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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended June 30, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period From _____ To _____

Commission file number: 001-37620

KURA ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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)**

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

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

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

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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of the close of business on August 3, 2020, the registrant had 56,283,079 shares of Common Stock ($0.0001 par value) outstanding.

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ITEM 1. FINANCIAL STATEMENTS

KURA ONCOLOGY, INC.

Condensed Balance Sheets
(In thousands, except par value data)

	June 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 134,758	$ 26,135
Short-term investments	204,111	210,756
Prepaid expenses and other current assets	3,317	2,712
Total current assets	342,186	239,603
Property and equipment, net	1,652	44
Restricted cash	210	—
Operating lease right-of-use assets	7,108	234
Other long-term assets	1,844	2,091
Total assets	$ 353,000	$ 241,972
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,801	$ 15,314
Current portion of long-term debt, net	1,750	250
Total current liabilities	18,551	15,564
Long-term debt, net	5,750	7,250
Operating lease liabilities, long-term	6,019	—
Other long-term liabilities	306	377
Total liabilities	30,626	23,191
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; 56,214 and 45,384 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	574,385	431,322
Accumulated other comprehensive income	557	331
Accumulated deficit	(252,574)	(212,877)
Total stockholders' equity	322,374	218,781
Total liabilities and stockholders' equity	$ 353,000	$ 241,972

See accompanying notes to unaudited condensed financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating Expenses:				
Research and development (includes related party amounts of $63 and $98 for the three months ended June 30, 2020 and 2019, respectively, and $195 and $151 for the six months ended June 30, 2020 and 2019, respectively)	$ 13,697	$ 11,440	$ 26,272	$ 21,822
General and administrative (includes related party amounts of $76 and $88 for the three months ended June 30, 2020 and 2019, respectively, and $187 and $175 for the six months ended June 30, 2020 and 2019, respectively)	7,476	4,451	15,101	9,020
Total operating expenses	21,173	15,891	41,373	30,842
Other Income (Expense):				
Management fee income, related party	12	74	27	200
Interest income	818	1,022	1,937	2,052
Interest expense	(144)	(148)	(288)	(293)
Total other income	686	948	1,676	1,959
Net Loss	$ (20,487)	$ (14,943)	$ (39,697)	$ (28,883)
Net loss per share, basic and diluted	$ (0.40)	$ (0.38)	$ (0.82)	$ (0.75)
Weighted average number of shares used in computing net loss per share, basic and diluted	51,633	38,928	48,522	38,550
Comprehensive Loss:				
Net loss	$ (20,487)	$ (14,943)	$ (39,697)	$ (28,883)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities and foreign currency	(4)	143	226	292
Comprehensive Loss	$ (20,491)	$ (14,800)	$ (39,471)	$ (28,591)

See accompanying notes to unaudited condensed financial statements.

KURA ONCOLOGY, INC.
Condensed Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2019	45,384	$ 5	$ 431,322	$ 331	$ (212,877)	$ 218,781
Issuance of common stock, net of offering costs	10,465	1	134,923	—	—	134,924
Share-based compensation expense	—	—	5,705	—	—	5,705
Issuance of common stock from exercise of options and employee stock purchase plan	365	—	2,435	—	—	2,435
Other comprehensive income	—	—	—	226	—	226
Net loss	—	—	—	—	(39,697)	(39,697)
Balance at June 30, 2020	56,214	$ 6	$ 574,385	$ 557	$ (252,574)	$ 322,374

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at March 31, 2020	45,430	$ 5	$ 434,722	$ 561	$ (232,087)	$ 203,201
Issuance of common stock, net of offering costs	10,465	1	134,923	—	—	134,924
Share-based compensation expense	—	—	2,552	—	—	2,552
Issuance of common stock from exercise of options and employee stock purchase plan	319	—	2,188	—	—	2,188
Other comprehensive loss	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(20,487)	(20,487)
Balance at June 30, 2020	56,214	$ 6	$ 574,385	$ 557	$ (252,574)	$ 322,374

See accompanying notes to unaudited condensed financial statements.

KURA ONCOLOGY, INC.
Condensed Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2018	38,148	$ 4	$ 310,849	$ (131)	$ (149,737)	$ 160,985
Issuance of common stock, net of offering costs	6,785	1	108,108	—	—	108,109
Share-based compensation expense	—	—	4,518	—	—	4,518
Issuance of common stock from exercise of options and employee stock purchase plan	256	—	1,560	—	—	1,560
Other comprehensive income	—	—	—	292	—	292
Net loss	—	—	—	—	(28,883)	(28,883)
Balance at June 30, 2019	45,189	$ 5	$ 425,035	$ 161	$ (178,620)	$ 246,581

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Capital	Income (Loss)	Deficit	Equity
Balance at March 31, 2019	38,169	$ 4	$ 313,220	$ 18	$ (163,677)	$ 149,565
Issuance of common stock, net of offering costs	6,785	1	108,108	—	—	108,109
Share-based compensation expense	—	—	2,249	—	—	2,249
Issuance of common stock from exercise of options and employee stock purchase plan	235	—	1,458	—	—	1,458
Other comprehensive income	—	—	—	143	—	143
Net loss	—	—	—	—	(14,943)	(14,943)
Balance at June 30, 2019	45,189	$ 5	$ 425,035	$ 161	$ (178,620)	$ 246,581

See accompanying notes to unaudited condensed financial statements.

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

	Six Months Ended June 30,	
	2020	**2019**
Operating Activities		
Net loss	$ (39,697)	$ (28,883)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	5,705	4,518
Depreciation expense	12	—
Amortization of premium and accretion of discount on marketable securities, net	(134)	(859)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(367)	(13)
Other long-term assets	533	(215)
Accounts payable and accrued expenses	(537)	(3,300)
Other long-term liabilities	(71)	70
Net cash used in operating activities	(34,556)	(28,682)
Investing Activities		
Maturities and sales of marketable securities	103,823	126,556
Purchases of marketable securities	(96,818)	(101,872)
Purchases of property and equipment	(1,231)	—
Net cash provided by investing activities	5,774	24,684
Financing Activities		
Proceeds from issuance of common stock, net	135,180	108,399
Proceeds from exercise of stock options and purchases under employee stock purchase plan	2,435	1,560
Net cash provided by financing activities	137,615	109,959
Net increase in cash, cash equivalents and restricted cash	108,833	105,961
Cash, cash equivalents and restricted cash at beginning of period	26,135	16,119
Cash, cash equivalents and restricted cash at end of period	$ 134,968	$ 122,080

See accompanying notes to unaudited condensed financial statements.

1. Organization and Basis of Presentation

The Company

Kura Oncology, Inc. is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

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

Basis of Presentation

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on February 25, 2020, from which we derived our balance sheet as of December 31, 2019. The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited condensed financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of the unaudited condensed financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect the amounts reported on our unaudited condensed financial statements and accompanying notes. The amounts reported could differ under different estimates and assumptions. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty, we continue to use the best information available to inform our critical accounting estimates. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

The extent to which the COVID-19 pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with any confidence, such as the duration and severity of the COVID-19 pandemic, steps required or mandated by governments to mitigate the impact of COVID-19 or the effectiveness of actions to prevent, contain and treat COVID-19, particularly in the geographies where we, our third party manufacturers, contract research organizations or current and planned clinical trial sites operate. We cannot presently predict the scope and severity of any potential business disruptions, interruptions or shutdowns. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, 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.

2. Summary of Significant Accounting Policies

Reclassifications

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

Restricted Cash

Under the terms of an office lease entered into in March 2020, we are required to maintain a standby letter of credit during the term of the lease. As of June 30, 2020, restricted cash of $0.2 million was pledged as collateral for the letter of credit.

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

	June 30, 2020	December 31, 2019	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 134,758	$ 26,135	$ 122,080	$ 16,119
Restricted cash	210	—	—	—
Total	$ 134,968	$ 26,135	$ 122,080	$ 16,119

Net Loss per Share

Net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, outstanding stock options, an outstanding warrant and employee stock purchase plan rights are excluded from the calculation of diluted net loss per common share for the periods presented as their effect would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the antidilutive effect of the securities. More specifically, for the three and six months ended June 30, 2020 and 2019, outstanding stock options, an outstanding warrant and employee stock purchase plan rights totaling approximately 5,141,000 shares and 4,140,000 shares, respectively, were excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive.

Recent Accounting Pronouncements

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

3. Investments

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

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

		June 30, 2020			
	Maturities (years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	1 or less	$ 129,433	$ —	$ —	$ 129,433
Short-term investments:					
U.S. Treasury securities	1 or less	77,164	322	(1)	77,485
Corporate debt securities	1 or less	68,197	241	(4)	68,434
Commercial paper	1 or less	58,192	—	—	58,192
Total short-term investments		203,553	563	(5)	204,111
Total		$ 332,986	$ 563	$ (5)	$ 333,544

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

The available-for-sale investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. As of June 30, 2020, all of our short-term investments had maturities less than one year. Realized gains and losses were de minimus for the three and six months ended June 30, 2020.

We evaluate our available-for-sale debt securities for credit losses when the amortized cost basis exceeds fair value. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive income (loss). When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, our intent to sell or the likelihood that we would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. As of June 30, 2020, marketable securities with a fair market value of $40.7 million were in immaterial gross unrealized loss positions. Based on our review of these securities, we believe none of the unrealized loss is a result of a credit loss as of June 30, 2020 because we do not intend to sell these securities and it is not more-likely-than-not that we will be required to sell these securities prior to recovery of their amortized cost basis.

4. Fair Value Measurements

As of June 30, 2020 and December 31, 2019, we had cash equivalents and short-term investments measured at fair value on a recurring basis. Available-for-sale marketable securities consist of U.S. Treasury securities, which were measured at fair value using Level 1 inputs, and corporate debt securities and commercial paper, which were measured at fair value using Level 2 inputs. We determine the fair value of Level 2 related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. We validate the fair values of Level 2 financial instruments by comparing these fair values to a third-party pricing source.

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:

	June 30, 2020		
	Balance	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 129,433	$ 129,433	$ —
Short-term investments:			
U.S. Treasury securities	77,485	77,485	—
Corporate debt securities	68,434	—	68,434
Commercial paper	58,192	—	58,192
Total short-term investments	204,111	77,485	126,626
Total	$ 333,544	$ 206,918	$ 126,626

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

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

5. Balance Sheet Detail

Property and equipment consisted of the following, in thousands:

	June 30, 2020	December 31, 2019
Computer software and equipment and laboratory equipment	$ 180	$ 136
Furniture and fixtures	546	—
Leasehold improvements	1,030	—
Property and equipment, gross	1,756	136
Less: accumulated depreciation	(104)	(92)
Property and equipment, net	$ 1,652	$ 44

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

	June 30, 2020	December 31, 2019
Accounts payable	$ 786	$ 3,526
Accrued research and development expenses	9,455	6,970
Accrued compensation and benefits	3,041	3,694
Lease liability, current portion	1,745	252
Other accrued expenses	1,774	872
Total accounts payable and accrued expenses	$ 16,801	$ 15,314

6. Long-Term Debt

On April 3, 2020, we entered into the First Amendment to Loan and Security Agreement with Silicon Valley Bank to extend the additional draw period. Under the terms of the loan and security agreement, as amended, we may, at our sole discretion, borrow up to an additional $12.5 million at any time until November 30, 2020. There were no other changes to the terms of the loan and security agreement.

7. Leases

We had a sublease with a related party for office space in San Diego, California, or Sublease, and a lease for office space in Cambridge, Massachusetts, that existed before January 1, 2019 and were classified as operating leases. In March 2019, the Sublease was amended to extend the expiration date from October 31, 2019 to April 30, 2020 with the monthly rent increased from approximately $16,000 to approximately $24,000 per month effective November 1, 2019. In April 2020, the Sublease was amended to extend the expiration date from April 30, 2020 to June 30, 2020 with no change to the amount of monthly rent. The Sublease was terminated in June 2020. See Note 10, Related Party Transactions, for further details of the Sublease. The lease for office space in Cambridge, Massachusetts expired on July 31, 2020.

In January 2020, we entered into an office lease agreement for our corporate offices in San Diego, California, which would have commenced on May 1, 2020. In May 2020, we entered into an amendment to such office lease agreement that subsequently amended the commencement date to August 1, 2020 and extended the lease expiration to November 30, 2025. We refer to such office lease agreement, as amended, as the San Diego Lease. The San Diego Lease provides for a one-time option to extend for a period of five additional years. The monthly base rent is approximately $58,000 for the first year, which amount will increase by 3.0% per year over the initial term. In addition, the San Diego Lease is subject to charges for common area maintenance and other costs. The San Diego Lease provides a four-month rent abatement period during the first year of the San Diego Lease and approximately $1.0 million in reimbursement for allowable tenant improvements, which effectively reduce the total lease payments owed for the San Diego Lease. For accounting purposes, the lease commencement date was determined to be March 2020 when we had control of the office space. We recorded an operating lease right-of-use, or ROU, asset and operating lease liability of approximately $2.1 million on our unaudited condensed balance sheet.

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

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

Maturities of lease liabilities as of June 30, 2020 are as follows, in thousands:

Year Ending December 31,		
2020 (remaining)*	$	250
2021		2,141
2022		2,098
2023		2,080
2024		1,558
2025		722
Total lease payments		8,849
Less: imputed interest		(1,086)
Total operating lease liabilities	$	7,763

* Includes the remaining tenant incentives of $0.5 million to be received from the landlord in 2020.

As of December 31, 2019, we had remaining lease liabilities of approximately $0.3 million which will mature in 2020. ROU assets are recorded in other long-term assets on our unaudited condensed balance sheets. Current and non-current lease liabilities are recorded in accounts payable and accrued expenses and other long-term liabilities, respectively, on our unaudited condensed balance sheets. As of June 30, 2020 and December 31, 2019, total operating lease ROU assets were $7.1 million and $0.2 million, respectively. As of June 30, 2020 and December 31, 2019, total operating lease liabilities were $7.8 million and $0.3 million, respectively, $6.0 million of which was recorded as noncurrent lease liability as of June 30, 2020. As of June 30, 2020 and December 31, 2019, the weighted-average discount rate was 5.5% and 6.5%, respectively. As of June 30, 2020 and December 31, 2019, the weighted-average remaining lease term was 4.5 years and 0.5 years, respectively.

Total cash paid for amounts included in the measurement of lease liabilities, net of tenant improvement reimbursements, was $0.1 million and $0.2 million for the six months ended June 30, 2020 and 2019, respectively. ROU assets obtained in exchange for operating lease liabilities were $7.5 million and $0.7 million for the six months ended June 30, 2020 and 2019, respectively.

Total operating lease expense was approximately $0.6 million and $0.1 million for the three months ended June 30, 2020 and 2019, respectively. Total operating lease expense was approximately $0.7 million and $0.2 million for the six months ended June 30, 2020 and 2019, respectively. We have entered into short-term operating leases that are not recorded on the unaudited condensed balance sheet. Total rent expense of all operating leases for the three months ended June 30, 2020 and 2019 was approximately $0.6 million and $0.1 million, respectively. Total rent expense of all operating leases for the six months ended June 30, 2020 and 2019 was approximately $0.9 million and $0.3 million, respectively.

8. Stockholders' Equity

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

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

9. Share-Based Compensation

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

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2020	**2019**	**2020**	**2019**
Research and development	$ 445	$ 884	$ 1,615	$ 1,681
General and administrative	2,107	1,365	4,090	2,837
Total share-based compensation expense	$ 2,552	$ 2,249	$ 5,705	$ 4,518

As of June 30, 2020, unrecognized compensation costs related to employee stock options was approximately $28.6 million, which is expected to be recognized over a weighted average period of approximately 2.8 years.

10. Related Party Transactions

Our president and chief executive officer is also the sole managing member of Araxes Pharma LLC, or Araxes, and is a significant stockholder of each of us and Araxes. The following is a summary of related party transactions for the three and six months ended June 30, 2020 and 2019:

- *Facility Sublease*

  We subleased office space in San Diego, California from Araxes pursuant to the Sublease. The Sublease commenced in June 2017 and would have expired on October 31, 2019. In March 2019, the Sublease was amended to extend until April 30, 2020, and the monthly rent increased to approximately $24,000 per month effective November 1, 2019, corresponding to the increase in Araxes' monthly rent. In April 2020, the Sublease was amended to extend the expiration date to June 30, 2020 with no change to the amount of monthly rent. The Sublease was terminated in June 2020. For the three months ended June 30, 2020 and 2019, rent expense, including operating costs, related to our sublease was approximately $0.1 million in both periods. For the six months ended June 30, 2020 and 2019, rent expense, including operating costs, related to our Sublease was approximately $0.2 million in both periods.

- *Management Fees*

  We have a management services agreement with Araxes pursuant to which Araxes pays us monthly fees for management services calculated based on costs incurred by us in the provision of services to Araxes, plus a reasonable mark-up. For the three months ended June 30, 2020 and 2019, we recorded approximately $0.1 million in management fee income in both periods. For the six months ended June 30, 2020 and 2019, we recorded approximately $0.1 million and $0.2 million in management fee income, respectively. In addition, the agreement allows for Araxes to reimburse us an amount equal to the number of full-time equivalents, or FTE, performing research and development services for Araxes, at an annual FTE rate of approximately $382,000, plus actual expenses as reasonably incurred. The initial term of this agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the three and six months ended June 30, 2020 and 2019, we recorded reimbursements of nil and approximately $0.1 million, respectively, for research and development services provided to Araxes, which was recorded as a reduction to research and development expenses, on our unaudited condensed statements of operations and comprehensive loss.

- *Services Agreement*

  We have a services agreement with Wellspring Biosciences, Inc., or Wellspring, a wholly owned subsidiary of Araxes, pursuant to which we pay Wellspring for research and development services provided to us in an amount equal to the number of FTE's performing the services, at an annual FTE rate of $400,000, plus actual expenses as reasonably incurred. The initial term of this services agreement expired on December 31, 2015 but, pursuant to the terms of the agreement, renews automatically for additional consecutive one-year periods. The agreement may be terminated by either party with a notice of at least 30 days prior to the expiration of the then-renewal term. For the three and six months ended June 30, 2020 and 2019, we recognized approximately $0.1 million in each period, from research and development services provided to us under this agreement as research and development expense on our unaudited condensed statements of operations and comprehensive loss.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial statements and notes thereto as of and for the fiscal year ended December 31, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission, or SEC, on February, 25, 2020.

This Quarterly Report includes forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections, that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "seek", "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

References to "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 plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights. We presently have two key product candidates in clinical trials, tipifarnib and KO-539.

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

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

free survival of 5.9 months and an objective response rate of 50% observed in recurrent/metastatic HRAS mutant HNSCC among the 18 patients on the RUN-HN study who were evaluable for efficacy.

On July 6, 2020, we amended the AIM-HN trial protocol to enable enrollment of patients with any HRAS mutation in order to assess the potential for clinical benefit in the overall HRAS mutant HNSCC population. While these amendments do not change the primary outcome measure of objective response rate in patients with high HRAS mutant variant allele frequency, AIM-HN will require an increased number of evaluable HNSCC patients. As a result of the COVID-19 pandemic and the additional patients required for the trial, we anticipate we will face delays in our timelines and milestones for the AIM-HN trial and, accordingly, are unable to reasonably forecast at this time when our AIM-HN trial will become fully enrolled.

In addition to studying tipifarnib in recurrent or metastatic HRAS mutant HNSCC as a monotherapy, we are also examining the potential use of tipifarnib in combination with other oncology therapies to address larger patient populations and pursue earlier lines of therapy. In particular, we have been developing pre-clinical data to support the potential for using tipifarnib in HNSCC patients whose tumors overexpress the HRAS gene in combination with a PI3 kinase alpha inhibitor.

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

We received orphan drug designation for KO-539 for the treatment of acute myeloid leukemia, or AML, from the FDA in July 2019. We initiated our Phase 1/2A clinical trial of KO-539 in relapsed or refractory AML in September 2019 and are actively recruiting at multiple sites in the United States and France with the anticipation of expanding to additional sites in the United States, France and other countries during the expansion phase of the study. Our menin-KMT2A Phase 1/2A clinical trial, which we call the Kura Oncology MEnin-KMT2A Trial, or KOMET-001, has an accelerated design and will determine a recommended Phase 2 dose and schedule, or RP2D, using a modified toxicity probability interval, or MTPI, model. We are seeking to achieve a RP2D for KO-539 with the potential to enrich in NPM1-mutant AML and KMT2A-rearranged genetically defined subgroups by the end of 2020.

Other Clinical Developments

On May 4, 2020, we announced the suspension and termination of certain development activities due to a strategic review. These changes included suspension of the initiation of a planned registration directed study for tipifarnib in T-cell lymphoma, suspension of a planned Phase 2 clinical trial for tipifarnib in pancreatic cancer and termination of our KO-947 extracellular signal related kinase, or ERK, inhibitor program.

The COVID-19 Pandemic

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

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

Liquidity Overview

As of June 30, 2020, we had cash, cash equivalents and short-term investments of $338.9 million. In May 2020, we completed a public offering in which we sold an aggregate of 10,465,000 shares of common stock at a price of $13.75 per share. Net proceeds from the public offering, after deducting underwriting discounts, commissions and offering expenses, were approximately $134.9 million. We have a term loan facility with Silicon Valley Bank under which we may, at our sole discretion, borrow up to an additional $12.5 million at any time until November 30, 2020. In addition, we have an at-the-market issuance sales agreement with SVB Leerink LLC and Stifel, Nicolaus & Company, Incorporated, or ATM facility, under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $75.0 million. We have not yet sold any shares of our common stock under the ATM facility. To date, we have not generated any revenues from product sales, and we do not have any approved products. Since our inception, we have funded our operations primarily through equity and debt financings. We anticipate that we will require significant additional financing in the future to continue to fund our operations as discussed more fully below under the heading “Liquidity and Capital Resources.”

Financial Operations Overview

Research and Development Expenses

We focus on the research and development of our product programs. Our research and development expenses consist of costs associated with our research and development activities including salaries, benefits, share-based compensation and other personnel costs, clinical trial costs, manufacturing costs for non-commercial products, fees paid to external service providers and consultants, facilities costs and supplies, equipment and materials used in clinical and preclinical studies and research and development. All such costs are charged to research and development expense as incurred. Payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses in other research and development projects or otherwise and therefore, no separate economic values, are expensed as research and development costs at the time such costs are incurred. As of June 30, 2020, we have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

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

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

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

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

General and Administrative Expenses

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

Other Income (Expense)

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

Income Taxes

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

Results of Operations

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Research and development expenses	$ 13,697	$ 11,440	$ 2,257	$ 26,272	$ 21,822	$ 4,450
General and administrative expenses	7,476	4,451	3,025	15,101	9,020	6,081
Other income, net	686	948	(262)	1,676	1,959	(283)

Comparison of the Three Months Ended June 30, 2020 and 2019

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

	Three Months Ended June 30,		
	2020	2019	Change
Tipifarnib-related costs	$ 7,520	$ 6,092	$ 1,428
KO-539-related costs	561	594	(33)
KO-947-related costs	512	863	(351)
Personnel costs and other expenses	4,659	3,007	1,652
Share-based compensation expense	445	884	(439)
Total research and development expenses	$ 13,697	$ 11,440	$ 2,257

The increase in tipifarnib-related research and development expenses for the three months ended June 30, 2020 compared to the same period in 2019 was primarily due to increases in costs related to our ongoing AIM-HN pivotal trial and other Phase 2 clinical trials, manufacturing and other preclinical development activities. The decrease in KO-947-related costs is due to the termination of the ERK inhibitor program. Personnel costs and other expenses include employee salaries and related expenses, facilities expense and overhead expenses. The increase in personnel costs and other expenses was to

support our registration-directed clinical trial for tipifarnib and the Phase 1/2A clinical trial of KO-539. We expect our research and development expenses to increase in future periods as we continue clinical development activities for tipifarnib and KO-539.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended June 30, 2020 compared to the same period in 2019 was primarily due to increases of $0.9 million in professional and legal fees, $0.8 million in pre-commercial planning expenses, $0.7 million in non-cash share-based compensation expense and $0.5 million in personnel costs. We expect our general and administrative expenses to increase in future periods to support our planned increase in research and development activities.

Comparison of the Six Months Ended June 30, 2020 and 2019

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

	Six Months Ended June 30,		
	2020	2019	Change
Tipifarnib-related costs	$ 13,712	$ 11,988	$ 1,724
KO-539-related costs	1,449	947	502
KO-947-related costs	1,281	1,843	(562)
Personnel costs and other expenses	8,215	5,363	2,852
Share-based compensation expense	1,615	1,681	(66)
Total research and development expenses	$ 26,272	$ 21,822	$ 4,450

The increase in tipifarnib-related research and development expenses for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to increases in costs related to our ongoing pivotal trial and other Phase 2 clinical trials, manufacturing and other preclinical development activities. The increase in KO-539-related research and development expenses was primarily due to the initiation of the Phase 1/2A clinical trial for KO-539 in September 2019. The decrease in KO-947-related costs is due to the termination of the ERK inhibitor program. Personnel costs and other expenses include employee salaries and related expenses, facilities expense and overhead expenses. The increase in personnel costs and other expenses was to support our registration-directed clinical trial for tipifarnib and the Phase 1/2A clinical trial of KO-539.

General and Administrative Expenses. The increase in general and administrative expenses for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to increases of $1.8 million in professional and legal fees, $1.7 million in pre-commercial planning expenses, $1.3 million in non-cash share-based compensation expense and $1.1 million in personnel costs.

Liquidity and Capital Resources

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

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

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

In November 2018, we entered into a loan and security agreement with Silicon Valley Bank providing for up to $20.0 million in a series of term loans. The loan and security agreement was subsequently amended in April 2020 to extend the second draw period. The loan and security agreement, as amended, shall be referred to as the loan agreement. Under the terms of the loan agreement, we borrowed $7.5 million, or Term A Loan, and we may, at our sole discretion, borrow up to an additional $12.5 million at any time until November 30, 2020, or Term B Loan, and together with Term A Loan, the Term Loans. In addition, each Term B Loan must be in an amount equal to the lesser of $5.0 million or the amount that is

remaining under the Term B Loan. All of the Term Loans will be due on the scheduled maturity date of May 1, 2023, or Maturity Date. Repayment of the Term Loans is interest only through November 30, 2020, followed by 30 equal monthly payments of principal plus accrued interest commencing on December 1, 2020. The per annum interest rate for the Term Loans is the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25%. In addition, a final payment of 7.75% of the amounts of the Term Loans drawn will be due on the earlier of the Maturity Date, acceleration or prepayment of the Term Loans. If we elect to prepay the Term Loans, a prepayment fee equal to 1% or 2% of the then outstanding principal balance also will be due, depending upon when the prepayment occurs.

Our obligations under the loan agreement are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. Our intellectual property is subject to negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions.

We have incurred operating losses since inception and negative cash flows from operating activities. As of June 30, 2020, we had an accumulated deficit of $252.6 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets remain volatile and uncertain, and for so long as they do, it may make any necessary capital financing more difficult to obtain, more costly and/or more dilutive. 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 June 30, 2020, we had cash, cash equivalents and short-term investments of $338.9 million. Based on our current plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2023. During the period of uncertainty of volatility related to the COVID-19 pandemic, we will continue to monitor our liquidity.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, pre-clinical development, laboratory testing and clinical trials for our product candidates, including as such activities may be adversely impacted by COVID-19;
- 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 pre-clinical 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 revenue from product sales. We do not expect to generate significant revenue

from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We are subject to all of the risks incident in the development of new therapeutic products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, collaborations, strategic partnerships or licensing arrangements. 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 lender. To the extent that we raise additional capital through the sale of stock or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global financial markets have experienced volatility and uncertainty. There can be no assurance that further volatility and uncertainty in the financial markets and declining confidence in economic conditions will not occur. If financial markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, including our other technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be unable to carry out our business plan. As a result, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and commercialize our product candidates even if we would otherwise prefer to develop and commercialize such product candidates ourselves, and our business, financial condition and results of operations would be materially adversely affected.

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

	Six Months Ended June 30,		
	2020	2019	Change
Net cash used in operating activities	$ (34,556)	$ (28,682)	$ (5,874)
Net cash provided by investing activities	5,774	24,684	(18,910)
Net cash provided by financing activities	137,615	109,959	27,656

Operating Activities. The increase in net cash used in operating activities for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to an increase of $10.8 million in net loss, offset by a decrease of $2.8 million in payments of accounts payable and accrued expenses and an increase of $1.2 million in non-cash share based compensation expense.

Investing Activities. The decrease in net cash provided by investing activities for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to a decrease of $22.7 million in maturities and sales of marketable securities and an increase of $1.2 million in purchases of property and equipment, offset by a decrease of $5.1 million in purchases of marketable securities.

Financing Activities. The increase in net cash provided by financing activities for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to increases of $26.8 million in proceeds from sale of common stock and $0.9 million in proceeds from exercise of stock options and purchases under our employee stock purchase plan.

Contractual Obligations

During the three months ended June 30, 2020, there were no material changes in contractual obligations from the amounts disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in our Quarterly Report on Form 10-Q for the period ended March 31, 2020.

Off-Balance Sheet Arrangements

As of June 30, 2020, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

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 unaudited condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed financial statements required estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the unaudited condensed financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty, we continue to use the best information available to inform our critical accounting estimates.

There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Management Estimates," included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in money market funds, corporate debt securities, U.S. Treasury securities and commercial paper. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For our short-term investments, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the unaudited condensed statements of operations and comprehensive loss. We believe that should a 10.0% change in interest rates were to have occurred on June 30, 2020, 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 June 30, 2020 bear interest at a rate equal to the greater of (i) 5.50% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal plus (b) 0.25% and are therefore exposed to changes in interest rates through their maturity date of May 2023. If a 10% change in interest rates were to have occurred on June 30, 2020, this change would not have had a material effect on our interest expense as of that date.

Inflation Risk

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during any periods presented herein.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Exchange Act is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this Quarterly Report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the quarter covered by this Quarterly Report.

Changes 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 June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the information included or incorporated by reference in this Quarterly Report and in our other public filings, you should carefully consider the risks described below in evaluating our company. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 25, 2020.

Risks Related to the Discovery and Development of Our Product Candidates

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

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

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

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

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

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

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

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

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

We have not previously submitted a new drug application, or NDA, to the FDA, or similar product approval filings to comparable foreign authorities, or received marketing approval for any product candidate, and we cannot be certain that tipifarnib or KO-539 will be successful in clinical trials or receive regulatory approval for any indication. We cannot anticipate whether or when we will seek regulatory review of tipifarnib or KO-539 for any other indications. If we do not receive regulatory approvals for and successfully commercialize tipifarnib on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market tipifarnib or KO-539, our revenues will be dependent, in part, on our third-party collaborator’s ability to commercialize the companion diagnostic as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the market opportunities for the treatment of HRAS mutant HNSCC, NPM1-mutant AML and KMT2A-rearranged AML and other diseases are not as significant as we estimate, our business and prospects may be harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

local radiology review. This may further reduce the number of subjects eligible to join AIM-HN within the small pool of HRAS mutant HNSCC patients.

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

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

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

- we may have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these diagnostic tests. We may also experience difficulties in having these diagnostic tests adopted and used at clinical sites, both during the clinical development phase and if and when approved for commercial sale. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a these diagnostic tests or any failure in having a sufficient

number of clinical sites adopt and use these diagnostic tests could delay or prevent approval of our product candidates, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

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

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

If the results of AIM-HN, KOMET-001 or other clinical trials are positive and we validate our biomarker hypotheses in those clinical trials, we plan to partner development and validation of companion diagnostic tests to aid in the selection of patients in any subsequent clinical trials we decide to pursue for those product candidates and to prepare and submit an application for IDE for use of the companion diagnostic in the clinical trials, when necessary. Any delay or failure by us or our third-party collaborators to develop or obtain IDE approval for use of companion diagnostics in our clinical trials could delay or prevent us from commencing or completing our clinical trials. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has frequently required a premarket approval application of companion diagnostics for cancer therapies. We presently anticipate that an approved companion diagnostic will be required in order to obtain approval for tipifarnib in HRAS mutant HNSCC and for KO-539 in NPM1-mutant AML and KMT2A-rearranged AML. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our product candidates. The approval of a companion diagnostic as part of the product label will limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

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

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

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

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

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

Risks Related to Our Financial Position and Need For Additional Capital

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

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

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

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

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

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

We are a clinical-stage company that has incurred losses since our inception and expect to continue to incur substantial losses in the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We expect our actual financial condition and operating results to fluctuate significantly from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control, including COVID-19. Factors relating to our business that may contribute to these fluctuations include:

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

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

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

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

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

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

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

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

In November 2018, we entered into the loan agreement with Silicon Valley Bank, providing for up to $20.0 million in a series of term loans, which was subsequently amended in April 2020 to extend the second draw period. Under the terms of the loan agreement, we have borrowed $7.5 million, with an additional $12.5 million available at any time until November 30, 2020. 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 and transactions with affiliates, among other customary covenants. If we default under our term loan facility, the lender may accelerate our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender’s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lender could declare a default under our term loan facility upon the occurrence of an event of default, which includes our failure to satisfy our payment obligations under the loan agreement, the breach of certain of our other covenants under the loan agreement or the occurrence of a material adverse change, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Subject to limited exceptions, our term loan facility also prohibits us from incurring indebtedness without the prior written consent of the

lender. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Risks Related to Our Dependence on Third Parties

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

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

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

Our reliance on these third parties to conduct our clinical trials reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA and other regulatory authorities require us to comply with good clinical practice guidelines for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

We do not own or operate facilities for the manufacture of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of clinical supplies of tipifarnib and KO-539 for preclinical and clinical testing. We will rely on

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

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

If we are unable to develop formulations of our product candidates with acceptable stability and sterility characteristics, or experience an unexpected delay or loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, our business may be harmed and we may experience delays, disruptions, suspensions or terminations of, or we may be required to restart or repeat, any pending or ongoing clinical trials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, we may be required to manufacture additional supplies of our product candidates to the extent our estimates of the amounts required prove inaccurate, we suffer unexpected losses of product candidate supplies, or to the extent that we are required to have fresh product candidate 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 tipifarnib and our other product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the

future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture our products, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

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

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

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.*

Our product candidates must be approved by the FDA pursuant to an NDA in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. In addition, the COVID-19 pandemic could also potentially affect the business of the FDA, the EMA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our product candidates may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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

As the composition of matter patents covering tipifarnib expired in the United States and in countries in Europe in 2016 and we have only a limited number of issued U.S. and foreign patents directed to our potential tipifarnib indications, our commercial strategy for tipifarnib relies on obtaining method of use and method of treatment patents, including those directed to specific indications and biomarkers, other patents related to tipifarnib, method of treatment patents related to farnesyl

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

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

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

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

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

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

A Fast Track Designation by the FDA, such as granted to tipifarnib for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy and for the treatment of adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma, follicular T-cell lymphoma and nodal peripheral T-cell lymphoma with T follicular helper phenotype, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.*

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a specific product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. We have been granted Fast Track Designation by the FDA for our tipifarnib product candidate for the treatment of patients with HRAS mutant HNSCC after progression on platinum therapy and for the treatment of adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma, follicular T-cell lymphoma and nodal peripheral T-cell lymphoma with T follicular helper phenotype, but this is no assurance we will receive this designation for any future product candidates. Further, even though we have received this designation for tipifarnib, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain drug approval.

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

We do not currently have Breakthrough Therapy Designation for any of our product candidates, but we intend to seek such designation if our clinical data supports such a designation. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

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

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

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

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-approval studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

conduct such trials could make it more difficult and costly to obtain regulatory approval of a combination drug than of a new drug containing only a single active pharmaceutical ingredient.

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

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

- the federal Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims, including the civil False Claims Act, which can be enforced by private citizens, on behalf of the government, through whistleblower actions, and civil monetary penalties laws which prohibits, among other things, individuals and entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, 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 the HITECH Act, and their implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information on covered entities which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity;
- 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, as defined by such law, and teaching hospitals, as well as certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians or their immediate family;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, thus complicating compliance efforts, including the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect on May 25, 2018, and imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, 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, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

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

There remain judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace 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. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. However, on April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. On December 14, 2018, a U.S. District Court Judge in Texas ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace ACA will impact ACA and our business. 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 through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws and other potential legislation may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. As a result, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. Although some of these and other potential measures may require additional regulation or legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Future legislation could potentially change drug pricing dynamics. We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business. It is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020,

CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

We have licensed patent rights from third parties for some of our development programs, including tipifarnib from Janssen and compounds in our menin-KMT2A program from the University of Michigan. As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

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

If we breach any of the agreements under which we license from third parties the commercialization rights to our product candidates, we could lose license rights that are important to our business and our operations could be materially harmed.*

We have in-licensed from Janssen the use, development and commercialization rights in all indications other than virology, for our lead product candidate, tipifarnib. We have also in-licensed rights to KO-539 and other compounds in our menin-KMT2A program from the University of Michigan. Additionally, we have an exclusive worldwide license from Memorial Sloan Kettering Cancer Center to a patent family pertaining to a method of use of tipifarnib. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of the Janssen agreement and the rights we license under it and our other in-license agreements. The Janssen license agreement and the University of Michigan license agreement each provide that we are subject to diligence obligations relating to the commercialization and development of the respective product candidates, milestone payments, royalty payments and other obligations. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of our license agreement with Janssen, University of Michigan or any of our other license agreements or license agreements we may enter into on which our business or product candidates are dependent, Janssen, University of Michigan or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. The loss of the rights licensed to us under our license agreement with Janssen, University of Michigan or our other license agreements or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

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.

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

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

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Even if our owned and licensed patents might provide such protection or competitive advantage, we may not have the resources to effectively enforce our rights under such patents, which can be expensive and time-consuming. Further, our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

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

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

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

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

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

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

Presently we have rights to intellectual property under an exclusive license from Janssen, to develop tipifarnib in all fields other than virology, an exclusive worldwide license from the University of Michigan for all therapeutic indications for KO-539 and other compounds in our menin-KMT2A program and an exclusive worldwide license from Memorial Sloan Kettering Cancer Center to a patent family pertaining to a method of use of tipifarnib. Because our programs may involve

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

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- our ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

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

We currently do not have sales or market access teams for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates continue to progress toward regulatory approval, we intend to establish sales and market access teams with expertise to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Capable managers with commercial experience may need to be identified and successfully recruited to our company. Any failure or delay in the development of our sales and market access capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems 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 tipifarnib, KO-539 and any other future product candidates. In the case of KO-539, one of our competitors recently published preliminary clinical data demonstrating that their inhibitor of the menin-KMT2A interaction was able to drive clinical benefit, including objective responses, in relapsed or refractory patients with KMT2A-rearranged AML. If that competitor is able to advance their clinical program more quickly than ours, our commercial opportunity for KO-539 could be reduced.

Our commercial opportunity also could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop alone or in combination with other drugs or biologics. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or slow our regulatory approval.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

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

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

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

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. In addition, drug-pricing by pharmaceutical companies has come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and provide an explanation of the reasons for the increase, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement

methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

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

Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

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

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

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

We are a clinical-stage company with a limited operating history, and, as of June 30, 2020, we had only 71 full-time employees. We are highly dependent on the expertise of Troy E. Wilson, Ph.D., J.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

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

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. From time to time, including recently as a result of the COVID-19 pandemic and actions taken to slow its spread, global financial markets have experienced volatility and uncertainty. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the

foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our CROs, collaborators and third-parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. As a result of the COVID-19 pandemic and the precautions to control the pandemic, we are increasingly dependent upon technology systems and data to operate our business. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that our office-based employees in the United States and in most of our other key markets work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies.

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

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

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

Risks Related to Ownership of our Common Stock

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

Our common stock has been listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol “KURA” since November 5, 2015. The high and low price per share of our common stock as reported by Nasdaq during the period from November 5, 2015 until June 30, 2020, were $24.03 and $2.50, respectively. We cannot predict the extent to which investor

interest in our company will sustain an active trading market on Nasdaq or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if an active trading market is not sustained or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

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

The market for our common stock could fluctuate substantially due to a variety of factors, some of which may be beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- the impact of the COVID-19 pandemic on our business and industry as well as the global economy;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- changes in the structure of healthcare payment systems;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- our dependence on third parties, including CROs as well as our potential partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results, liquidity or other indicators of our financial condition;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- market conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;

- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including recently as a result of the COVID-19 pandemic and actions taken to slow its spread. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. These events may also lead to securities litigation, which can be expensive and time-consuming to defend, regardless of the merit or outcome. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

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

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

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

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

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

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

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

As a public company, we have incurred and will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with current

corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, as well as rules implemented by the SEC or Nasdaq or any other stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years.

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

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

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, outstanding stock options, warrants, or otherwise, could result in dilution to the percentage ownership of our stockholders and could cause our stock price to fall.*

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

If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders or the perception that such sales could occur could cause the market price of our common stock to decline. In March 2019, we entered into the ATM facility under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $75.0 million. We have not yet sold any shares of our common stock under the ATM facility.

Pursuant to our Amended and Restated 2014 Equity Incentive Plan, or 2014 Plan, we are authorized to grant equity awards consisting of shares of our common stock to our employees, directors and consultants. As of June 30, 2020, we had 1,246,073 shares of common stock reserved for future issuance under the 2014 Plan and options to purchase up to an aggregate of 5,101,309 shares of common stock outstanding. The number of shares available for future grant under the 2014 Plan will automatically increase on January 1 of each year through January 1, 2025 by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. On January 1, 2020, an automatic increase pursuant to the 2014 Plan occurred, resulting in 1,815,361 additional shares available for future grant under the 2014 Plan.

In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2015 Employee Stock Purchase Plan, or ESPP. As of June 30, 2020, we had 183,264 shares of common stock reserved for future issuance under the ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year through January 1, 2025 by the lesser of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year and 2,000,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In December 2019, the board of directors elected not to automatically increase the number of shares of our common stock reserved for issuance under the ESPP in 2020. In addition, a warrant to purchase up to 33,988 shares of our common stock at an exercise price of $3.31 per share was outstanding as of June 30, 2020.

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

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

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

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- division of our board of directors into three classes;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66⅔% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 66⅔% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation;
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

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

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

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

- any derivative action or proceeding brought on our behalf;

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

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

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

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

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

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

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

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

We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any payment of cash dividends in the future would depend on our financial condition, contractual restrictions, including under our term loan facility, solvency tests imposed by applicable corporate laws, results of operations,

anticipated cash requirements and other factors and will be at the discretion of our board of directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
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 issued by Registrant on April 27, 2016 to Oxford Finance LLC.		10-Q (Exhibit 4.3)	8/10/2016	001-37620
10.1	First Amendment to Loan and Security Agreement, dated April 3, 2020, by and between the Registrant and Silicon Valley Bank.		8-K (Exhibit 10.1)	4/7/2020	001-37620
10.2	Second Amendment to Sublease, dated April 22, 2020 by and between the Registrant and Araxes Pharma LLC.		10-Q (Exhibit 10.7)	5/4/2020	001-37620
10.3	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
10.4+	Amended and Restated Nonemployee Director Compensation Policy.	X			
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.	X			
101.INS	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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Kura Oncology, Inc.
A Delaware corporation

Date: August 6, 2020

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

Date: August 6, 2020

By: /s/ Marc Grasso, M.D.
Marc Grasso, M.D.
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

Exhibit 10.4

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the ***"Board"***) who is not also serving as an employee of Kura Oncology, Inc. (***"Kura"***) or any of its subsidiaries (each such member, an ***"Eligible Director"***) will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service. This Policy is effective as of March 12, 2020 for the Lead Independent Director Service Retainer and as of January 1, 2020 for all other service retainers (the ***"Effective Date"***) and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating & Governance Committee: $4,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
   a. Chairman of the Audit Committee: $7,500
   b. Chairman of the Compensation Committee: $5,000
   c. Chairman of the Nominating & Governance Committee: $4,000

4. Annual Lead Independent Director Service Retainer: $27,500

Equity Compensation

The equity compensation set forth below will be granted under the Kura Oncology, Inc. Amended and Restated 2014 Equity Incentive Plan (the ***"Plan"***). All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of Kura on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service

other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: On the date of the Eligible Director's initial election to the Board, for each Eligible Director who is first elected to the Board on or following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 46,000 shares (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal annual installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each Kura's annual stockholder meeting held after the Effective Date, for each Eligible Director who continues to serve as a non-employee member of the Board (or who is first elected to the Board at such annual stockholder meeting), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 23,000 shares (the "***Annual Grant***"). In addition, each Eligible Director who is first elected to the Board following (i) the Effective Date and (ii) the date of Kura's first annual stockholder meeting, and other than at an annual stockholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted an Annual Grant, pro-rated for the number of months remaining until the next annual stockholder meeting. The shares subject to the Annual Grant will vest on the one year anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

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

Exhibit 31.2

CERTIFICATION

I, Marc Grasso, M.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2020

/s/ Marc Grasso, M.D.
Marc Grasso, M.D.
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Kura Oncology, Inc. (the "Company") for the period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Troy E. Wilson, Ph.D., J.D., as President and Chief Executive Officer of the Company, and Marc Grasso, M.D., as Chief Financial Officer and Chief Business Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

/s/ Troy E. Wilson, Ph.D., J.D.
Troy E. Wilson, Ph.D., J.D.
President and Chief Executive Officer

Date: August 6, 2020

/s/ Marc Grasso, M.D.
Marc Grasso, M.D.
Chief Financial Officer and Chief Business Officer

Date: August 6, 2020