, which includes, among other things, our failure to satisfy our payment obligations under the Loan Agreement, the breach of certain of our other covenants under the Loan Agreement or the occurrence of a material adverse change, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

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

Events involving limitations to liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry, or concerns or rumors about any events of these kinds or other similar risks, have in the past led and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or FDIC, was appointed as receiver. Subsequently, the FDIC announced that all deposits with SVB are fully insured. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each placed into receivership and on May 1, 2023, First Republic Bank was placed into receivership. We regularly maintain cash balances at third-party financial institutions in excess of the FDIC standard insurance limit, with balances concentrated at a small number of financial institutions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or with which we do business, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. In addition, if any of our partners or parties with whom we conduct business are unable to access funds due to the status of their financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

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

Risks Related to Our Dependence on Third Parties

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

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

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

For our KURRENT-HN trial, in addition to relying upon third-party service providers, we depend upon Novartis to supply alpelisib in accordance with the terms of our collaboration agreement. If Novartis does not perform in accordance with the agreement, or the agreement is terminated, the KURRENT-HN trial, and our development plans for tipifarnib in combination with alpelisib, could be materially adversely impacted. Similarly, we depend on Mirati to supply adagrasib for the NSCLC combination cohort of our FIT-001 trial. If Mirati does not perform in accordance with the agreement, or the agreement is terminated, the NSCLC combination cohort of our FIT-001 trial, and our development plans for KO-2806 in combination with adagrasib, could be materially adversely impacted.

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

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

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

We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of clinical supplies of ziftomenib, tipifarnib and KO-2806 for preclinical and clinical testing. We expect to rely on third parties as well for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We also expect to rely on other third parties to package and label the drug product as well as to store and distribute drug supplies for our clinical trials.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of drug formulation and manufacturing techniques and process controls. Manufacturers of 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.

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

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the applicable regulatory authorities, including the FDA, pursuant to inspections that 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 ziftomenib, tipifarnib, KO-2806 and our other product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture our products, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

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

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

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

Our product candidates must be approved by the FDA pursuant to an NDA in the United States 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, public health epidemics or outbreaks 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 for tipifarnib if another company obtains regulatory approval for tipifarnib before we do.

The composition of matter patents covering tipifarnib expired in the United States and in countries in Europe in 2016. Our commercial strategy for tipifarnib relies on obtaining method of use and method of treatment patents, including those directed to specific indications and biomarkers, other patents related to tipifarnib, and 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 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.

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

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

In July 2019, the FDA granted orphan drug designation to ziftomenib for the treatment of AML. If ziftomenib receives marketing approval for an indication broader than AML, ziftomenib may no longer be eligible for marketing exclusivity. Furthermore, orphan drug exclusivity may not effectively protect ziftomenib from the competition of different drugs for the same orphan condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same condition if the FDA concludes that 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 Breakthrough Therapy Designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

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

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

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

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

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 data 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 API 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 API.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens, on behalf of the government, through whistleblower actions, and civil monetary penalties laws which prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also 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), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians or their immediate family; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

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

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

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

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or collectively CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data maintained by covered businesses about California residents. Similar laws are being considered in several other states. In addition, data privacy and security laws have been proposed at the federal and local levels in recent years, which could further complicate compliance efforts.

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

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

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

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

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

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

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

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

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

There have been executive, judicial and Congressional challenges 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. Furthermore, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed 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 Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. We cannot predict the ultimate content, timing or effect of healthcare reform legislation or regulation or the impact of potential legislation or regulation on us.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, that due to subsequent legislative amendments, will stay in effect until 2032. 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. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and other potential legislation may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. As a result, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law. The IRA, among other things, (1) extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, (2) directs HHS to negotiate, subject to a specified cap, the price of a set number of certain single-source drugs and biologics covered under Medicare each year starting in 2026, (3) imposes rebates under Medicare Part B and Medicare Part D to penalize manufacturers for price increases that outpace inflation, and (4) makes several changes to the Medicare Part D benefit, including by significantly lowering the beneficiary maximum annual out-of-pocket costs, and through a change in manufacturer liability under the program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued, and will continue to issue and update, guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry and could negatively affect our business and financial condition. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023,

the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Future legislation could potentially change drug pricing dynamics. We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business.

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, 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. For example, 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. 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.

Ziftomenib

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

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

Patent term extension may be available in the United States or in other jurisdictions to account for regulatory delays in obtaining marketing approval for a product candidate; however, only one patent may be extended per marketed product. The applicable authorities, including the U.S. PTO and the FDA, and any equivalent patent or regulatory authorities 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 ziftomenib so long as the competitors do not infringe any patents that we may hold. Competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Tipifarnib

Our patent rights in tipifarnib are limited in ways that affect our ability to exclude third parties from competing against us. In particular, the patent term for the composition of matter patents covering the API of tipifarnib expired in 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.

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

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 patent or regulatory authorities 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.

KO-2806

We have filed patent applications in the United States, and under the Patent Cooperation Treaty, covering the composition of matter of KO-2806 and certain structurally related compounds and methods of using KO-2806 for treating cancers. However, there is no guarantee that patents will be granted from such applications or that, if granted, would provide protection against third parties.

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

We have licensed patent rights from third parties for some of our development programs, including compounds in our menin-KMT2A program from the University of Michigan and tipifarnib from Janssen. 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.

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

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

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

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

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

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

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO or third-party preissuance observations to the European Patent Office, or EPO, or become involved in patent office post-grant proceedings, such as opposition, derivation, reexamination, inter partes review, or post-grant review proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding, or in litigation, could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, 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.

For instance, under the Unitary Patent Court system that has been implemented in Europe, patent applicants have the option, upon grant of a patent by the EPO, of electing grant of a Unitary Patent, which will be subject to the jurisdiction of the Unified Patent Court, or UPC. This is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

We currently do not have a sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis 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 or expand our sales, marketing, analytics 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 commercial capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or

certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies, which may directly compete with ziftomenib, tipifarnib, KO-2806 and any other future product candidates. If any competitor is able to advance their clinical program more quickly than ours, the commercial opportunity for our product candidates could be reduced. In the case of ziftomenib, in January 2024, Syndax announced the NDA submission for revumenib in relapsed or refractory KMT2A-rearranged acute leukemia, and could receive regulatory approval for this indication in 2024.

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. Further, any companion diagnostic that we or our collaborators develop will be subject to separate coverage and reimbursement determinations by third-party payors.

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

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

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

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

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and market access personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees, and recruiting additional key employees, may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery 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, regulatory, operations, medical affairs, market access and marketing capabilities and potentially implement sales 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, medical affairs, 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.

Third-party expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

In recent years, there has been an increased focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Third-party providers of ESG ratings and reports on companies have increased in number, resulting in varied and, in some cases, inconsistent standards. Topics taken into account in such assessments include, among others, the company's efforts and impacts with respect to climate change and human rights, ethics and compliance with the law, and the role of the company's board of directors in supervising various sustainability issues. In addition to the topics typically considered in such reviews, in our industry, the public's ability to access our medicines is of particular importance.

Some investors may use third-party ESG ratings and reports to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our desirability as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to adequately pursue or fulfill any goals and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could expose us to additional regulatory, social or other scrutiny of us, the imposition of unexpected costs, or damage to our reputation, which in turn could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

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

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

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

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

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

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

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

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention, interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

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

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

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

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

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.

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

While many health organizations have declared that the COVID-19 pandemic has ended, the pandemic and previous actions to slow its spread had an adverse impact on our operations, including our ability to conduct our clinical trials, and we cannot predict if or when other similar disease outbreaks will emerge that cause similar disruptions.

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

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

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power, and any future blackouts could disrupt our operations. We are vulnerable to a major earthquake, wildfire and other natural disasters, 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, 2023, 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;
- 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 as a result of the COVID-19 pandemic, bank failures, actual or perceived changes in interest rates and economic inflation. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. These events may also lead to securities litigation, which can be expensive and time-consuming to defend, regardless of the merit or outcome. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders or the perception that such sales could occur could cause the market price of our common stock to decline. On November 2, 2023, we entered into the ATM Facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We have not sold any shares of our common stock under the ATM Facility.

Pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of December 31, 2023, we had 3,713,092 shares of common stock available for grant under the 2014 Plan, options to purchase up to an aggregate of 10,297,245 shares of common stock outstanding, 956,032 unvested restricted stock units outstanding and 1,313,100 unvested performance-based restricted stock units outstanding. Also, pursuant to our 2023 Inducement Option Plan, or Inducement Plan, we are authorized to grant nonstatutory stock options to individuals that were not previously our employees or directors (or following a bona fide period of non-employment), as an inducement material to the individual's entry into employment with us, pursuant to Nasdaq Listing Rule 5635(c)(4). As of December 31, 2023, we had 600,000 shares of common stock available for grant under the Inducement 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, 2023, we had 653,852 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 (or a duly authorized committee thereof) to take action to reduce the size of the increase in any given year. In December 2023, the compensation committee of the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in 2024.

In addition, as of December 31, 2023, (i) warrants to purchase up to (a) 33,988 shares of our common stock at an exercise price of $3.31 per share and (b) 26,078 shares of our common stock at an exercise price of $14.38 per share and (ii) pre-funded warrants to purchase up to 3,034,782 shares of our common stock at an exercise price of $0.0001 per share were outstanding. In connection with our January 2024 private placement, on January 26, 2024 we issued additional pre-funded warrants to purchase up to 7,318,886 shares of our common stock at an exercise price of $0.0001 per share.

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

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

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

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;

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

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

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

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

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

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

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, we expect an increase in our net deferred tax assets and an offsetting similarly sized increase in our valuation allowance over these amortization periods. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur and whether we conduct our research and development activities inside or outside the United States.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. 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 fundamentals and prospects of our business.

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

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

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

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

actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the Foreign Corrupt Practices Act, 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 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic, financial, or competitive in nature, information related to our clinical trials and preclinical studies and information of our employees, or Information Systems and Data.

Our Information Technology, or IT, department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, manual and automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats and threat actors, evaluating threats that are reported to us, using external intelligence feeds, engaging in internal and external audits, and engaging third parties to conduct threat assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, a disaster recover/business continuity plan and information security policy, encrypting certain data, data segmentation, network security controls, access and physical security controls, asset management, tracking and disposal, systems monitoring, employee training, maintaining cyber insurance and using third party threat detection software.

The head of our IT department reports to our Chief Operating Officer, or COO, and works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. We have established an Incident Review Team, which consists of representatives of our Finance, IT and Legal departments, to investigate, evaluate and respond to cybersecurity incidents. The Incident Review Team is responsible for escalating confirmed cybersecurity incidents to a Materiality Assessment Team, consisting of members of management. The Materiality Assessment Team is responsible for reporting cybersecurity incidents to the audit committee of the board of directors, as appropriate based upon the nature of the incident (or series of incidents).

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example threat intelligence service providers, cybersecurity software, and darkweb monitoring services. We also use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the section entitled “Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions.”

Governance

Our cybersecurity risk assessment and management processes are implemented and maintained by certain company management, including the head of our IT department. The head of IT is responsible for integrating cybersecurity risk considerations into our overall risk management strategy, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to our Materiality Assessment Team, comprised of members of management. In addition, our cybersecurity incident response policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives regular reports from the head of our IT department concerning the measures we have taken to monitor and evaluate our cybersecurity threat environment and any cybersecurity incidents that have occurred.

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 2031, and approximately 5,315 square feet of office and lab space in San Diego, California under a lease that expires in August 2025. 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

Our common stock is listed on the Nasdaq Global Select Market under the symbol "KURA".

Holders of Record

As of February 20, 2024, there were approximately 106 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

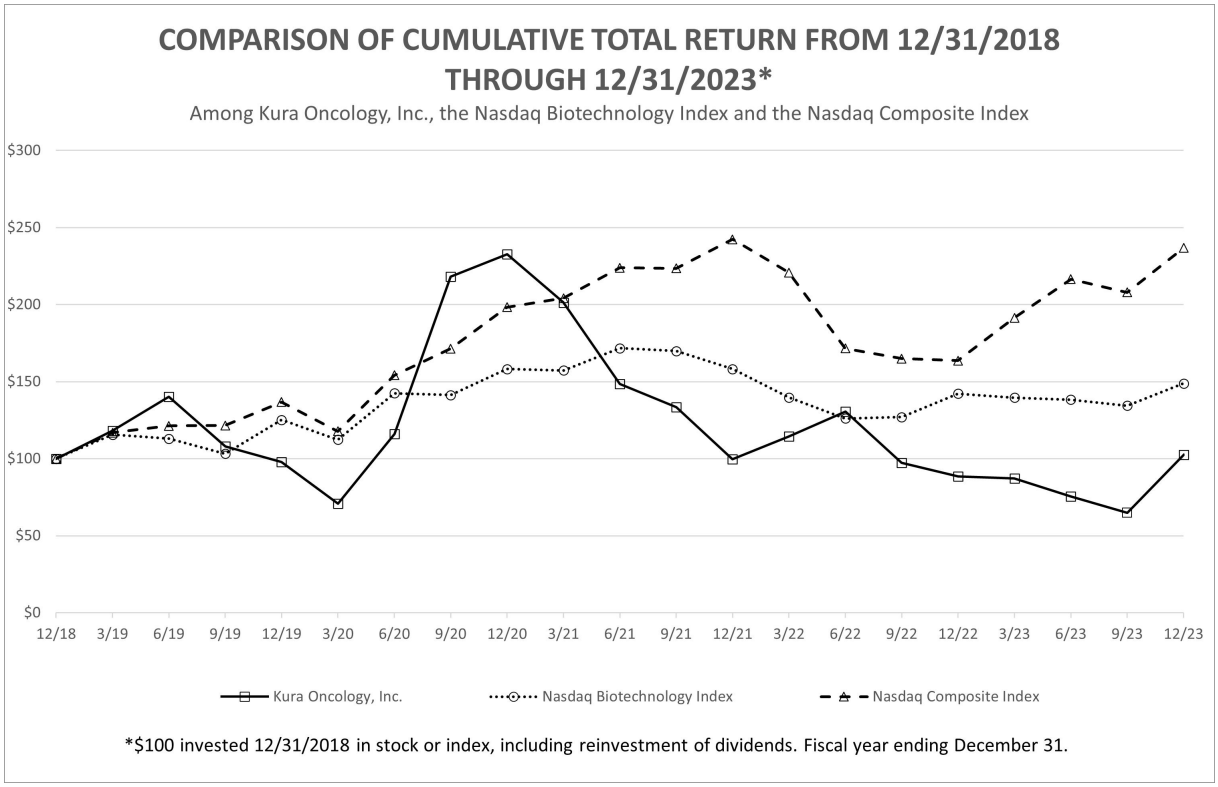
Recent Sales of Unregistered Securities

Not applicable.

Stock Performance Graph and Cumulative Total Return

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2018 (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. [Reserved].

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, 2022 and 2021, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 23, 2023.

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 are conducting clinical trials of three product candidates: ziftomenib, tipifarnib and KO-2806. We also have additional programs that are at a discovery stage. We own global commercial rights to all of our programs and product candidates. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

Ziftomenib. Our first product candidate, ziftomenib, is a potent, selective, reversible and oral small molecule inhibitor that blocks the interaction of two proteins, menin and the protein expressed by the KMT2A gene (formerly referred to as the mixed-lineage leukemia 1 gene).

We received orphan drug designation for ziftomenib for the treatment of AML from the FDA in July 2019. We initiated our global menin-KMT2A Phase 1/2 clinical trial of ziftomenib in relapsed or refractory AML, which we call KOMET-001, in September 2019. In the Phase 1a dose-escalation portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all-comer population of 30 patients with relapsed or refractory AML. A total of 53 patients were treated in the Phase 1b dose-validation and dose-expansion portions of the trial, which consisted of two randomized expansion cohorts, each comprised of NPM1-mutant and KMT2A-rearranged AML patients. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the RP2D.

On June 11, 2023, we presented updated clinical data from KOMET-001, including data from Phase 1b, during a late-breaking oral session at the EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a CR with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after HCT and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with IDH co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an ORR of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The DoR for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M3271 was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of DS was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed or refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024. In May 2023, we amended the KOMET-001 protocol to include a sub-study of ziftomenib in patients with ALL, and two sub-studies of ziftomenib in patients with non-NPM1-mutant and non-KMT2A-rearranged AML. We dosed the first patients in the ALL sub-study in the first quarter of 2024, and we expect to dose the first patients in non-NPM1-mutant and non-KMT2A-rearranged AML by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. KOMET-007 is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with cytarabine and daunorubicin, or 7+3, in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. We initiated dosing of patients in KOMET-007 in the third quarter of 2023.

On January 30, 2024, we announced preliminary data from the first 20 patients in the KOMET-007 study. The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk NPM1-mutant or KMT2A-rearranged AML and 15 patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. Patients are considered “adverse risk” if they are more than 60 years old and/or have treatment-related AML and/or adverse risk cytogenics per European LeukemiaNet.

Continuous daily dosing of ziftomenib at 200 mg was well tolerated and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a CR with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-mutant AML and one patient with KMT2A-rearranged AML. The ORR among relapsed or refractory patients treated with ziftomenib and venetoclax/azacitidine was 53% (8/15). Among all patients treated with ziftomenib and venetoclax/azacitidine, 40% (6/15) received prior treatment with a menin inhibitor. The rate of CRs or CRhs in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-mutant AML and 50% (2/4) in patients with KMT2A-rearranged AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-mutant AML. As of the data cutoff, 80% (16/20) of patients remained on trial, including 100% (11/11) of all NPM1-mutant patients.

The 200 mg dose of ziftomenib cleared the safety threshold for dose escalation in the relapsed or refractory venetoclax/azacitidine cohorts and enrollment at the 400 mg dose is ongoing. We anticipate determining the RP2D of ziftomenib in combination with venetoclax and azacitidine by mid-2024, upon which we plan to initiate a Phase 1b dose validation/expansion of ziftomenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutant AML (without adverse risk) or KMT2A- rearranged AML. We also have escalated to the 400 mg dose of ziftomenib in the frontline NPM1-mutant 7 + 3 cohort, and we expect to determine the RP2D of ziftomenib in combination with 7 + 3 by mid-2024.

KOMET-008 is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with fludarabine, cytarabine, G-CSF, and FLAG-IDA, or LDAC, in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. On February 26, 2024, we announced that we dosed the first patient in KOMET-008.

We also intend to evaluate the use of ziftomenib as a maintenance therapy in patients with NPM1-mutant or KMT2A-rearranged AML who have undergone HCT. HCT represents the only potentially curative treatment for AML, yet the most common reason for long-term failure after HCT is disease relapse. We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy following HCT. We expect to initiate the post-transplant maintenance program in the first quarter of 2024.

On December 8, 2023, we announced a clinical collaboration with LLS to evaluate ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia. Under the terms of the collaboration agreement, LLS will serve as the coordinating sponsor of a Phase 1 study of ziftomenib in pediatric patients with acute leukemias in North America, the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands will serve as the coordinating sponsor of the study in Europe, and Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

Tipifarnib. Our second product candidate, tipifarnib, is a potent, selective and orally bioavailable FTI 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.

In February 2021, tipifarnib was granted Breakthrough Therapy Designation from the FDA for the treatment of patients with HNSCC, with high VAF.

In July 2021, we announced a clinical collaboration with Novartis, to evaluate the combination of tipifarnib and alpelisib, a PI3 kinase alpha inhibitor, in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification. In the fourth quarter of 2021, we commenced the KURRENT-HN trial, to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of the combination for the treatment of such patients. Under the terms of our collaboration agreement with Novartis, we sponsor the KURRENT-HN trial and supply tipifarnib, and Novartis supplies alpelisib. In December 2021, we announced dose administration for the first patient in the PIK3CA cohort in KURRENT-HN. In October 2022, we reported the first demonstration of a durable clinical response with the combination of tipifarnib and alpelisib in a patient with PIK3CA-mutated squamous cell carcinoma of the tonsil. Since that time, we have continued dose escalation and have observed evidence of clinical activity, along with a manageable safety profile, at multiple doses. We continue to evaluate patients in the dose-escalation study to inform the selection of the OBAD for the combination, which we expect to determine by the end of 2024. Once we determine the OBAD, we will continue to evaluate whether the activity supports the development and commercialization of the combination in HNSCC.

KO-2806. Our newest product candidate, KO-2806, is a next-generation FTI that we believe demonstrates improved potency, pharmacokinetic and physicochemical properties relative to earlier FTI drug candidates. In January 2023, we announced the clearance by the FDA of our IND application for KO-2806 for the treatment of advanced solid tumors.

We delivered multiple presentations of preclinical data in 2023 that we believe support the development of FTIs such as KO-2806 in combination with targeted therapies.

In April 2023, we presented preclinical data at the American Association for Cancer Research Annual Meeting highlighting the potential use of FTIs in combination with two distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic TKI, axitinib in cell- and PDX models of ccRCC. The second poster reported regression of multiple models of KRAS inhibitor-resistant NSCLC by addition of tipifarnib to adagrasib or sotorasib.

On September 28, 2023, we presented preclinical data in an oral session at the 5th RAS-Targeted Drug Development Summit supporting the development of KO-2806 in combination with KRAS^{G12C} inhibitors to drive tumor regressions and durable responses in KRAS^{G12C}-mutant NSCLC. KRAS^{G12C} inhibitors have previously been shown to activate receptor tyrosine kinase signaling, leading to ERK-RSK and/or mTOR-S6 pathway reactivation. Our preclinical data show that co-treatment of preclinical models of KRAS^{G12C}-mutant NSCLC with KO-2806 and adagrasib deepens signaling inhibition at multiple nodes, including the mitogen-activated protein kinase and mTOR pathways, while decreasing cell proliferation. In both CDX and PDX models originating from NSCLC tumors, the combination of KO-2806 with adagrasib induced tumor regressions. In addition, the CDX and PDX models demonstrated enhanced duration and depth of antitumor response compared to adagrasib as a single-agent therapy.

On October 13, 2023, we presented preclinical data at the AACR-NCI-EORTC International Conference supporting the development of KO-2806 with targeted therapies, including TKIs, KRAS^{G12C} inhibitors and KRAS^{G12D} inhibitors. The first of

three posters illustrated that KO-2806 potentiates the antitumor activity of cabozantinib in ccRCC models. The second poster illustrated that KO-2806 blocks oncogenetic signaling at multiple nodes to enhance the antitumor activity of $KRAS^{G12C}$ inhibitor adagrasib in $KRAS^{G12C}$ NSCLC. The third poster illustrated that KO-2806 constrains compensatory signaling reactivation to deepen responses to $KRAS^{G12D}$ inhibition.

We believe these data support our rationale to combine KO-2806 with TKIs in ccRCC and with $KRAS^{G12C}$ inhibitors in NSCLC.

We are evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of KO-2806 as a monotherapy and in combination with other targeted therapies in the FIT-001 trial. On October 19, 2023, we announced that we dosed the first patient in the monotherapy portion of the FIT-001 trial. We anticipate dosing the first patients with KO-2806 in combination with cabozantinib in ccRCC by mid-2024. On November 2, 2023, we announced a clinical collaboration with Mirati, to evaluate the combination of KO-2806 and adagrasib in patients with NSCLC whose tumors have a $KRAS^{G12C}$ mutation. Under the terms of the agreement, Mirati will supply us with adagrasib for the NSCLC combination cohort of the FIT-001 trial, and we sponsor the trial. We anticipate initiation of the $KRAS^{G12C}$-mutant NSCLC cohort by mid-2024.

Liquidity Overview

As of December 31, 2023, we had cash, cash equivalents and short-term investments of $424.0 million.

On January 26, 2024, we completed a private placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share), or the Private Placement. We received aggregate gross proceeds from the Private Placement of approximately $150.0 million, before deducting estimated offering expenses.

In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of common stock at a price of $11.50 per share as well as pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of $11.4999 per pre-funded warrant. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately $93.6 million.

In February 2022, we entered into a Sales Agreement with SVB Securities LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co. under which we could offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We did not sell any shares of our common stock under the agreement. On November 2, 2023, we terminated the agreement with SVB Securities LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co.

On November 2, 2023, we entered into a new Sales Agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., or the ATM Facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We have not sold any shares of our common stock under the ATM facility.

In November 2022, we entered into the Loan Agreement with the Lenders, and Hercules in its capacity as administrative agent and collateral agent for itself and the Lenders, providing for up to $125.0 million in a series of Term Loans. Upon entering into the Loan Agreement, we borrowed $10.0 million of an initial $25.0 million tranche of Term Loans. On September 15, 2023, the draw period for the remaining $15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to $35.0 million at any time until March 15, 2024. We may borrow (i) an additional tranche of term loans in the amount of up to $40.0 million which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of term loans in the amount of up to $25.0 million, subject to the Lenders' investment committee approval in its sole discretion.

Also, in November 2022, we entered into a securities purchase agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which BMS purchased 1,370,171 shares of our common stock in a registered direct offering, at a purchase price of approximately $18.25 per share, for gross proceeds of approximately $25.0 million.

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 pipeline programs. Our research and development expenses consist of costs associated with our research and development activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of December 31, 2023, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

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

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

- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of doses that patients receive;
- the number of patients that participate in the clinical trials;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of analyses and tests performed during the clinical trial;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

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

Other Income, Net

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

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, 2023 and 2022

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

	Years Ended December 31,		
	2023	2022	Change
Research and development expenses	$ 115,235	$ 92,812	$ 22,423
General and administrative expenses	50,569	47,053	3,516
Other income, net	13,173	4,025	9,148

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,		
	2023	2022	Change
Ziftomenib-related costs	$ 35,933	$ 21,067	$ 14,866
Tipifarnib-related costs	12,190	19,991	(7,801)
KO-2806-related costs	10,629	5,370	5,259
Discovery stage program-related costs	5,399	2,545	2,854
Personnel costs and other expenses	38,424	33,466	4,958
Share-based compensation expense	12,660	10,373	2,287
Total research and development expenses	$ 115,235	$ 92,812	$ 22,423

The increase in ziftomenib-related research and development expenses for the year ended December 31, 2023 compared to 2022 was primarily due to increases in costs related to our registration-directed clinical trial of ziftomenib and the initiation of the ziftomenib combination trials. The decrease in tipifarnib-related research and development expenses for the year ended December 31, 2023 compared to 2022 was primarily due to the closure of our registration-directed trial of tipifarnib. The increase in KO-2806-related research and development expenses for the year ended December 31, 2023 compared to 2022 was primarily due to increased costs related to our Phase 1 clinical trial. The increase in discovery stage program-related research and development expenses for the year ended December 31, 2023 compared to 2022 was primarily due to increased research activities for our preclinical-stage product candidates. The increase in personnel costs and other expenses for the year ended December 31, 2023 compared to 2022 was primarily due to increased costs to support our ongoing clinical trials and includes employee salaries and related expenses, facilities expenses and overhead expenses. We expect our research and development expenses to increase in future periods as we continue clinical development activities for our ziftomenib and FTI programs.

General and Administrative Expenses. The increase in general and administrative expenses for the year ended December 31, 2023 compared to 2022 was primarily due to increases in professional fees and personnel costs. We expect our general and administrative expenses to increase in future periods to support our planned increase in research and development activities.

Other income, net. The increase in other income, net for the year ended December 31, 2023 compared to 2022 was primarily due to an increase in interest income.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through equity and debt financings. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities.

On January 26, 2024, we completed the Private Placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share). We received aggregate gross proceeds from the Private Placement of approximately $150.0 million, before deducting estimated offering expenses.

In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of common stock at a price of $11.50 per share as well as pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of $11.4999 per pre-funded warrant. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately $93.6 million.

On November 2, 2022, we entered into the Loan Agreement with the Lenders and Hercules, in its capacity as agent, providing for up to $125.0 million in a series of Term Loans. Under the terms of the Loan Agreement, we borrowed $10.0 million of an initial $25.0 million tranche of Term Loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining $15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to $35.0 million, or the Tranche 2 Loan, at any time until March 15, 2024. Thereafter, we may borrow (i) an additional tranche of Term Loans in the amount of up to $40.0 million, or the Tranche 3 Loan, which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of Term Loans in the amount of up to $25.0 million, or the Tranche 4 Loan, subject to the Lenders' investment committee approval in its sole discretion. All of the Term Loans have a maturity date of November 2, 2027, or the Maturity Date. Repayment of the Term Loans is interest only through (a) May 1, 2025, with the satisfaction of the Interest Only Milestone 1 Conditions (as defined in the Loan Agreement), (b) November 1, 2025, if we satisfy the Interest Only Milestone 2 Conditions (as defined in the Loan Agreement), and (c) November 1, 2026, if we satisfy the Approval Milestone (as defined in the Loan Agreement). After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%.

At our option, we may prepay all or any portion of the outstanding Term Loans at any time. Prepayments made on or prior to the third anniversary of the date of the Loan Agreement will be subject to a prepayment fee equal to 1.50% of the principal amount being prepaid. In addition, we paid a facility charge of approximately $0.1 million upon closing and an additional approximately $0.2 million of facility charges in November 2023 due to the availability of the Tranche 2 Loan. Additional facility charges will be incurred upon the availability of the Tranche 3 Loan or Tranche 4 Loan, in each case in the amount of 0.50% of the amount of such tranche of loans. The Loan Agreement also provides for an end of term fee in an amount equal to the greater of approximately (i) $1.5 million (which is 6.05% of the maximum amount of the first tranche of loans) or (ii) 6.05% of the aggregate principal amount of loan advances actually made under the Loan Agreement, which fee is due and payable on the earliest to occur of (i) the Maturity Date, (ii) the date we prepay the outstanding loans in full, and (iii) the date that the secured obligations become due and payable. Our obligations under the Loan Agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. As part of the Loan Agreement, we are subject to certain negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

On November 2, 2023, we entered into the ATM Facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We have not sold any shares of our common stock under the ATM Facility.

We have incurred operating losses and negative cash flows from operating activities since inception. As of December 31, 2023, we had an accumulated deficit of $721.4 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. 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, 2023, we had cash, cash equivalents and short-term investments of $424.0 million. Based on our current plans, we believe that our cash, cash equivalents and short-term investments as of December 31, 2023, together with the net proceeds from the Private Placement, will be sufficient to enable us to fund our operating expenses into 2027. 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. Other than our term loan facility, we do not have any committed external source of funds. Additional capital may not be available on reasonable terms, if at all. Subject to limited exceptions, our term loan facility also prohibits us from incurring indebtedness without the prior written consent of the Lenders. To the extent that we raise additional capital through the sale of stock or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, including our other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be unable to carry out our business plan. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and commercialize our product candidates even if we would otherwise prefer to develop and commercialize such product candidates ourselves, and our business, financial condition and results of operations would be materially adversely affected.

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

	Years Ended December 31,		
	2023	2022	Change
Net cash used in operating activities	$ (124,824)	$ (110,062)	$ (14,762)
Net cash provided by investing activities	15,557	32,627	(17,070)
Net cash provided by financing activities	94,783	38,565	56,218

Operating Activities. The increase of $14.8 million in net cash used in operating activities for the year ended December 31, 2023 compared to 2022 was primarily due to an increase of $16.8 million in net loss adjusted for $11.0 million in accretion of discount on marketable securities, offset by changes in operating assets and liabilities of $10.8 million.

Investing Activities. Net cash provided by investing activities for the years ended December 31, 2023 and 2022 was primarily due to maturities, offset by purchases of marketable securities.

Financing Activities. Net cash provided by financing activities for the year ended December 31, 2023 primarily related to net proceeds of $93.6 million from the sale of shares of our common stock and pre-funded warrants to purchase shares of our common stock in our June 2023 public offering. Net cash provided by financing activities for the year ended December 31, 2022 primarily related to net proceeds of $24.7 million from the BMS equity investment in November 2022, proceeds of $4.4 million from the issuance of shares of common stock under our equity plans and net proceeds of $9.4 million from the issuance of long-term debt.

Contractual Obligations and Commitments

The following is a summary of our significant contractual obligations and commitments as of December 31, 2023, in thousands:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases[1]	$ 11,362	$ 1,545	$ 3,308	$ 2,769	$ 3,740
Long-term debt[2]	10,000	—	6,105	3,895	—
Interest payments on long-term debt[3]	4,533	1,108	1,693	1,732	—
Total	$ 25,895	$ 2,653	$ 11,106	$ 8,396	$ 3,740

(1) Future minimum lease payments under our operating leases in San Diego, California and Boston, Massachusetts.

(2) Principal payments under our term loan facility.

(3) Interest payments on our term loan facility. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%. As of December 31, 2023, the interest rate on the Term Loans was 10.90%. In addition, an end of term fee will be due in an amount equal to the greater of approximately (i) $1.5 million or (ii) 6.05% of the aggregate principal amount of loan advances actually made, payable on the earliest of the maturity date, acceleration or prepayment of the Term Loans.

We enter into short-term and cancellable agreements in the normal course of operations 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 through purchase orders or other documentation. Such short-term agreements are generally outstanding for periods less than one year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice of 90 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. 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 in-license agreements are cancelable by us with written notice within 180 days or less. We may be required to pay up to approximately $80.0 million in milestone payments, plus sales royalties, in the event that regulatory and commercial milestones under the in-license agreements are achieved.

Critical Accounting Policies and Management Estimates

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

While our significant accounting policies are described in more detail in Note 2 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.

Recently Adopted Accounting Pronouncements

See Note 2 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 U.S. Treasury securities, corporate debt securities, non-U.S. government debt securities, money market funds and U.S. Agency bonds. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our 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, 2023, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Any changes would only be realized if we sold the investments prior to maturity.

We are also subject to interest expense fluctuations through our Term Loans which, as of December 31, 2023, bear interest at a rate equal to the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65% and are therefore exposed to changes in interest rates through their maturity date in November 2027. For interest expense, we do not believe that an increase or decrease in the interest rate would have a significant impact on the statements of operations and comprehensive loss. We believe that should a 10.0% change in the interest rate were to have occurred on December 31, 2023, this change would not have had a material effect on interest expense as of that date.

Inflation Risk

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended December 31, 2023, 2022 or 2021.

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 principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based on the foregoing, our principal executive and financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

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 principal executive and 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, 2023.

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, 2023 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, 2023 that have materially affected, or are reasonably likely to material affect, our internal control over financial reporting.

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, 2023, 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, 2023, 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 the Company as of December 31, 2023 and 2022, 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, 2023, and the related notes and our report dated February 27, 2024 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 27, 2024

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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 2024 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, 2023, and is incorporated herein by reference.

We have adopted a written code of ethics for directors, officers, including our principal executive and financial officer and our principal 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 & Media page. 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. 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 Accountant 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. Exhibit and Financial Statement Schedules.

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

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	Form of Warrant Agreement issued by the Registrant on November 2, 2022 to certain Lenders.		10-K (Exhibit 4.3)	2/23/2023	001-37620
4.4	Amended and Restated Warrant Agreement, dated as of November 29, 2022, by and between the Registrant and Hercules Capital, Inc.		10-K (Exhibit 4.4)	2/23/2023	001-37620
4.5	Warrant Agreement, dated as of November 29, 2022, by and between the Registrant and Hercules Capital IV, L.P.		10-K (Exhibit 4.5)	2/23/2023	001-37620
4.6	Form of Pre-Funded Warrant.		8-K (Exhibit 4.1)	6/14/2023	001-37620
4.7	Description of Registrant's Common Stock.		10-K (Exhibit 4.3)	2/25/2020	001-37620
4.8	Form of Pre-Funded Warrant.		8-K (Exhibit 4.1)	1/26/2024	001-37620
4.9***	Registration Rights Agreement, dated January 26, 2024, by and among the Registrant and the persons party thereto.		8-K (Exhibit 10.2)	1/26/2024	001-37620

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.1+	Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.		8-K (Exhibit 99.1)	6/2/2023	001-37620
10.2+	Form of Restricted Stock Purchase Agreement and Restricted Stock Purchase Award Notice under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan.		8-K (Exhibit 10.2)	3/12/2015	000-53058
10.3+	Kura Oncology, Inc. 2015 Employee Stock Purchase Plan.		8-K (Exhibit 10.3)	3/12/2015	000-53058
10.4+	Form of Indemnification Agreement by and between the Registrant and each of its directors and officers.		8-K (Exhibit 10.4)	3/12/2015	000-53058
10.5*	License Agreement, dated December 18, 2014, by and between the Registrant and Janssen Pharmaceutica NV.		10-K (Exhibit 10.5)	2/24/2021	001-37620
10.6*	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.		10-K (Exhibit 10.8)	2/24/2021	001-37620
10.7*	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.		10-K (Exhibit 10.9)	2/24/2021	001-37620
10.8+	Amended and Restated Executive Employment Agreement, effective as of January 29, 2016, by and between the Registrant and Troy E. Wilson, Ph.D., J.D.		10-K (Exhibit 10.15)	3/17/2016	001-37620
10.9	Amendment No. 1 to License Agreement, dated June 6, 2016, by and between the Registrant and Janssen Pharmaceutica NV.		10-Q (Exhibit 10.3)	8/10/2016	001-37620
10.10**	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
10.11+	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
10.12	Office Lease Agreement, dated January 8, 2020, by and between the Registrant and BRE CA Office Owners LLC.		10-Q (Exhibit 10.28)	2/25/2020	001-37620
10.13	Office Lease Agreement, dated March 24, 2020, by and between the Registrant and East Office Operating Limited Partnership.		10-Q (Exhibit 10.5)	5/4/2020	001-37620
10.14	First Amendment to Office Lease Agreement, dated May 2, 2020 by and between the Registrant and BRE CA Office Owner LLC.		10-Q (Exhibit 10.8)	5/4/2020	001-37620

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.15+	Amended and Restated Non-Employee Director Compensation Policy.		10-Q (Exhibit 10.1)	8/9/2023	001-37620
10.16+	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 10.2)	8/9/2023	001-37620
10.17	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
10.18+	Amendment to Amended and Restated Executive Employment Agreement, effective as of February 19, 2021, by and between the Registrant and Troy E. Wilson, Ph.D., J.D.		10-K (Exhibit 10.36)	2/24/2021	001-37620
10.19+	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.		10-K (Exhibit 10.22)	2/23/2023	001-37620
10.20+	Executive Employment Agreement, effective as of July 22, 2020, by and between the Registrant and Stephen Dale, M.D.		10-Q (Exhibit 10.7)	5/6/2021	001-37620
10.21+	Amendment to Executive Employment Agreement, effective as of February 22, 2021, by and between the Registrant and Stephen Dale, M.D.		10-Q (Exhibit 10.8)	5/6/2021	001-37620
10.22	Lease Agreement, dated May 11, 2021, by and between the Registrant and BP3-SD5 5510 Morehouse Drive LLC.		10-Q (Exhibit 10.1)	8/5/2021	001-37620
10.23+	Form of International Restricted Stock Unit Award Grant Notice and International Restricted Stock Unit Award Agreement under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan.		10-K (Exhibit 10.30)	2/24/2022	001-37620
10.24+	Executive Employment Agreement, effective as of October 18, 2021, by and between the Registrant and Teresa Bair.		10-K (Exhibit 10.31)	2/24/2022	001-37620
10.25	Loan and Security Agreement dated as of November 2, 2022 by and between the Registrant and Hercules Capital, Inc.		8-K (Exhibit 10.2)	11/3/2022	001-37620
10.26+	Executive Employment Agreement, effective as of August 14, 2023, by and between the Registrant and Brian Powl.		10-Q (Exhibit 10.1)	11/2/2023	001-37620
10.27	First Amendment to Lease, dated as of August 30, 2023, by and between the Registrant and East Office Operating Limited Partnership.		10-Q (Exhibit 10.2)	11/2/2023	001-37620
10.28	First Amendment to Loan and Security Agreement, dated as of October 2, 2023, by and between the Registrant and Hercules Capital, Inc.		10-Q (Exhibit 10.3)	11/2/2023	001-37620

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.29	Sales Agreement, dated November 2, 2023, by and among the Registrant, Leerink Partners LLC and Cantor Fitzgerald & Co.		10-Q (Exhibit 10.4)	11/2/2023	001-37620
10.30+	Kura Oncology, Inc. 2023 Inducement Option Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder.		8-K (Exhibit 99.1)	12/22/2023	001-37620
23.1	Consent of Independent Registered Public Accounting Firm.	X			
24.1	Power of Attorney (see signature page).	X			
31.1	Certification of Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive and Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.	X			
97.1	Kura Oncology, Inc. Incentive Compensation Recoupment Policy.	X			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101.INS).	X			

+ 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.
*** Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Kura Oncology, Inc.

Date: February 27, 2024

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 Thomas Doyle, 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 and Financial Officer)*	February 27, 2024
/s/ Thomas Doyle **Thomas Doyle**	Senior Vice President, Finance & Accounting *(Principal Accounting Officer)*	February 27, 2024
/s/ Helen Collins, M.D. **Helen Collins, M.D.**	Director	February 27, 2024
/s/ Faheem Hasnain **Faheem Hasnain**	Director	February 27, 2024
/s/ Thomas Malley **Thomas Malley**	Director	February 27, 2024
/s/ Diane Parks **Diane Parks**	Director	February 27, 2024
/s/ Carol Schafer **Carol Schafer**	Director	February 27, 2024
/s/ Mary Szela **Mary Szela**	Director	February 27, 2024

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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 27, 2024 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 2023, the Company incurred $115.2 million for research and development expenses and as of December 31, 2023, the Company accrued $7.7 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 are accrued and expensed based on estimates of the period in which services and efforts are expended by contract research organizations ("CROs") and other third parties. Estimates are determined by reviewing cost information provided by CROs and other third-party vendors, contractual arrangements with CROs and the scope of work to be performed. Auditing management's accounting for accrued third-party clinical trial research and development expenses is especially 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.
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 third-party clinical trial research and development expenses. This included management's assessment of the assumptions and data underlying the accrued third-party clinical trial research and development expenses estimate. To test the completeness of the Company's accrued third-party 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 supporting evidence of clinical trial and project status review between internal personnel and third-party service providers to corroborate the status of significant research and development activities. We performed inquiries with clinical project managers to corroborate the status of significant research and development activities. To test 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 third-party clinical trial research and development expenses.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

San Diego, California
February 27, 2024

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 37,318	$ 51,802
Short-term investments	386,639	386,183
Prepaid expenses and other current assets	8,524	8,441
Total current assets	432,481	446,426
Property and equipment, net	1,859	2,540
Operating lease right-of-use assets	6,993	3,842
Other long-term assets	7,602	3,498
Total assets	$ 448,935	$ 456,306
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 33,757	$ 21,739
Current operating lease liabilities	1,506	2,318
Total current liabilities	35,263	24,057
Long-term debt, net	9,332	9,158
Long-term operating lease liabilities	6,362	2,548
Other long-term liabilities	705	265
Total liabilities	51,662	36,028
Commitments and contingencies (Note 8)		
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; 74,350 and 68,314 shares issued and outstanding as of December 31, 2023 and 2022, respectively	7	7
Additional paid-in capital	1,119,976	997,111
Accumulated other comprehensive loss	(1,271)	(8,032)
Accumulated deficit	(721,439)	(568,808)
Total stockholders' equity	397,273	420,278
Total liabilities and stockholders' equity	$ 448,935	$ 456,306

See accompanying notes to financial statements.

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Operating Expenses:			
Research and development	$ 115,235	$ 92,812	$ 84,721
General and administrative	50,569	47,053	46,537
Total operating expenses	165,804	139,865	131,258
Other Income (Expense):			
Interest and other income, net	14,722	4,254	1,206
Interest expense	(1,549)	(229)	(414)
Total other income, net	13,173	4,025	792
Net Loss	$ (152,631)	$ (135,840)	$ (130,466)
Net loss per share, basic and diluted	$ (2.08)	$ (2.03)	$ (1.97)
Weighted average number of shares used in computing net loss per share, basic and diluted	73,229	66,990	66,352
Comprehensive Loss:			
Net loss	$ (152,631)	$ (135,840)	$ (130,466)
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities and foreign currency	6,761	(6,243)	(1,835)
Comprehensive loss	$ (145,870)	$ (142,083)	$ (132,301)

See accompanying notes to financial statements.

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Capital			
Balance as of December 31, 2020	66,194	$ 7	$ 913,354	$ 46	$ (302,502)	$ 610,905
Share-based compensation expense	—	—	23,579	—	—	23,579
Issuance of common stock under equity plans	378	—	4,426	—	—	4,426
Other comprehensive loss	—	—	—	(1,835)	—	(1,835)
Net loss	—	—	—	—	(130,466)	(130,466)
Balance as of December 31, 2021	66,572	7	941,359	(1,789)	(432,968)	506,609
Issuance of common stock, net of offering costs	1,370	—	24,721	—	—	24,721
Share-based compensation expense	—	—	26,318	—	—	26,318
Issuance of common stock under equity plans	372	—	4,419	—	—	4,419
Issuance of warrants in connection with debt facility	—	—	294	—	—	294
Other comprehensive loss	—	—	—	(6,243)	—	(6,243)
Net loss	—	—	—	—	(135,840)	(135,840)
Balance as of December 31, 2022	68,314	7	997,111	(8,032)	(568,808)	420,278
Issuance of common stock, net of offering costs	5,661	—	60,919	—	—	60,919
Issuance of pre-funded warrants to purchase common stock, net of offering costs	—	—	32,658	—	—	32,658
Share-based compensation expense	—	—	28,082	—	—	28,082
Issuance of common stock under equity plans	375	—	1,206	—	—	1,206
Other comprehensive income	—	—	—	6,761	—	6,761
Net loss	—	—	—	—	(152,631)	(152,631)
Balance as of December 31, 2023	74,350	$ 7	$ 1,119,976	$ (1,271)	$ (721,439)	$ 397,273

See accompanying notes to financial statements.

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Operating Activities			
Net loss	$ (152,631)	$ (135,840)	$ (130,466)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	28,082	26,318	23,579
Amortization of premium and accretion of discounts on marketable securities, net	(9,420)	1,610	4,391
Depreciation expense	849	759	558
Non-cash interest expense	477	73	399
Loss from extinguishment of debt	—	—	212
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,960)	(2,935)	(357)
Operating lease right-of-use and other long-term assets	(685)	571	(329)
Accounts payable and accrued expenses	10,327	(802)	(2,518)
Other long-term liabilities	137	184	(20)
Net cash used in operating activities	(124,824)	(110,062)	(104,551)
Investing Activities			
Maturities of marketable securities	425,549	303,908	319,969
Purchases of marketable securities	(409,824)	(270,655)	(445,657)
Purchases of property and equipment	(168)	(626)	(1,147)
Net cash provided by (used in) investing activities	15,557	32,627	(126,835)
Financing Activities			
Proceeds from issuances of common stock and pre-funded warrants, net of offering costs	93,577	24,721	—
Proceeds from issuance of stock under equity plans	1,206	4,419	4,426
Proceeds from long-term debt	—	10,000	—
Payment of fees related to issuance of long-term debt	—	(575)	—
Repayment of long-term debt	—	—	(7,250)
Payment of fees related to extinguishment of debt	—	—	(611)
Net cash provided by (used in) financing activities	94,783	38,565	(3,435)
Net decrease in cash, cash equivalents	(14,484)	(38,870)	(234,821)
Cash and cash equivalents at beginning of period	51,802	90,672	325,493
Cash and cash equivalents at end of period	$ 37,318	$ 51,802	$ 90,672
Supplemental disclosure of cash flow information:			
Interest paid	$ 1,064	$ 73	$ 784
Supplemental non-cash disclosures:			
Warrants issued in connection with debt facility	$ —	$ 294	$ —

See accompanying 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 are conducting clinical trials of three product candidates: ziftomenib, tipifarnib and KO-2806. We also have additional programs that are at a discovery stage. We own global commercial rights to all of our programs and product candidates. 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

The prior period restricted cash balance of approximately $0.2 million has been reclassified to other long-term assets in the accompanying financial statements. See Note 8, Commitments and Contingencies, for further details.

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. Troy E. Wilson, our president and chief executive officer, who serves as the 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.

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 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 and other income, net on the statements of operations and comprehensive loss.

Allowance for Credit Losses

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

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

Concentration of Credit Risk

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

Employee Retention Credit

Under the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, we were eligible to claim the employee retention credit, which is a refundable tax credit against certain employment taxes. For the year ended December 31, 2023, we recognized $2.8 million of employee retention credits related to wages paid to our employees from July 2020 through September 2021 within operating expenses as a reduction to personnel costs in the statements of operations and comprehensive loss. We filed for the credit with the Internal Revenue Service in the first quarter of 2023. As of December 31, 2023, an employee retention credit receivable of $2.8 million was included within prepaid expenses and other current assets on the balance sheets.

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.

Property and Equipment

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

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, 2023, 2022 and 2021, 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. We do not separate lease components from non-lease components. For our operating leases, we generally cannot determine the interest rate implicit in the lease, in which case we use our incremental borrowing rate as the discount rate for the lease. We estimate our incremental borrowing rate for our operating leases based on what we would normally pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments. Operating lease expense is recognized on a straight-line basis over the lease term.

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

Research and Development Expenses

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 when these expenditures have no alternative future uses. We are obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as expense as the related goods are delivered or the related services are performed or such time when we do not expect the goods to be delivered or services to be performed. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise, and therefore have no separate economic value, are expensed as research and development costs at the time such costs are incurred. As of December 31, 2023, 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 contracts. Accordingly, our clinical trial expense accrual is dependent upon the timely and accurate reporting of CROs and other third-party vendors. If the contracted amounts are modified, for instance, as a result of changes in the clinical trial protocol or scope of work to be performed, we modify our accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Historically, we have had no material changes in clinical trial expense that had a material impact on our results of operations or financial position.

Patent Costs

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

Share-Based Compensation

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 assumptions including volatility, expected term, risk-free rate and the fair value of the underlying common stock. We estimate the fair value of restricted stock units and performance-based restricted stock units granted based on the closing market price of our common stock on the date of grant. 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.

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 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, which includes the shares related to outstanding pre-funded warrants (see Note 9), but excludes other potential common stock equivalents. Pre-funded warrants are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little or no additional consideration, and are fully vested and exercisable. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period. As we have reported net loss for the years ended December 31, 2023, 2022 and 2021, dilutive net loss per common share is the same as basic net loss per common share for those periods. Common stock equivalents outstanding are comprised of stock options, restricted stock units, performance-based restricted stock units, warrants and employee stock purchase plan rights and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. Common stock equivalents outstanding as of December 31, 2023, 2022 and 2021 totaling approximately 12,642,000, 9,266,000 and 7,156,000, respectively, were excluded from the computation of dilutive weighted-average shares outstanding because their effect would be anti-dilutive.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that we adopt as of the specified effective date. We have evaluated recently issued accounting pronouncements and, based on our preliminary assessment, we do not believe any will have a material impact on our financial statements or related footnote disclosures.

3. Investments

We invest in available-for-sale securities consisting of U.S. Treasury securities, corporate debt securities, non-U.S. government and supranational debt securities, money market funds, U.S. Agency bonds and commercial paper. 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, 2023			
	Maturities (years)	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Estimated Fair Value**
Cash equivalents:					
Money market funds	1 or less	$ 13,590	$ —	$ —	$ 13,590
Short-term investments:					
U.S. Treasury securities	2 or less	300,388	395	(569)	300,214
Corporate debt securities	2 or less	64,591	4	(825)	63,770
Non-U.S. government debt securities	1 or less	15,000	—	(273)	14,727
U.S. Agency bonds	1 or less	7,931	—	(3)	7,928
Total short-term investments		387,910	399	(1,670)	386,639
Total		$ 401,500	$ 399	$ (1,670)	$ 400,229

	Maturities (years)	December 31, 2022 Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:					
Money market funds	1 or less	$ 37,878	$ —	$ —	$ 37,878
U.S. Agency bonds	1 or less	9,956	—	—	9,956
Total cash equivalents		47,834	—	—	47,834
Short-term investments:					
U.S. Treasury securities	2 or less	183,051	16	(3,018)	180,049
Corporate debt securities	2 or less	115,763	—	(3,931)	111,832
Commercial paper	1 or less	52,941	—	—	52,941
Non-U.S. government and supranational debt securities	2 or less	26,268	—	(950)	25,318
U.S. Agency bonds	1 or less	16,192	11	(160)	16,043
Total short-term investments		394,215	27	(8,059)	386,183
Total		$ 442,049	$ 27	$ (8,059)	$ 434,017

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, 2023 and 2022, short-term investments of $336.6 million and $274.3 million, respectively, had maturities less than one year, and short-term investments of $50.0 million and $111.9 million, respectively, had maturities between one to two years. Realized gains and losses were de minimis for the years ended December 31, 2023, 2022 and 2021.

As of December 31, 2023 and 2022, 16 available-for-sale securities with a fair market value of $155.2 million and 34 available-for-sale securities with a fair market value of $290.0 million, respectively, were in gross unrealized loss positions, $105.0 million and $172.4 million of which were in a continuous unrealized loss position for greater than 12 months, respectively. We do not intend to sell these available-for-sale 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 securities, the unrealized losses as of December 31, 2023 were primarily due to changes in interest rates and not due to increased credit risks associated with specific securities. We have no allowance for credit losses as of December 31, 2023 and 2022. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss.

Accrued interest receivable on available-for-sale securities were $1.1 million and $0.9 million as of December 31, 2023 and 2022, respectively. We have not written off any accrued interest receivables for the years ended December 31, 2023, 2022 and 2021.

4. Fair Value Measurements

As of December 31, 2023 and 2022, we had cash equivalents and short-term investments measured at fair value on a recurring basis.

Available-for-sale securities consist of U.S. Treasury securities, which are measured at fair value using Level 1 inputs, and corporate debt securities, non-U.S. government and supranational debt securities, U.S. Agency bonds 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, 2023		
	Total	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 13,590	$ 13,590	$ —
Short-term investments:			
U.S. Treasury securities	300,214	300,214	—
Corporate debt securities	63,770	—	63,770
Non-U.S. government debt securities	14,727	—	14,727
U.S. Agency bonds	7,928	—	7,928
Total short-term investments	386,639	300,214	86,425
Total	$ 400,229	$ 313,804	$ 86,425

	December 31, 2022		
	Total	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 37,878	$ 37,878	$ —
U.S. Agency bonds	9,956	—	9,956
Total cash equivalents	47,834	37,878	9,956
Short-term investments:			
U.S. Treasury securities	180,049	180,049	—
Corporate debt securities	111,832	—	111,832
Commercial paper	52,941	—	52,941
Non-U.S. government and supranational debt securities	25,318	—	25,318
U.S. Agency bonds	16,043	—	16,043
Total short-term investments	386,183	180,049	206,134
Total	$ 434,017	$ 217,927	$ 216,090

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 6, Long-Term Debt, for further discussion of our term loan facility.

5. Balance Sheet Detail

Property and equipment consisted of the following, in thousands:

	December 31,	
	2023	2022
Laboratory and computer equipment	$ 1,657	$ 1,568
Leasehold improvements	1,543	1,543
Furniture and fixtures	1,111	1,032
Property and equipment, gross	4,311	4,143
Less: accumulated depreciation	(2,452)	(1,603)
Property and equipment, net	$ 1,859	$ 2,540

Depreciation expense was $0.8 million, $0.8 million and $0.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

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

	December 31,	
	2023	2022
Accounts payable	$ 2,300	$ 1,533
Accrued clinical trial research and development expenses	7,737	2,440
Accrued other research and development expenses	9,265	5,030
Accrued compensation and benefits	13,153	10,300
Other accrued expenses	1,302	2,436
Total accounts payable and accrued expenses	$ 33,757	$ 21,739

6. Long-Term Debt

On November 2, 2022, we entered into a loan and security agreement, or Loan Agreement, with several banks and other financial institutions or entities party thereto, or collectively Lenders, and Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent for itself and the Lenders, or in such capacity, Agent. Under the terms of the Loan Agreement, we borrowed $10.0 million of an initial $25.0 million tranche of term loans, or the Tranche 1 Loan. On September 15, 2023, the draw period for the remaining $15.0 million of the Tranche 1 Loan expired without us drawing down the additional loan. We have achieved the Tranche 2 Milestone (as defined in the Loan Agreement) and may borrow up to $35.0 million at any time until March 15, 2024. Thereafter, we may borrow (i) an additional tranche of Term Loans in the amount of up to $40.0 million which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan Agreement, and (ii) a final tranche of term loans in the amount of up to $25.0 million, subject to the Lenders' investment committee approval in its sole discretion. All of the Term Loans have a maturity date of November 2, 2027, or the Maturity Date. Repayment of the Term Loans is interest only through (a) May 1, 2025, with the satisfaction of the Interest Only Milestone 1 Conditions (as defined in the Loan Agreement), (b) if we satisfy the Interest Only Milestone 2 Conditions (as defined in the Loan Agreement), November 1, 2025, and (c) if we satisfy the Approval Milestone (as defined in the Loan Agreement), November 1, 2026. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The per annum interest rate for the Term Loans is the greater of (i) the prime rate as reported in The Wall Street Journal minus 6.25% plus 8.65% and (ii) 8.65%. As of December 31, 2023, the interest rate on the Term Loans was 10.90%.

At our option, we may prepay all or any portion of the outstanding Term Loans at any time. Prepayments made on or prior to the third anniversary of the date of the Loan Agreement will be subject to a prepayment fee equal to 1.50% of the principal amount being prepaid. In addition, we paid a facility charge of approximately $0.1 million upon closing and an additional approximately $0.2 million of facility charges in November 2023 due to the availability of the Tranche 2 Loan. Additional facility charges will be incurred upon the availability of the Tranche 3 Loan or Tranche 4 Loan, in each case in the amount of 0.50% of the amount of such tranche of loans. The Loan Agreement also provides for an end of term fee in an amount equal to the greater of approximately (i) $1.5 million (which is 6.05% of the maximum amount of the first tranche of loans) or (ii) 6.05% of the aggregate principal amount of loan advances actually made under the Loan Agreement, which fee is due and payable on the earliest to occur of (i) the Maturity Date, (ii) the date we prepay the outstanding loans in full, and (iii) the date that the secured obligations become due and payable. Our obligations under the Loan Agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. As part of the Loan Agreement, we are subject to certain negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

The Loan Agreement also contains a minimum cash covenant, commencing on June 1, 2024, requiring us to hold cash in the United States and subject to a first-priority perfected security interest in favor of the Lenders in an amount greater than or equal to (x) 55.0% of the outstanding loan obligations if we have not received FDA approval for ziftomenib, or (y) 35.0% of the outstanding loan obligations if we have received FDA approval for ziftomenib, provided that neither (x) nor (y) will apply at any time our market capitalization is equal to or greater than $1,250.0 million. Additionally, the Loan Agreement contains minimum cash requirements in the event of (i) any Corporate Collaborations (as defined in the Loan Agreement) or (ii) any cash payment in respect of permitted convertible debt subject to the satisfaction of the Redemption Conditions (as defined in the Loan Agreement).

In addition, the Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. The Loan Agreement also contains events of default that are customary for financings of this type relating to, among other things, payment defaults, breach of covenants, material adverse effects, breach of representations and warranties, cross-default to material indebtedness, bankruptcy-related defaults, judgment defaults, breach of the financial covenants described above, and the occurrence of certain change of control events. Following an event of default and any applicable cure period, a default interest rate equal to the then-applicable interest rate plus 5.0% may be applied to the outstanding principal balance, and the Lenders will have the right upon notice to terminate any undrawn commitments and may accelerate all amounts outstanding under the Loan Agreement, in addition to other remedies available to them as our secured creditors. We were in compliance with all covenants of the Loan Agreement as of December 31, 2023.

In addition, in connection with the entry into the Loan Agreement, we issued warrants to certain of the Lenders, or collectively, the Warrants, to purchase up to 26,078 shares of our common stock at an exercise price of $14.38 per share, or the Warrant Shares. The Warrants may be exercised through the earlier of (i) the seventh anniversary of November 2, 2022 and (ii) the consummation of certain acquisition transactions involving us, as set forth in the Warrants. The number of Warrant Shares for which the Warrants are exercisable and the associated exercise price are subject to certain customary proportional adjustments for fundamental events, including stock splits and reverse stock splits, as set forth in the Warrants. If we make additional draws on the Tranche 2 Loan, Tranche 3 Loan or Tranche 4 Loan, upon the funding of such additional tranches, the Warrants shall become exercisable for an additional aggregate number of shares of our common stock equal to 1.50% of each drawn amount divided by the exercise price of $14.38 per share.

The initial tranche 1 borrowing of $10.0 million and the warrants issued upon closing to purchase 26,078 shares of our common stock are accounted for as freestanding debt and equity financial instruments, respectively, as they are legally detachable and separately exercisable. The additional borrowings available under the Tranche 1 Loan, Tranche 2 Loan, Tranche 3 Loan and Tranche 4 Loan plus the additional warrants to purchase shares of our common stock, which would be issued concurrently, are accounted for as a single freestanding financial instrument that are not assets or obligations of ours; this financial instrument meets the loan commitment derivative scope exception and will be accounted for when and if we borrow additional tranches in the future.

In connection with the Loan Agreement, we recognized the initial 26,078 issued warrants at their relative fair value of approximately $0.3 million, and we incurred debt issuance costs of $0.6 million, which were recorded as debt discounts. The fair value of the warrants, debt issuance costs and end of term fee are being amortized and accreted into interest expense using the effective interest rate method over the term of the loan.

The following table summarizes maturities of principal obligation payments under the term loan facility as of December 31, 2023, in thousands:

Years Ending December 31,		
2025	$	2,307
2026		3,798
2027		3,895
Total principal outstanding		10,000
Less: unamortized discounts		(668)
Long-term debt, net	$	9,332

In November 2018, we entered into a loan and security agreement with Silicon Valley Bank, or 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 SVB Term Loan. The SVB Term Loan had a scheduled maturity date of May 1, 2023. In May 2021, we paid $6.6 million to repay all amounts owed under the SVB Term Loan, which included a final payment of $0.6 million, representing 7.75% of the SVB Term Loan which was being accrued through interest expense using the effective interest method, and a prepayment fee of $30,000. In accordance with ASC 470-50, Debt Modifications and Extinguishments, we accounted for the transaction as an extinguishment of debt. Accordingly, we recorded a loss of approximately $0.2 million, which is included in interest expense on the statements of operations and comprehensive loss for the year ended December 31, 2021.

7. License Agreements

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 ziftomenib. 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.

Janssen License Agreement

In December 2014, we entered into a license agreement with Janssen which was amended in June 2016, under which we received certain intellectual property rights related to tipifarnib in all indications other than virology for a non-refundable $1.0 million upfront license fee and payments upon achievement of certain development and sales-based milestones. Tipifarnib is a clinical-stage compound and all ongoing development, regulatory and commercial work will be completed fully and at our sole expense.

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.

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, 2023, we have paid milestone payments totaling $0.3 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.

8. Commitments and Contingencies

Operating Leases

We currently have three operating leases for administrative and research and development office and lab space in San Diego, California and Boston, Massachusetts that expire between July 2024 and July 2031. Under the terms of the operating leases, we are required to pay our proportionate share of property taxes, insurance and normal maintenance costs. Two of our leases include renewal options for an additional five years, which were not included in the determination of the ROU asset or lease liability as the renewal was not reasonably certain at the inception of the lease. Our San Diego corporate headquarters lease and our San Diego lease for lab and office space provided for $1.0 million and $0.1 million, respectively, in reimbursements for allowable tenant improvements, which effectively reduced the total lease payments owed.

On August 30, 2023, we entered into an amendment to the lease agreement for office space in Boston, Massachusetts, or the Amendment, pursuant to which the term of the lease was extended by seven years, or the Extended Term, such that the lease will now expire in July 2031. The minimum rent payable during the Extended Term is approximately $0.1 million per month for the first year, which amount will increase by 2% per year over the Extended Term. The Amendment provides (i) a rent credit in the amount of approximately $0.5 million to be applied as a credit against the rent payments due for the months of August 2023 through July 2024, inclusive, and (ii) a tenant improvement allowance in an amount not to exceed approximately $0.8 million, in each case subject to certain conditions. We elected to apply the tenant improvement allowance as a credit against the rent payments due for the months of August 2024 through March 2025, inclusive. Prior to the Amendment, we were required to maintain a standby letter of credit of approximately $0.2 million during the term of the lease. Under the terms of the Amendment, we are required to maintain a cash deposit of approximately $0.2 million during the term of the lease which was included within other long-term assets in the balance sheet.

Maturities of our lease liabilities as of December 31, 2023 are as follows, in thousands:

Year Ending December 31,		
2024	$	1,545
2025		1,964
2026		1,344
2027		1,371
2028		1,398
Thereafter		3,740
Total lease payments		11,362
Less: imputed interest		(3,494)
Total operating lease liabilities	$	7,868

As of December 31, 2023 and 2022, the weighted-average discount rate was 10.4% and 5.5%, respectively, and the weighted-average remaining lease term was 6.2 years and 2.3 years, respectively.

Total cash paid for amounts included in the measurement of operating lease liabilities, net of tenant improvement reimbursements, was $2.1 million, $2.3 million and $2.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. Operating lease ROU assets obtained in exchange for operating lease liabilities were $4.7 million, zero and $1.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Total operating lease expense and rent expense were approximately $2.0 million for all the years ended December 31, 2023, 2022 and 2021.

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.

9. Stockholders' Equity

In June 2023, we completed a public offering in which we sold an aggregate of 5,660,871 shares of our common stock at a price of $11.50 per share and pre-funded warrants to purchase 3,034,782 shares of our common stock at a price of $11.4999 per pre-funded warrant. The exercise price of each pre-funded warrant is $0.0001 per share and the pre-funded warrants are exercisable from the date of issuance until fully exercised. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately $93.6 million.

In February 2022, we entered into a Sales Agreement with SVB Securities LLC, Credit Suisse Securities (USA) LLC and Cantor Fitzgerald & Co., or the 2022 Sales Agreement, under which we could offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We did not sell any shares of our common stock under the 2022 Sales Agreement.

On November 2, 2023, we terminated the 2022 Sales Agreement and we entered into a new Sales Agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., or the ATM Facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million. We have not sold any shares of our common stock under the ATM Facility.

In November 2022, we entered into a securities purchase agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which BMS purchased an aggregate of 1,370,171 shares of our common stock at a purchase price of approximately $18.25 per share, for gross proceeds of approximately $25.0 million.

In November 2022, in connection with the Loan Agreement, we issued warrants to certain of the Lenders to purchase up to 26,078 shares of our common stock at an exercise price of $14.38 per share, which are outstanding as of December 31, 2023.

In connection with the loan and security agreement with Oxford Finance LLC and Silicon Valley Bank in 2016, we issued a warrant to Oxford Finance LLC to purchase up to 33,988 shares of our common stock at an exercise price of $3.31 per share, which remains outstanding as of December 31, 2023.

10. Share-Based Compensation

Equity Incentive Plan

In March 2015, our board of directors adopted our Amended and Restated 2014 Equity Incentive Plan, which was most recently amended in May 2023, or 2014 Plan, to, among other things, increase the shares available for future grant by 4,050,000 shares and remove the automatic annual 4% increase to shares available for future grant. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation to our employees, consultants and members of our board of directors. We issue shares of common stock upon the exercise of options and vesting of restricted stock unit awards and performance-based restricted stock unit awards with the source of those shares of common stock being newly issued shares. As of December 31, 2023, 24,327,686 shares of common stock had been reserved for issuance and 3,713,092 shares of common stock were available for grant under the 2014 Plan.

Inducement Option Plan

On December 18, 2023, our board of directors adopted the 2023 Inducement Option Plan, or Inducement Plan, to reserve 600,000 shares of our common stock to be used exclusively for grants of nonstatutory stock options to individuals that were not previously our employees or directors (or following a bona fide period of non-employment), as an inducement material to the individual's entry into employment with us, pursuant to Nasdaq Listing Rule 5635(c)(4). The terms and conditions of the Inducement Plan are substantially similar to our 2014 Plan. As of December 31, 2023, there were 600,000 shares available to be issued from the Inducement Plan.

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 six-month 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. 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 2023, the compensation committee of our board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in 2024. As of December 31, 2023, we have issued 250,573 shares of common stock, and 653,852 shares of common stock are reserved for future issuance under the ESPP. Share-based compensation expense related to the ESPP for the years ended December 31, 2023, 2022 and 2021 was $0.3 million in each year.

Stock Options, Restricted Stock Unit Awards and Performance-Based Restricted Stock Unit Awards

Stock Options

The exercise price of all stock options granted was equal to the fair market value of such stock on the date of grant. Stock options generally vest over a 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, 2023, in thousands (except per share and years data):

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	8,425	$ 18.12		
Granted	2,857	$ 11.74		
Exercised	(83)	$ 6.40		
Canceled	(902)	$ 18.01		
Outstanding as of December 31, 2023	10,297	$ 16.46	7.3	$ 12,883
Vested and expected to vest as of December 31, 2023	10,297	$ 16.46	7.3	$ 12,883
Exercisable as of December 31, 2023	5,962	$ 17.76	6.3	$ 6,000

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock as of December 31, 2023 of $14.38 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 (except per share data):

	Years Ended December 31,		
	2023	2022	2021
Cash received from options exercised	$ 534	$ 3,756	$ 3,809
Intrinsic value of options exercised	$ 280	$ 701	$ 3,475
Weighted-average grant date fair value per share	$ 6.99	$ 8.90	$ 17.84

As of December 31, 2023, unrecognized estimated compensation expense related to stock options was $37.1 million, which is expected to be recognized over the weighted-average remaining requisite service period of approximately 2.4 years.

Restricted Stock Unit Awards

Restricted stock unit awards, or RSUs, are share awards that, upon vesting, will deliver to the holder shares of our common stock. We began issuing RSUs in 2021. The RSUs generally vest annually over four years.

The following is a summary of RSU activity for the year ended December 31, 2023, in thousands (except per share and years data):

	Number of RSUs	Weighted Average Grant Date Fair Value per Share	Weighted Average Remaining Vesting Period (years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	768	$ 16.20		
Granted	528	$ 11.97		
Released	(218)	$ 16.59		
Canceled	(122)	$ 14.25		
Outstanding as of December 31, 2023	956	$ 14.03	1.2	$ 13,748
Expected to vest as of December 31, 2023	956	$ 14.03	1.2	$ 13,748

As of December 31, 2023, unrecognized estimated compensation expense related to RSUs was $9.1 million, which is expected to be recognized over the weighted-average remaining requisite service period of approximately 2.2 years.

Performance-Based Restricted Stock Unit Awards

On May 31, 2023, upon approval by our stockholders of our amended 2014 Plan, we granted an aggregate of 1,313,100 performance-based restricted stock units, or PSUs, to certain executives. The PSUs vest in six equal tranches upon the achievement of certain milestones and service conditions.

As of December 31, 2023, we determined that the vesting of the PSUs was not probable and therefore have not included them in share-based compensation expense or unrecognized estimated compensation expense.

Share-Based Compensation Expense

Total share-based compensation expense included on the statements of operations and comprehensive loss was comprised of the following, in thousands:

	Years Ended December 31,		
	2023	2022	2021
Research and development	$ 12,660	$ 10,373	$ 7,454
General and administrative	15,422	15,945	16,125
Total share-based compensation expense	$ 28,082	$ 26,318	$ 23,579

We estimated the fair value of stock options and ESPP stock purchase rights using the Black-Scholes model based on the date of grant with the following assumptions:

	Options			ESPP		
	Years Ended December 31,			Years Ended December 31,		
	2023	2022	2021	2023	2022	2021
Expected term (in years)	5.48 — 6.05	5.45 — 6.57	5.50 — 6.08	0.50	0.50	0.50
Expected volatility	59.9% — 66.9%	67.1% — 71.9%	72.0% — 74.6%	51.0% — 52.7%	61.0% — 75.8%	44.8% — 61.8%
Risk-free interest rate	3.5% — 4.7%	1.6% — 4.2%	0.6% — 1.3%	5.4%	1.6%— 4.6%	0.0%— 0.1%
Expected dividend yield	—	—	—	—	—	—

Expected term. The expected term of stock options represents the period that the stock options are expected to remain outstanding. Beginning in 2022, we determined our expected term assumption using our own historical exercise experience. In prior years, due to our limited historical exercise behavior, we determined the expected term assumption using the simplified method. The expected term of the ESPP stock purchase rights is six months, which represents the length of each purchase period.

Expected volatility. Beginning in 2022, expected volatility for stock options was calculated based on our historical volatility. In prior years, due to our limited trading history, expected volatility was based, in part, on our historical volatility and the historical volatility of comparable publicly-traded companies. Expected volatility for the ESPP stock purchase rights is based on our historical volatility.

Risk-free interest rate. 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.

Expected dividend yield. 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.

11. 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. 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, 2023, 2022 and 2021, we recorded management fee income of approximately $0.1 million each year, which is included in interest and other income, net on the statements of operations and comprehensive loss. In addition, the agreement allows for Araxes to reimburse us an amount equal to the number of full-time equivalents performing research and development services for Araxes, plus actual expenses as reasonably incurred. For the years ended December 31, 2023, 2022 and 2021, we did not record any reimbursements for research and development expenses provided to Araxes.

12. 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 provided a safe harbor contribution of 4.0% of the employee's compensation, not to exceed eligible limits. For the years ended December 31, 2023, 2022 and 2021, we incurred approximately $1.5 million, $1.2 million and $1.0 million, respectively, in expenses related to the safe harbor contribution.

13. Income Taxes

For the years ended December 31, 2023, 2022 and 2021, 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, 2023, 2022 and 2021, due to the following, in thousands:

	Years Ended December 31,		
	2023	2022	2021
Income taxes at statutory federal rate	$ (32,053)	$ (28,526)	$ (27,398)
State income tax, net of federal benefit	(11,027)	(9,721)	(9,758)
Research and development tax credits	(10,551)	(6,970)	(5,850)
Share-based compensation	4,125	3,998	2,819
Other	(332)	(69)	(496)
Valuation allowance	49,838	41,288	40,683
Income tax expense	$ —	$ —	$ —

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

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 144,451	$ 125,986
Research and development tax credit carryforwards	31,816	20,876
Section 174 capitalization	33,947	16,684
Share-based compensation	8,946	6,599
Accruals	3,396	2,713
Operating lease liabilities	2,311	1,430
Other	1,139	1,018
Other comprehensive income	373	2,360
Total deferred tax assets	226,379	177,666
Deferred tax liabilities	(2,198)	(1,338)
Less: valuation allowance	(224,181)	(176,328)
Net deferred tax assets	$ —	$ —

As of December 31, 2023, we had federal net operating loss, or NOL, carryforwards of $457.3 million, of which $381.8 million can be carried forward indefinitely. The remaining federal net operating loss carryforwards of $75.5 million will begin to expire in 2034, unless previously utilized. As of December 31, 2023, we had state loss carryforwards of $703.4 million, which will begin to expire in 2030, unless previously utilized. We also have federal and state research and development credit carryforwards of $35.1 million and $7.7 million, respectively, as of December 31, 2023. The federal research and development credits will begin to expire in 2034, unless previously utilized. Of the state research and development credits, $3.7 million will carryforward indefinitely and approximately $4.0 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 increased by $47.9 million from December 31, 2023.

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, 2021. We plan to complete a 382 study for 2023, however, we do not expect any material limitations to the utilization of NOL's 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.

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

	December 31,		
	2023	2022	2021
Gross unrecognized tax benefits at the beginning of the year	$ 6,485	$ 4,402	$ 2,978
Increases related to prior year tax positions	82	67	—
Increases from tax positions taken in the current year	3,547	2,016	1,424
Gross unrecognized tax benefits at the end of the year	$ 10,114	$ 6,485	$ 4,402

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 on the balance sheets as of December 31, 2023 and 2022, and we have not recognized interest and penalties on the statements of operations and comprehensive loss for the years ended December 31, 2023, 2022 or 2021.

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.

14. Subsequent Events

On January 26, 2024, we completed a private placement in which we sold to certain institutional accredited investors an aggregate of 1,376,813 shares of our common stock at a purchase price of $17.25 per share and pre-funded warrants to purchase up to an aggregate of 7,318,886 shares of common stock at a purchase price of $17.2499 per pre-funded warrant (representing the $17.25 per share purchase price less the exercise price of $0.0001 per warrant share), or the Private Placement. We received aggregate gross proceeds from the Private Placement of approximately $150.0 million, before deducting estimated offering expenses.

Exhibit 23.1

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. 333-275279 and 333-276995) of Kura Oncology, Inc.,
2. Registration Statement (Form S-8 Nos. 333-203504, 333-210260 and 333-263000) 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, 333-236621, 333-253441, 333-269974 and 333-272389) pertaining to the Amended and Restated 2014 Equity Incentive Plan of Kura Oncology, Inc.;

of our reports dated February 27, 2024, 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, 2023.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2024

Exhibit 31.1

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

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

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

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

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

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

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

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

Date: February 27, 2024

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

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

Exhibit 32.1

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

In connection with the Annual Report of Kura Oncology, Inc. (the "Company") on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, Ph.D., J.D., as President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: February 27, 2024

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

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

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.

Exhibit 97.1

KURA ONCOLOGY, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") of Kura Oncology, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an

Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any

action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

KURA ONCOLOGY, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Kura Oncology, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Kura Oncology, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

EXECUTIVE OFFICER

By: _____
Name: _____
Title: _____
Date: _____

KURA ONCOLOGY, INC.

By: _____
Name: _____
Title: _____
Name: _____