**CURIS INC** 

Form 10-Q

November 01, 2018

**Table of Contents** 

**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  $\circ_{1934}$ 

For the quarterly period ended September 30, 2018

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: 000-30347

#### CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 04-3505116 (State or Other Jurisdiction of Incorporation or Organization) 04-3505116 (I.R.S. Employer Identification No.)

4 Maguire Road

Lexington, Massachusetts 02421

(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 503-6500

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. ý 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). ý 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 ý

Non-accelerated filer "Smaller reporting company ý

Emerging growth company

nn emerging growth company indicate by check mark if the

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. "

### Table of Contents

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). " Yes  $\circ$  Yes

As of October 26, 2018, there were 33,113,146 shares of the registrant's common stock outstanding.

## Table of Contents

# CURIS, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q INDEX

DADTI		Page Number
	FINANCIAL INFORMATION Unaudited Financial Statements	<u>3</u>
	Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017	<u>3</u>
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017	<u>4</u>
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017	<u>5</u>
	Notes to Condensed Consolidated Financial Statements	<u>6</u>
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>21</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>32</u>
Item 4.	Controls and Procedures	<u>32</u>
PART II.	OTHER INFORMATION	
Item 1A.	Risk Factors	<u>33</u>
Item 6.	<u>Exhibits</u>	<u>67</u>
<u>SIGNAT</u>	<u>URE</u>	<u>68</u>
2		

#### PART I—FINANCIAL INFORMATION

#### Item 1. CONDENSED FINANCIAL STATEMENTS

# CURIS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

(Unaudited)

	September 30 2018	), December 2017	31,
ASSETS	2010	2017	
Current Assets:			
Cash and cash equivalents	\$ 25,561	\$ 38,288	
Investments	5,272	21,944	
Accounts receivable	2,855	3,073	
Prepaid expenses and other current assets	1,127	989	
Total current assets	34,815	64,294	
Property and equipment, net	312	366	
Long-term investment – restricted	153	153	
Goodwill	8,982	8,982	
Other assets	3	3	
Total assets	\$ 44,265	\$ 73,798	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities:			
Accounts payable	\$ 3,008	\$ 5,423	
Accrued liabilities	3,300	2,793	
Current portion of long-term debt, net	6,925	5,886	
Total current liabilities	13,233	14,102	
Long-term debt, net	30,221	35,669	
Other long-term liabilities	29	34	
Total liabilities	43,483	49,805	
Stockholders' Equity:			
Common stock, \$0.01 par value—67,500,000 shares authorized, 33,113,146 shares issue	d		
and outstanding at September 30, 2018; 45,000,000 shares authorized, 33,075,949 shares	331	331	
issued and 32,831,380 shares outstanding at December 31, 2017			
Additional paid-in capital	979,350	977,453	
Treasury stock, at cost, 0 shares at September 30, 2018 and 244,569 shares at December	_	(1,524	)
31, 2017			,
Accumulated deficit	(978,899)	(952,265	)
Accumulated other comprehensive income	_	(2	)
Total stockholders' equity	782	23,993	
Total liabilities and stockholders' equity	\$ 44,265	\$ 73,798	
The accompanying notes are an integral part of these condensed consolidated financial st	atements.		

# CURIS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands, except share and per share data) (Unaudited)

	Three Months Ended Nine Months Ended				
	Septemb	er 30,	September 30,		
	2018	2017	2018	2017	
Revenues:					
Royalties	\$2,781	\$2,412	\$7,649	\$6,706	
Research and development, net	66	32	24	(70	)
Total revenues	2,847	2,444	7,673	6,636	
Costs and expenses:					
Cost of royalty revenues	154	124	417	331	
Research and development	4,983	13,382	19,700	38,177	
General and administrative	4,127	3,409	11,741	10,760	
Total costs and expenses	9,264	16,915	31,858	49,268	
Loss from operations	(6,417)	(14,471)	(24,185)	(42,632	)
Other (expense) income:					
Other (expense) income	_		_	(104	)
Interest income	166	123	541	331	
Interest expense	(972)	(1,109)	(2,990)	(2,884	)
Total other expense, net	(806)	(986)	(2,449)	(2,657	)
Net loss	\$(7,223)	\$(15,457)	\$(26,634)	\$ (45,289	)
Net loss per common share (basic and diluted)	\$(0.22)	\$(0.53)	\$(0.80)	\$(1.57	)
Weighted average common shares (basic and diluted)	33,161,59	929,302,839	33,117,290	)28,824,14	13
Total comprehensive loss	\$(7,222)	\$(15,454)	\$(26,632)	\$ (45,285	)
The accompanying notes are an integral part of these c	condensed	consolidated	d financial s	tatements.	

# CURIS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands) (Unaudited)

	Nine Months Ended			
	Septembe	er	30,	
	2018		2017	
Cash flows from operating activities:				
Net loss	\$(26,634	.)	\$(45,289	))
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	139		176	
Stock-based compensation expense	3,309		3,980	
Amortization of debt issuance costs	25		135	
Non-cash interest (income) expense on investments	(131	)	(31	)
Changes in operating assets and liabilities:				
Accounts receivable	218		3	
Prepaid expenses and other assets	(138	)	98	
Accounts payable and accrued and other liabilities	( )	)	78	
Total adjustments	1,509		4,439	
Net cash used in operating activities	(25,125	)	(40,850	)
Cash flows from investing activities:				
Purchase of investments	(26,145	)	(44,291	)
Sales and maturities of investments	42,950		43,379	
Purchases of property and equipment	(85	)	(147	)
Net cash provided by/(used in) investing activities	16,720		(1,059	)
Cash flows from financing activities:				
Proceeds from issuance of common stock associated with offerings, net of issuance costs	_		41,809	
Proceeds from issuance of common stock under the Company's share-based compensation plans	3 1 1 2		1,020	
Proceeds from credit agreement with HealthCare Royalty Partners, III, L.P.	_		45,000	
Payment of debt issuance costs	_		*	)
Payment on termination of credit agreement with BioPharma-II	_		(18,303	)
Payments on Curis Royalty's debt		-	(-)	)
Net cash (used in)/provided by financing activities			65,708	
Net (decrease)/increase in cash and cash equivalents	(12,727	-		
Cash and cash equivalents, beginning of period	38,288		26,038	
Cash and cash equivalents, end of period	\$25,561		\$49,837	
The accompanying notes are an integral part of these condensed consolidated financial statemen	ts.			

#### **Table of Contents**

CURIS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share and per share data)

#### 1. Nature of Business

Curis, Inc. is a biotechnology company seeking to develop and commercialize innovative drug candidates for the treatment of human cancers. As used throughout these consolidated financial statements, the term "the Company" refers to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term "Curis" refers to Curis, Inc.

The Company conducts its research and development programs both internally and through strategic collaborations. The Company's clinical stage drug candidates are fimepinostat (CUDC-907), CA-4948 and CA-170:

Fimepinostat is currently being explored in clinical studies in patients with MYC-altered diffuse large B-cell lymphoma (DLBCL) and solid tumors and has been granted Orphan Drug Designation and Fast Track Designation for the treatment of DLBCL by the U.S. Food and Drug Administration, or FDA in April 2015

• and May 2018, respectively. The Company is planning a combination study with venetoclax in DLBCL patients with alterations in both MYC and the BCL2 gene, also referred to as double-hit lymphoma, with planned enrollment commencing in the first half of 2019. The Company expects to have initial clinical data from this combination study in the second half of 2019.

CA-4948 is being tested in a dose escalating clinical trial in patients with non-Hodgkin lymphomas, including those with myeloid differentiation primary response 88, or MYD88, alterations. The Company plans to have initial clinical data from this study in mid-year 2019.

CA-170 is currently undergoing testing in a clinical study in patients with advanced solid tumors and lymphomas. The Company has amended the current study to include mesothelioma patients and the Company plans to begin enrollment of these patients in the first half of 2019 and plans to have initial clinical data from this study with respect to mesothelioma in the second half of 2019.

The Company's pipeline also includes CA-327, which is a pre-Investigational New Drug (IND) stage oncology drug candidate. The Company is party to a collaboration with F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under which Roche and Genentech are commercializing Erivedge, a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor. Erivedge® (vismodegib) is approved for the treatment of advanced basal cell carcinoma, or BCC.

In January 2015, and as amended in September 2016, the Company entered into a collaboration, option and license agreement focused on immuno-oncology and selected precision oncology targets with Aurigene Discovery Technologies Limited, or Aurigene.

The collaboration with Aurigene is comprised of multiple programs, and Curis has the option to exclusively license each program, including data, intellectual property and compounds associated therewith, once a development candidate is nominated within such program. In October 2015, the Company exercised options to license two programs under this collaboration. The first licensed program is in the immuno-oncology field and the Company has named CA-170, an orally-available small molecule antagonist of two immune checkpoints, V-domain Ig suppressor of T cell activation (VISTA) and programmed death ligand-1 (PDL1), as the development candidate from this program. The second licensed program is in the precision oncology field and the Company has named CA-4948, an orally-available small molecule inhibitor of Interleukin-1 receptor-associated kinase 4 (IRAK4) as the development candidate. In October 2016, the Company exercised its option to license a third program in the collaboration, and designated CA-327, a distinct orally available small molecule antagonist of two immune checkpoints, PDL1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM3) as the development candidate from this program. In March 2018, the Company exercised its option to license a fourth program, which is an immuno-oncology program.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any products that are successfully developed and commercialized would be used in the healthcare industry and would be regulated in the United States by the FDA and in overseas markets by similar regulatory authorities.

The Company is subject to risks common to companies in the biotechnology industry as well as risks that are specific to the Company's business, including, but not limited to: the Company's ability to advance and expand its research and development programs; the Company's reliance on Aurigene to successfully discover and preclinically develop drug candidates under the parties' collaboration agreement; the Company's reliance on Roche and Genentech to successfully commercialize Erivedge in the approved indication of advanced BCC and to progress its clinical development in indications other than BCC;

the Company's ability to obtain adequate financing to fund its operations; the ability of the Company and its wholly-owned subsidiary, Curis Royalty, LLC, or Curis Royalty, to satisfy the terms of its credit agreement with HealthCare Royalty Partners III, L.P., a Delaware limited partnership managed by HealthCare Royalty Management, LLC, or HealthCare Royalty; the Company's ability to obtain and maintain necessary intellectual property protection; development by the Company's competitors of new or better technological innovations; the Company's dependence on key personnel; the Company's ability to comply with regulatory requirements; the Company's ability to obtain and maintain applicable regulatory approvals and commercialize any approved product candidates and the Company's ability to execute on its overall business strategies.

The Company's future operating results will largely depend on the progress of drug candidates currently in its development pipeline and the magnitude of payments that it may receive and make under its current and potential future collaborations. The results of the Company's operations have varied and will likely continue to vary significantly from year to year and quarter to quarter and depend on a number of factors, including, but not limited to: the timing, outcome and cost of the Company's preclinical studies and clinical trials for its drug candidates; Aurigene's ability to successfully discover and develop preclinical programs under the Company's collaboration with Aurigene, as well as the Company's decision to exclusively license and further develop programs under this collaboration; Roche and Genentech's ability to successfully commercialize Erivedge; and positive results in Roche and Genentech's ongoing clinical trials.

The Company has incurred losses and negative cash flows from operations since its inception. As of September 30, 2018, the Company had an accumulated deficit of approximately \$978.9 million. The Company anticipates that its \$30.8 million of existing cash, cash equivalents and investments at September 30, 2018 should enable it to maintain its planned operations into the third quarter of 2019. In order to ensure adequate cash resources for 12 months from the issuance date of these financial statements, the Company will reduce or delay spending on its research and development programs, including related clinical trials, and operating expenses to the extent it is unable to raise additional capital through its current at-the-market sale agreement with Cowen and Company, LLC, or Cowen or other potential financing. To the extent that the Company is required to implement reduced or delayed spending plans, the Company expects that such measures would enable the Company to maintain its planned operations into the first quarter of 2020. The Company's ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of its control and it may be unable to raise financing in the next 12 months, or on terms favorable to the Company. The Company's inability to obtain additional funds in the next 12 months would delay, or cause the Company to reduce in scope or eliminate some of its development programs, potentially delaying the time to market for any of its product candidates, and would have a negative impact on the Company's financial condition and ability to pursue its business strategies.

#### 2. Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the U.S., or GAAP, for complete financial statements and should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission, or the SEC, on March 8, 2018. In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary for a fair statement of the Company's financial position at September 30, 2018 and the results of operations for the three and nine-month periods ended September 30, 2018 and 2017 and the cash flows for the nine-month periods ended September 30, 2018 and 2017. The condensed consolidated balance sheet at December 31, 2017 was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements.

Effective as of 5:00 p.m. Eastern Time on May 29, 2018, as previously disclosed, the Company effected a 1-for-5 reverse stock split of its common stock. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements have been restated to reflect the reverse stock split on a retroactive basis.

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include the performance obligations under the Company's collaboration agreements; the estimated repayment term of the Company's debt and related short- and long-term classification; the fair value of the Company's debt; the collectability of receivables; the carrying value of property and equipment and intangible assets; the assumptions used in the Company's valuation of stock-based compensation and the value of certain investments and liabilities. Actual results may differ from such estimates.

These interim results are not necessarily indicative of results to be expected for a full year or subsequent interim periods.

#### 3. Revenue Recognition

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's drug candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. The Company has adopted the provisions of the Financial Accounting Standards Board, or FASB, Accounting Standard Codification (ASC) 606, Revenue from Contracts with Customers, or Topic 606. This guidance supersedes the provisions of ASC 605, Revenue Recognition.

Under the new guidance, a company can adopt Topic 606 using either the full retrospective method or the modified retrospective method. Under the full retrospective method, a company recasts the amount by which each financial statement line item presented in the current filing is affected as if the new guidance has always existed. Under the modified retrospective method, prior year financial statements would not need to be recast. Instead, a company applies the cumulative effect of initially applying the new standard as an adjustment to the opening retained earnings balance. The Company performed a detailed accounting assessment to quantify the effect of the transition from the former guidance to the new guidance and concluded that there was no material effect on the Company's consolidated financial statements under either the full retrospective or the modified retrospective methods. The Company has concluded that it will elect the modified retrospective method to avoid restatement of prior filings.

There are multiple options for the transition method under the new guidance, one of which allows a company to apply this guidance retrospectively either to all contracts at the date of initial application or only to contracts that are not completed contracts at the date of initial application. The Company has elected to apply the guidance to only contracts that are not completed contracts as of January 1, 2018. The only contract not completed as of January 1, 2018 is the collaboration agreement with Genentech (see Note 4). The Company has assessed the potential effects to the consolidated financial statements and retained earnings and has concluded that, upon adoption of the new standard, there was no impact.

#### License Fees and Multiple Element Arrangements

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from, the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

If the Company is involved in a steering committee as part of a multiple element arrangement, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Appropriate methods of measuring progress include output methods and input methods. In determining the appropriate method for measuring progress, the Company considers the nature of service that the Company promises to transfer to the customer. When the Company decides on a method of measurement, the Company will apply that single method of measuring progress for each performance obligation satisfied over time and will apply that method consistently to similar performance obligations and in similar circumstances.

If the Company cannot reasonably measure its progress toward complete satisfaction of a performance obligation because it lacks reliable information that would be required to apply an appropriate method of measuring progress, but the Company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then revenue is not recognized until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated

period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. Contingent Research Milestone Payments

#### **Table of Contents**

Under the new guidance, there exists a constraint on the amount of variable consideration included in the transaction price in that either all, or a portion, of an amount of variable consideration should be included in the transaction price. The variable consideration amount should be included only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The assessment of whether variable consideration should be constrained is largely a qualitative one that has two elements: the likelihood of a change in estimate, and the magnitude thereof. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized is not significant, for example.

If the consideration in a contract includes a variable amount, a company will estimate the amount of consideration in exchange for transfer of promised goods or services. The consideration also can vary if a company's entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event. The Company considers contingent research milestone payments to fall under the scope of variable consideration, which should be estimated for revenue recognition purposes at the inception of the contract and reassessed ongoing at the end of each reporting period. The Company assesses whether contingent research milestones should be considered variable consideration that should be constrained and thus not part of the transaction price. This includes an assessment of the probability that all or some of the milestones revenue could be reversed when the uncertainty around whether or not the achievement of each milestone is resolved, and the amount of reversal could be significant.

The guidance provides factors to consider when assessing whether variable consideration should be constrained. All of the factors should be considered, and no factor is determinative. The Company considers all relevant factors. Reimbursement of Costs

Reimbursement of research and development costs by third party collaborators is recognized as revenue over time provided the Company has determined that it transfers control (i.e. performs the services) of a service over time and, therefore, satisfies a performance obligation according to the provisions outlined in the ASC 606-10-25-27, Revenue Recognition.

#### Royalty Revenue

Since the first quarter of 2012, the Company has recognized royalty revenues related to Genentech's and Roche's sales of Erivedge. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company expects to continue recognizing royalty revenue from Genentech's sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any (see Note 4). However, Erivedge royalties will service Curis Royalty's debt until this debt is repaid in full (see Note 7).

#### Summary

During the nine months ended September 30, 2018 and 2017, total gross revenues are 100% from the Company's collaboration with Genentech.

#### Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Significant judgments are required in the application of revenue recognition guidance. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue, or applied against future co-development costs, within the next fiscal year. Amounts that the Company expects will not be recognized in the next fiscal year would be classified as long-term deferred revenue. However, this estimate would be based on the Company's operating plan as of the balance sheet date and on its estimated performance periods under the collaboration in which the Company has recorded deferred revenues. If the Company's operating plan or its estimated performance period would change, the Company could recognize a different amount of deferred revenue over the reporting period.

With respect to each of the foregoing areas of revenue recognition, the Company exercises significant judgment in determining whether an arrangement contains multiple elements, and, if so, how much revenue is allocable to each element. In addition, the Company exercises its judgment in determining when its significant obligations have been

met under such agreements and the specific time periods over which it recognized revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from the Company's initial judgments, its revenue recognition with respect to such transactions would change accordingly and any such change could affect its reported financial results.

#### 4. Research and Development Collaborations

#### (a) Genentech

In June 2003, the Company licensed its proprietary Hedgehog pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit the Hedgehog pathway for the treatment of various cancers. The collaboration is currently focused on the development of Erivedge, which is being commercialized by Genentech in the U.S. and by Genentech's parent company, Roche, in several other countries for the treatment of advanced BCC. Pursuant to the agreement, the Company is eligible to receive up to an aggregate of \$115.0 million in contingent cash milestone payments, exclusive of royalty payments, in connection with the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this amount, the Company has received \$59.0 million in cash milestone payments as of September 30, 2018. In addition to these payments and pursuant to the agreement, the Company is entitled to a royalty on net sales of Erivedge that ranges from 5% to 7.5%. The royalty rate applicable to Erivedge may be decreased by 2% on a country-by-country basis in certain specified circumstances, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority in another country, and is being sold in such country, by a third party for use in the same indication as Erivedge, or, when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded. In 2015, the FDA and the European Medicine Agency's Committee for Medicinal Products for Human Use, approved another Hedgehog signaling pathway inhibitor, Odomzo® (sonidegib), which is marketed by Sun Pharmaceutical Industries Ltd., for use in locally advanced BCC. Beginning in the fourth quarter of 2015, Genentech applied the 2% royalty reduction on U.S. sales of Erivedge as a result of the first commercial sale of Odomzo® in the U.S.

In November 2012, the Company formed a wholly-owned subsidiary, Curis Royalty, to receive a \$30.0 million loan, at an annual interest rate of 12.25%, pursuant to a credit agreement between Curis Royalty and BioPharma-II, a Luxembourg limited liability company managed by Pharmakon Advisors (see Note 7). In connection with the loan, the Company transferred to Curis Royalty its right to receive royalty and royalty-related payments from Genentech. The loan and accrued interest was an obligation of Curis Royalty, with no recourse to the Company, to be repaid using the royalty and royalty-related payments from Genentech.

In March 2017, the Company and Curis Royalty entered into a new credit agreement with HealthCare Royalty Partners III, L.P., or HealthCare Royalty, for the purpose of refinancing the loan from BioPharma-II. Accordingly, HealthCare Royalty made a \$45.0 million loan at an annual interest rate of 9.95% to Curis Royalty, which was used in part to pay off \$18.4 million in remaining loan obligations to Biopharma-II under the prior loan, with the residual proceeds of \$26.6 million distributed to the Company as sole equity member of Curis Royalty.

The Company has identified the following performance obligations related to the Genentech collaboration:

To grant the license for its Hedgehog (Hh) antagonist programs and to provide service on both a Joint Steering

- 1. Committee and Co-Development Steering Committee. This performance obligation has been satisfied and only contingent royalty revenue remains to be recognized in the future.
- To provide reimbursable research and development services. This performance obligation has been satisfied and no revenue remains to be recognized in the future.

The Company recognized \$2.8 million and \$2.4 million in royalty revenue under the Genentech collaboration during the three months ended September 30, 2018 and 2017, respectively, and \$7.6 million and \$6.7 million during the nine months ended September 30, 2018 and 2017, respectively. The Company recorded costs of royalty revenues within the costs and expenses section of its condensed consolidated statements of operations and comprehensive loss of \$0.2 million and \$0.1 million during the three months ended September 30, 2018 and 2017, respectively, and \$0.4 million and \$0.3 million during the nine months ended September 30, 2018 and 2017, respectively. Cost of royalty revenues is comprised of 5% of the royalties earned by Curis Royalty with respect to Erivedge outside Australia, and 2% direct net sales in Australia (subject to decrease on expiration of the patent in April 2019 to 5% of the royalty payments that Curis Royalty receives from Genentech, through February 2022), that the Company is obligated to pay to university licensors. As further discussed in Note 7, the Company expects that all royalty revenues received from Genentech on

net sales of Erivedge will be used to pay principal and interest under the loan received from HealthCare Royalty, until such time as the loan is fully repaid.

The Company recorded \$0.1 million research and development revenue during the three months ended September 30, 2018 and an immaterial amount of research and development revenue during the three months ended September 30, 2017, and \$0.1 million and \$0.1 million during the nine months ended September 30, 2018 and 2017, respectively, related to expenses incurred by the Company on behalf of Genentech that were paid by the Company and for which Genentech is obligated to reimburse the Company.

#### **Table of Contents**

Genentech incurred expenses of an immaterial amount and \$0.1 million during the three months ended September 30, 2018 and 2017, respectively, and \$0.1 million and \$0.2 million during the nine months ended September 30, 2018 and 2017, respectively, under this collaboration which the Company is obligated to reimburse to Genentech, and which the Company has recorded as contra-revenues which have been net against research and development revenues in its consolidated statements of operations and comprehensive loss. The Company will continue to recognize revenue for expense reimbursement as such reimbursable expenses are incurred, provided that the provisions of the ASC 606 are met.

#### (b) Aurigene

In January 2015, the Company entered into an exclusive collaboration agreement with Aurigene for the discovery, development and commercialization of small molecule compounds in the areas of immuno-oncology and selected precision oncology targets. Under the collaboration agreement, Aurigene granted the Company an option to obtain exclusive, royalty-bearing licenses to relevant Aurigene technology to develop, manufacture and commercialize products containing certain of such compounds anywhere in the world, except for India and Russia, which are territories retained by Aurigene.

During 2015, the Company exercised options to license the first two programs under this collaboration, resulting in an aggregate one-time payment of \$6.0 million (satisfying the \$3.0 million option exercise fee for each program) by the Company to Aurigene.

Also in 2015, the Company selected a preclinical program for potential further development within the immuno-oncology part of the collaboration resulting in a one-time payment of \$2.0 million. In October 2016, the Company licensed the program and designated CA-327 as the development candidate as described in Note 1, resulting in a one-time payment of \$1.5 million.

In connection with the collaboration agreement, the Company issued to Aurigene 3,424,026 shares of its common stock valued at \$24.3 million in partial consideration for the rights granted to the Company under the collaboration agreement, which the Company recognized as expense during the year ended December 31, 2015. The shares were issued pursuant to a stock purchase agreement with Aurigene dated January 18, 2015.

In September 2016, the Company and Aurigene entered into an amendment to the collaboration agreement. Under the terms of the amendment, in exchange for the issuance by the Company to Aurigene of 2,041,666 shares of its common stock, Aurigene waived payment of up to a total of \$24.5 million in potential milestones and other payments associated with the first four programs in the collaboration that may have become due from the Company under the collaboration agreement. To the extent any of these waived milestones or other payments are not payable by the Company, for example in the event one or more of the milestone events do not occur, the Company will have the right to deduct the unused waived amount from any one or more of the milestone payment obligations tied to achievement of commercial milestone events. The amendment also provides that, in the event supplemental program activities are performed by Aurigene, the Company will provide up to \$2.0 million of additional funding for each of the third and fourth licensed program. The shares were issued pursuant to a stock purchase agreement with Aurigene dated September 7, 2016.

As of September 30, 2018, the Company has exercised its option to license four programs under the collaboration:

- 1. IRAK4 Program a precision oncology program of small molecule inhibitors of IRAK4. The development candidate is CA-4948, an orally available small molecule inhibitor of IRAK4.
  - PD1/VISTA Program an immuno-oncology program of small molecule antagonists of PD1 and VISTA immune
- 2. checkpoint pathways. The development candidate is CA-170, an orally available small molecule antagonist of VISTA and PDL1.
  - PD1/TIM3 Program an immuno-oncology program of small molecule antagonists of PD1 and TIM3 immune
- 3. checkpoint pathways. The development candidate is CA-327, an orally available small molecule antagonist of PDL1 and TIM3.
- 4. In March 2018, the Company exercised its option to license a fourth program, which is an immuno-oncology program.

For each option to license (as described above) exercised by the Company, the Company is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product in each of the U.S., specified countries in the European Union and Japan, and Aurigene is obligated to use commercially reasonable efforts to perform its obligations under the development plan for such licensed program in an expeditious manner.

Subject to specified exceptions, Aurigene and the Company agreed to collaborate exclusively with each other on the discovery, research, development and commercialization of programs and compounds within immuno-oncology for an initial period of approximately two years from the effective date of the collaboration agreement. At the Company's option, and subject to specified conditions, it may extend such exclusivity for up to three additional one-year periods by paying to Aurigene additional exclusivity option fees on an annual basis. The Company exercised the first one-year exclusivity option fee in the first quarter of 2017. The fee for this exclusivity option exercise was \$7.5 million, which the Company paid in two equal

installments in the first and third quarters of 2017. The Company has elected not to further exercise its exclusivity option and thus will not make the \$10.0 million payment required for this additional exclusivity in 2018. As a result of the Company's election to not further exercise its exclusivity option, Curis is no longer operating under broad immuno-oncology exclusivity with Aurigene. The Company has, however, as provided in the agreement, elected to exercise its option to extend exclusivity on a program-by-program, year-by-year, basis for the IRAK4 Program and the PD1/VISTA Program, both of the licensed programs currently in clinical trials.

Since January 2015, the Company has paid \$14.5 million in research payments and has waived \$19.5 million in milestone payments under the terms of the 2016 amendment.

For each of the IRAK4, PD1/VISTA,PD1/TIM3 programs, and the fourth immuno-oncology program: the Company has remaining unpaid or unwaived payment obligations of \$42.5 million per program, related to regulatory approval and commercial sales milestones, plus specified additional payments for approvals for additional indications, if any. In addition to the collaboration agreement, in June 2017, the Company entered into a master development and manufacturing agreement with Aurigene for the supply of drug substance and drug product, under which it has made cash payments to Aurigene totaling \$1.3 million.

#### 5. Fair Value Measurements

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted Level 2 prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In accordance with the fair value hierarchy, the following table shows the fair value as of September 30, 2018 and December 31, 2017 of those financial assets and liabilities that are measured at fair value on a recurring basis.

	Quoted Prices in Active Markets (Level 1)	other Observable Unobservable Inputs (Level 2) Inputs (Level 3) Total Fair V		
As of September 30, 2018:				
Cash equivalents:				
Money market funds	\$ 19,461	\$ —	\$	<b></b> \$ 19,461
Corporate commercial paper, bonds and notes		5,145		5,145
Municipal and government securities		135		135
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	_	5,272	_	5,272
Total assets at fair value	\$ 19,461	\$ 10,552	\$	<b></b> \$ 30,013

#### **Table of Contents**

	Quoted Prices in Active Markets (Level 1)	Other Observabl Inputs (Level 2)	e Unobservab Inputs (Lev	ole el 3) <sup>Total</sup> Fair Value
As of December 31, 2017:				
Cash equivalents:				
Money market funds	\$ 35,308	\$ —	\$	<b></b> \$ 35,308
Municipal bonds	_	260		260
Short-term investments:				
Corporate commercial paper, stock, bonds and		21,944		21,944
notes	<del>_</del>	21,944	<del>_</del>	21,944
Total assets at fair value	\$ 35,308	\$ 22,204	\$	<b></b> \$ 57,512
No investments held at September 30, 2018 were	transferred betwe	en levels.		

#### 6. Investments

Cash equivalents are highly liquid investments purchased with original maturities of three months or less. All other liquid investments are classified as marketable securities. The Company's short-term investments are marketable securities with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and the Company's long-term investments are marketable securities with original maturities of greater than twelve months from the balance sheet date. Marketable securities consist of commercial paper, corporate bonds and notes, and government obligations. All of the Company's short-term and long-term investments have been designated available-for-sale and are stated at fair value with any unrealized holding gains or losses included as a component of stockholders' equity and any realized gains and losses recorded in the statement of operations in the period during which the securities are sold.

Unrealized gains and temporary losses on investments are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Realized gains and losses, dividends and interest income are included in other income (expense). Any premium or discount arising at purchase is amortized and/or accreted to interest income.

The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of September 30, 2018 are as follows:

	Amortized	Unrealized	Unrealized	Total Fair Value
	Cost	Gain	Loss	Total Fair Value
Corporate bonds and notes – short-term	n\$ 5,272	\$ -	-\$ -	<b>-</b> \$ 5,272
Total investments	\$ 5,272	\$ -	-\$ -	-\$ 5,272

Short-term investments have maturities ranging from one to 12 months with a weighted-average maturity of 0.2 years at September 30, 2018.

The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of December 31, 2017 are as follows:

	Amortized	Unrealized Unrealized		Total Fair Walse	
	Cost	Gain	Loss	Total Fair Value	
Corporate bonds and notes – short-term	ı\$ 21,946	\$ -	-\$ (2 )	\$ 21,944	
Total investments	\$ 21,946	\$ -	-\$ (2 )	\$ 21,944	

Short-term investments have maturities ranging from one to 12 months with a weighted-average maturity of 0.2 years at December 31, 2017.

As of September 30, 2018, the Company did not have any debt securities in an unrealized loss position.

#### 7. Debt

(a)BioPharma-II

In December 2012, Curis' wholly owned subsidiary, Curis Royalty, received a \$30.0 million loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II. In connection with the loan, Curis transferred to Curis Royalty its right to receive royalty and royalty-related payments on the commercial sales of Erivedge that it receives from Genentech (see Note 4(a)). The loan and accrued interest was being repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constituted an obligation of Curis Royalty, and was non-recourse to Curis, Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech were first applied to pay, collectively: (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis' royalty obligations to university licensors, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Subsequently, remaining amounts were applied first to pay interest and second, principal on the loan. Curis remained entitled to receive any contingent payments upon achievement of clinical development objectives. Curis Royalty retained its right to royalty payments related to sales of Erivedge following repayment of the loan.

The final maturity date of the loan was the earlier of the date when the principal was paid in full or the termination of Curis Royalty's right to receive royalties under the collaboration agreement with Genentech. Because the repayment of the term loan was contingent upon the level of Erivedge royalties received, the short- and long-term classification of the debt was based on the Company's estimate of the timing of amounts to be repaid. The Company was not able to estimate when the loan would be repaid as repayments were impacted by numerous factors, all of which were beyond the Company's control. The repayment term could be shortened or extended depending on the actual level of Erivedge royalties received. In addition, if Erivedge royalties were insufficient to pay the accrued interest on the outstanding loan, any unpaid interest outstanding would be added to the principal on a quarterly basis. At any time after January 1, 2017, Curis Royalty was entitled to, subject to certain limitations, to prepay the outstanding principal of the loan in whole or in part, at a price equal to 105% of the outstanding principal on the loan, plus accrued but unpaid interest. The loan was paid off and terminated in March 2017.

#### (b) HealthCare Royalty Partners III

On March 6, 2017, the Company and Curis Royalty entered into a new credit agreement, referred to herein as the credit agreement, with HealthCare Royalty for the purpose of refinancing Curis' and Curis Royalty's existing royalty financing arrangement with BioPharma-II, referred to herein as the prior loan. On March 22, 2017, the prior loan was terminated in its entirety.

Pursuant to the credit agreement, HealthCare Royalty made a \$45.0 million loan at an interest rate of 9.95% to Curis Royalty, which was used to pay off \$18.4 million in remaining loan obligations to Biopharma-II under the prior loan. The remaining proceeds of \$26.6 million were distributed to Curis as sole equity holder of Curis Royalty. The loan from HealthCare Royalty will be repaid from certain Erivedge royalty and royalty-related payments owed by Genentech under the Genentech collaboration agreement, the rights to which were transferred from Curis to Curis Royalty in 2012. Under the terms of the credit agreement with HealthCare Royalty, quarterly Erivedge royalty and royalty-related payments from Genentech will first be applied to pay, collectively: (i) escrow fees payable by the Company pursuant to an escrow agreement, (ii) the Company's royalty obligations to academic institutions, (iii) certain expenses incurred by HealthCare Royalty in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by the Company enforcing its right to indemnification under the collaboration agreement. Subsequently, remaining amounts will be applied first, to pay interest and second, to pay principal on the loan. If royalties owed under the Genentech collaboration agreement are insufficient to pay the accrued interest on the outstanding loan, the unpaid interest outstanding will be added to the loan principal on a quarterly basis.

(c) Respective Debt Payments to BioPharma-II and HealthCare Royalty Partners III During the nine months ended September 30, 2018 and 2017, Curis Royalty made payments totaling \$7.4 million and \$6.5 million, respectively, of which \$4.4 million and \$3.6 million have been applied to the principal, respectively, with the remainder applied to accrued interest. As of September 30, 2018, the Company recorded short- and long-term debt of \$6.9 million and \$30.2 million, respectively, and at December 31, 2017, the Company recorded short- and long-term debt of \$5.9 million and \$35.7 million, respectively, with such amounts recorded within the Company's condensed consolidated balance sheets.

In addition, the Company recorded related accrued interest on its debt of \$0.2 million and \$0.2 million as of September 30, 2018 and December 31, 2017, respectively, with such amounts included in the Company's accrued liabilities section of its condensed consolidated balance sheets. For the three months ended September 30, 2018 and 2017, the Company recognized interest expense related to its debt of \$1.0 million and \$1.1 million, respectively, in the condensed consolidated statement of operations and comprehensive loss. For the nine months ended September 30, 2018 and 2017, the Company recognized interest expense related to its debt of \$3.0 million and \$2.9 million, respectively, in the condensed consolidated statement of operations and comprehensive loss.

At September 30, 2018, the fair value of the debt approximates its carrying value due to the expected repayment period and because the interest rate yield is near current market rate yields. Due to the assumptions required in estimating future Erivedge royalties, the expected repayment period and weighting of various royalty projection scenarios, the fair value of the debt is measured using Level 3 inputs.

During the nine months ended September 30, 2017, the Company incurred debt issuance costs totaling \$0.2 million in connection with its HealthCare Royalty financing transaction, all of which were incurred directly by the Company. The direct costs incurred by the Company were recorded as contra-debt, which directly reduces the outstanding debt balance on the Company's Consolidated Balance Sheet. All issuance costs will be amortized over the estimated term of the debt using the straight-line method, which approximates the effective interest method. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs requires management to make estimates that could impact the Company's short- and long-term classification of these costs, as well as the period over which these costs will be amortized.

#### 8. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30,	December 31,
	2018	2017
Accrued compensation	\$ 2,587	\$ 2,187
Professional fees	227	148
Accrued interest on debt (Note 7)	173	193
Other	313	265
Total	\$ 3,300	\$ 2,793

#### 9. Accounting for Stock-Based Compensation

As of September 30, 2018, the Company had two shareholder-approved, share-based compensation plans: (i) the Amended and Restated 2010 Employee Stock Purchase Plan, or the ESPP, adopted by the board of directors in April 2017 and approved by shareholders in June 2017, which amended the 2010 Employee Stock Purchase Plan, and the (ii) the Third Amended and Restated 2010 Stock Incentive Plan, or the 2010 Plan, adopted by the board of directors in March 2018 and approved by shareholders in May 2018, which was amended to, among other things, add an additional 11,950,000, or 2,390,000 on a post-reverse stock split basis, shares under the 2010 Plan, and set a new expiration date of May 14, 2028 for the 2010 Plan. New employees are typically issued options as an inducement equity award under Nasdaq Listing Rule 5635(c)(4) outside of the 2010 Plan. Effective as of 5:00 p.m. Eastern Time on May 29, 2018, the number of shares of common stock available for issuance under the plans and the number of shares of common stock issuable upon the exercise of then outstanding options have been adjusted to reflect a 1-for-5 reverse stock split.

During the nine months ended September 30, 2018, the Company's board of directors granted options to purchase a total of 1,982,596 shares of the Company's common stock to employees of the Company, under the 2010 Plan or in the form of inducement awards pursuant to Nasdaq Marketplace Rules. Of these options, options to purchase 1,545,596 shares were granted to employees and vest as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period, and are exercisable at a price equal to the closing price of the Company's common stock on the

Nasdaq Global Market on the grant dates. The Company's board of directors granted the remaining options to purchase 437,000 shares of the Company's common stock to its officers in January 2018. Such stock options have an exercise price equal to \$3.45 per share, the closing price of the Company's common stock on the Nasdaq Global Market on the date of grant, and will vest and become exercisable as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period; provided that such awards would terminate and

be forfeited if the Company's stockholders did not approve an amendment to the 2010 Plan to increase the number of shares authorized for issuance thereunder within 12 months of the grant date; and further provided that such options would not be exercisable and no common stock would be issued thereunder, before the approval of such stock incentive plan amendment by the Company's stockholders. As mentioned above, the shareholders approved such amendment in May 2018 and options to purchase an aggregate of 437,000 shares of common stock were awarded to the Company's officers.

Also during the nine months ended September 30, 2018, the Company's board of directors granted restricted stock awards, or RSAs, to officers of the Company for an aggregate amount of 109,250 shares of the Company's common stock under the 2010 Plan. These RSAs will vest as to 25% of the shares underlying the RSA on the first anniversary of the date of grant and as to an additional 25% annually thereafter until all such shares become vested, based upon continued service to the Company over a four-year period.

During the nine months ended September 30, 2018, the Company's board of directors granted RSAs to its non-employee directors for an aggregate amount of 185,000 shares of the Company's common stock under the 2010 Plan. These RSAs will vest as to 100% of the shares underlying the RSA on the first anniversary of the date of grant, subject to continued service to the Company over the course of such year.

**Employee and Director Grants** 

Vesting Tied to Service Conditions

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. The Black-Scholes option pricing model employs the following key assumptions for employee and director options awarded during the nine months ended September 30, 2018 and 2017 based on the assumptions noted in the following table:

	Nine Months		
	Ended		
	Septembe	er 30,	
	2018	2017	
Expected life (years) - employees	5.5	5.5	
Expected life (years) - officers	5.5	5.5	
Expected life (years) – directors	6.25	6.25	
Risk-free interest rate	2.5-3.0%	2.0-2.1%	
Volatility	66-73%	63-64%	
Dividends	None	None	

The expected volatility is based on the annualized daily historical volatility of the Company's stock price for a time period consistent with the expected term of each grant. Management believes that the historical volatility of the Company's stock price best represents the future volatility of the stock price.

The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for the expected term of the respective grant. The Company has not historically paid cash dividends, and does not expect to pay cash dividends in the foreseeable future.

The expected terms and stock price volatility utilized in the calculation involve management's best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. GAAP also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. A summary of stock option activity under the 2010 Plan, the 2000 Stock Incentive Plan, the 2000 Director Stock Option Plan and nonstatutory inducement awards is summarized as follows:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding, December 31, 2017	3,206,858	\$ 12.08		
Granted	1,982,596	2.58		
Exercised	_			
Canceled	(1,386,817)	10.14		
Outstanding, September 30, 2018	3,802,637	\$ 7.84	6.68	\$ 122
Exercisable at September 30, 2018	1,759,429	\$ 11.94	3.97	\$ —
Vested and unvested expected to vest at September 30, 2018	3,384,567	\$ 8.43	6.35	\$ 88

The weighted average grant-date fair values of these stock options granted during the nine months ended September 30, 2018 and 2017 were \$1.46 and \$7.15, respectively. As of September 30, 2018, there was approximately \$4.0 million of unrecognized compensation cost related to unvested employee stock option awards outstanding, net of the impact of estimated forfeitures, that is expected to be recognized as expense over a weighted-average period of 3.21 years. There were no options exercised during the nine months ended September 30, 2018. The intrinsic value of employee stock options exercised during the nine months ended September 30, 2017 was \$1.0 million.

The following table presents a summary of outstanding RSAs under the 2010 Plan as of September 30, 2018:

		Weighted
	Number	Average
	of	Grant
	Shares	Date Fair
		Value
Outstanding, December 31, 2017		\$ —
Awarded	294,250	3.45
Vested	_	_
Forfeited	(68,000)	3.45
Outstanding, September 30, 2018	226,250	\$ 3.45

As of September 30, 2018, there were 226,250 shares outstanding covered by RSAs that are expected to vest. The weighted average fair value of these shares of restricted stock was \$3.45 per share and the aggregate fair value of these shares of restricted stock was approximately \$1.0 million. As of September 30, 2018, there were approximately \$0.3 million of unrecognized compensation costs, net of estimated forfeitures, related to RSAs granted to officers and non-employee directors, which are expected to be recognized as expense over a remaining weighted average period of 0.86 years.

#### **Employee Stock-Based Compensation Expense**

The Company recorded a total of \$0.8 million and \$2.9 million, respectively, in compensation expense for the three and nine months ended September 30, 2018 and \$1.3 million and \$4.0 million, respectively, for the three and nine months ended September 30, 2017 related to employee and director stock option grants. The total fair values of vested stock options for each of the nine months ended September 30, 2018 and 2017 was \$3.2 million and \$2.8 million, respectively.

The Company recorded \$0.1 million and \$0.4 million in compensation expense during the three and nine months ended September 30, 2018, net of expected forfeitures, related to officer and director restricted stock awards. Total Stock-Based Compensation Expense

For the three and nine months ended September 30, 2018 and 2017, the Company recorded stock-based compensation expense to the following line items in its costs and expenses section of the condensed consolidated statements of operations and comprehensive loss, including expense related to its ESPP:

#### **Table of Contents**

	Three	<b>;</b>		
	Months		Nine Months	
	Ended		Ended	
	September		September 30,	
	30,			
	2018	2017	2018	2017
Research and development expenses	\$295	\$370	\$1,143	\$1,072
General and administrative expenses	600	923	2,166	2,908
Total stock-based compensation expense	\$895	\$1,293	\$3,309	\$3,980

#### 10. Accumulated Other Comprehensive Income (Loss)

The following tables summarize the changes in accumulated other comprehensive income (loss) as of September 30, 2018 and 2017:

	Unrealized Loss on Securities Available-for-Sale		
Balance, as of December 31, 2017	\$	(2	)
Unrealized loss on marketable securities	2		
Amounts reclassified from accumulated other comprehensive income (loss)			
Net current period other comprehensive income	2		
Balance, as of September 30, 2018	\$		

The above amounts do not reflect a tax effect because the Company expects to record a net loss for 2018.

Gain on Securities Avai	Unrealized Losses and	
	Gain on	
	lable-for-Sale	
Balance, as of December 31, 2016 \$ (4	)	
Unrealized loss on marketable securities 4		
Amounts reclassified from accumulated other comprehensive income (loss) —		
Net current period other comprehensive income 4		
Balance, as of September 30, 2017 \$ —		

#### 11. Common Stock and Treasury Stock

Effective as of 5:00 p.m. Eastern Time on May 29, 2018, all share amounts and per share amounts have been adjusted to reflect a 1-for-5 reverse stock split.

(a)ATM Sales Agreement

On July 2, 2015, the Company entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which the Company may sell from time to time up to \$30.0 million of the Company's common stock through an "at-the-market" equity offering program under which Cowen acts as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. In addition, with the Company's prior written approval, Cowen may also sell the common stock by any other method permitted by law, including pursuant to negotiated transactions. Cowen is obligated to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdag Global Market to sell on the Company's behalf all of the shares requested to be sold by the Company. The Company has no obligation to sell any of the common stock under the sales agreement. Either the Company or Cowen may at any time suspend solicitations and offers under the sales agreement upon notice to the other party. The sales agreement may be terminated at any time by either the Company or Cowen upon written notice to the other party as specified in the sales agreement. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. Each party has agreed in the sales agreement to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, subject to the terms of the sales agreement. The shares sold under the sales agreement have been issued and sold pursuant to the universal shelf registration statement on Form S-3, filed with the Securities and Exchange Commission on July 2, 2015. Since inception, the Company has sold 420,796 shares of common stock under this sales agreement for net proceeds of \$6.2 million. The remaining shares that may be sold under the sales agreement are expected to be issued and sold, if at all, pursuant to the currently effective universal shelf registration statement on Form S-3, filed with the Securities and Exchange Commission on May 3, 2018.

#### (b)Treasury Stock Retirement

Since 2002, the Company has repurchased 244,569 shares of common stock at a total cost of \$1.5 million. The shares were repurchased through a combination of a repurchase program of up to \$3.0 million approved by the Board of Directors in 2002 and through employee purchases of common stock upon the exercise of stock options by remittance of shares of Company stock. The Company accounts for its common stock repurchases as treasury stock under the cost method.

In March 2018, the Company retired all 244,569 shares of common stock at a total cost of \$1.5 million. This was a non-cash transaction and thus only affected the classifications within the stockholders' equity section of the Company's consolidated balance sheet.

#### 12. Loss Per Common Share

Basic and diluted loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for the three months ended September 30, 2018 and 2017, because the effect of the potential common stock equivalents would be antidilutive due to the Company's net loss position for these periods. Antidilutive securities consist of stock options outstanding of 3,802,637 and 3,398,760 as of September 30, 2018 and 2017, respectively.

# 13. Related Party Transactions(a) Letter Agreement with David Tuck

On May 24, 2018, the Company announced that David Tuck, M.D., Chief Medical Officer, provided notice of his intention to retire from the Company, effective as of August 31, 2018. Dr. Tuck subsequently determined to retire on August 3, 2018. The Company and Dr. Tuck entered into a letter agreement on August 1, 2018 (the "Letter Agreement") pursuant to which Dr. Tuck agreed to provide the Company with specified advisory services commencing on August 4, 2018 and extending until May 3, 2019, subject to earlier termination (the "Advisory Period"). In consideration for Dr. Tuck's advisory services, the Company has agreed to (i) pay him a monthly retainer of \$35,000 during the Advisory

Period and (ii) reimburse him for any pre-approved reasonable, documented out-of-pocket expenses relating to his advisory services. In addition, the Company and Dr. Tuck have agreed to amend his stock option agreements such that his outstanding options will cease to vest as of his date of resignation on August 3, 2018. The Letter Agreement may be terminated (i) at any time upon the mutual written consent of the parties, (ii) at any time by the Company immediately upon Dr. Tuck's breach or threatened breach of the terms of his Invention, Non-Disclosure and Non-Competition Agreement with the Company, or (iii) by the Company at any time upon Dr. Tuck's material breach of the terms of the Letter Agreement and failure to cure such breach within five days after written notice from the Company. In the event of termination of the Letter Agreement, Dr. Tuck will be entitled to payment for services performed and expenses paid or incurred prior to the effective date of termination that have not previously been paid. The Letter Agreement also contains other customary terms and conditions relating to his advisory service.

While the Company may utilize Dr. Tuck's consulting services in the future, the Company deemed the services to be a reduced level of service and not substantive. Under ASC 450, Contingencies, when an employee terminates and enters into a consulting agreement and the services to be provided are not deemed substantive, the transaction should be accounted for as a severance arrangement with no future service requirement. Based on this guidance, the Company recognized \$0.3 million of expense during the three and nine months ended September 30, 2018 representing the total obligation under the Letter Agreement.

#### 14. New Accounting Pronouncements

Recently Issued and Adopted

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation: Improvements to Nonemployee Share-based Payment Accounting, which simplifies the accounting for nonemployee share-based payment transactions resulting from expanding the scope of ASC 718, Compensation - Stock Compensation. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2018, and early adoption is permitted, but no earlier than an entity's adoption date of ASC 606, Revenue from Contracts with Customers. The Company did not have any outstanding nonemployee awards as of June 30, 2018, and adopted this update as of that date. There is no impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Scope of Modification Accounting, which clarifies the scope under which modification accounting should be applied to a share-based payment award under ASC 718. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2017, and early adoption is permitted for interim or annual periods beginning after January 1, 2017. As such, the Company adopted this standard as of January 1, 2018 and concluded there was no material impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Simplifying the Test for Goodwill Impairment, which simplifies the subsequent measurement of goodwill under the current standard in testing the interim or annual impairment of goodwill. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2019, and early adoption is permitted for interim or annual period beginning after January 1, 2017. As such, the Company adopted this standard as of January 1, 2018 and concluded there was no material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments, which helps to clarify the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under ASC 230, Statement of Cash Flows, by addressing eight specific cash flow issues. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2017, and early adoption is permitted for interim or annual periods. As such, the Company adopted this standard as of January 1, 2018 and concluded there was no material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which amends prior guidance on accounting for equity investments and financial liabilities. The new standard amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in results of operations. The new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. The guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within such years. As such, the Company adopted this standard as of January 1, 2018 and concluded there was no material impact on its

consolidated financial statements.

In May 2014, the FASB issued new revenue recognition guidance in ASU 2014-09, Revenue from Contracts with Customers, for entities, providing a single, comprehensive model to account for revenue arising from contracts with customers. In addition, the FASB recently issued ASUs 2016-08, 2016-10, 2016-12, 2016-20 and 2017-13, all of which are further clarifying amendments to ASU 2014-09. This new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity's nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially

adopting the ASU recognized at the date of initial application. The Company adopted the modified retrospective method. To date, the Company's sources of collaboration and other revenue have primarily been collaboration agreements. The most significant differences between Topic 606 and previous guidance for license and collaboration revenue are: (i) allocating consideration to performance obligations; and (ii) estimating and determining the timing of recognition of variable consideration received from licensees, including up-front license payments, contingent milestones and royalties. The guidance is effective for interim and annual periods beginning after December 15, 2017 and early adoption is permitted. The Company has adopted the guidance as of January 1, 2018. The Company has evaluated the impact that ASU 2014-09 may have on the financial position and results of operations and has concluded that the adoption of this guidance has no material impact on its consolidated financial statements. For more detail, see Note 3, Revenue Recognition.

# Recently Issued, Not Yet Adopted

In August 2018, the FASB issued Accounting Standards Update (ASU) 2018-13, Fair Value Measurement, which modified the disclosure requirements for fair value measurement under ASC 820. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the effects of this standard and does not expect that adoption of this standard will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. In addition, the FASB recently issued ASUs 2018-10 and 2018-11, all of which are further clarifying amendments to ASU 2016-02. The standard requires organizations that lease assets to recognize on the balance sheet assets or liabilities, as applicable, for the rights and obligations created by those leases. Additionally, the guidance modifies current guidance for lessor accounting and leveraged leases, and is effective for fiscal years beginning after December 15, 2018, and interim periods within such years. Early adoption is permitted, but the Company does not anticipate electing early adoption. The Company has begun to assess the current state of accounting for leases, to catalog all current leases effected and understand the gaps between the current state and required future state and to implement the new processes and controls required. The Company currently expects that adoption of this standard will increase both total assets and liabilities in its consolidated financial statements and is currently evaluating whether the impact will be material.

# $_{\mbox{\scriptsize Item 2.}}$ MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes appearing elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, or Form 10-Q, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used throughout this report, the terms "the Company," "we," "us," and "our" refer to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term "Curis" refers to Curis, Inc. Unless otherwise indicated, all information in this Form 10-Q gives effect to a 1-for-5 reverse stock split of Curis' common stock, that became effective as of 5:00 p.m. Eastern Time on May 29, 2018. All common shares and per share amounts have been adjusted to reflect such reverse stock split.

# Overview

We are a biotechnology company seeking to develop and commercialize innovative and effective drug candidates for the treatment of human cancers. Our clinical stage drug candidates are:

Fimepinostat (CUDC-907), for which our clinical studies in patients with relapsed refractory DLBCL including those with MYC alterations are ongoing. Fimepinostat was granted Orphan Drug Designation in April 2015 and Fast Track Designation in May 2018 by the FDA for the treatment of DLBCL. We are planning a Phase 1 combination study with venetoclax in DLBCL patients with alterations in both MYC and the BCL2 gene, also referred to as double-hit

lymphoma, with planned enrollment commencing in the first half of 2019. We expect to have initial clinical data from this combination study in the second half of 2019;

CA-4948, for which, in January 2018 we initiated a dose escalating clinical trial in patients with non-Hodgkin 4ymphomas including those with MYD88 alterations. We plan to have initial clinical data from this study in mid-year 2019; and

CA-170, for which we are currently conducting a clinical study in patients with advanced solid tumors and lymphomas. We have amended the current study to include mesothelioma patients. We plan to begin enrollment of these patients in the first half of 2019 and plan to have initial clinical data from this study with respect to mesothelioma in the second half of 2019.

#### **Table of Contents**

Our pipeline also includes CA-327, which is a pre-Investigational New Drug, or IND, stage oncology drug candidate. In March 2018, we exercised our option to license a fourth program, which is an immuno-oncology program, from our collaboration partner Aurigene.

In addition, we are party to a collaboration with F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under which Roche and Genentech are commercializing Erivedge, a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor. Erivedge® (vismodegib) is approved for the treatment of advanced BCC.

Finally, on January 18, 2015, we entered into a collaboration agreement with Aurigene, a specialized, discovery-stage biotechnology company and wholly-owned subsidiary of Dr. Reddy's Laboratories for the discovery, development and commercialization of small molecule compounds in the areas of immune-oncology and precision oncology, which we refer to as the Aurigene agreement, which was amended in September 2016. As of September 30, 2018, we have licensed four programs under the Aurigene collaboration.

- 1. IRAK4 Program a precision oncology program of small molecule inhibitors of IRAK4. The development candidate is CA-4948.
- 2. PD1/VISTA Program an immuno-oncology program of small molecule antagonists of PD1 and VISTA immune checkpoint pathways. The development candidate is CA-170.
- 3. PD1/TIM3 Program an immuno-oncology program of small molecule antagonists of PD1 and TIM3 immune checkpoint pathways. The development candidate is CA-327.
- 4. In March 2018, we exercised our option to license a fourth program, which is an immuno-oncology program. Based on our clinical development plans for our pipeline, we intend to predominantly focus our available resources on the continued development of fimepinostat, as well as CA-4948 and CA-170 in collaboration with Aurigene in the near term.

We recently implemented a reduction of costs and re-allocation of resources from preclinical activities to clinical activities to strengthen focus on clinical development. We expect the net result of expense reductions in pre-clinical R&D and G&A expenditure and targeted increases in clinical operations to result in a total cash burn reduction from approximately \$11 million to \$8 million per quarter.

#### Our Collaborations and License Agreements

For additional information regarding our collaboration and license agreements, refer to Note 4, Research and Development Collaborations, in the accompanying Notes to the Condensed Consolidated Financial Statements included in Item 1 of Part I of this Form 10-Q and Items 7 and 8 of our Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on March 8, 2018. Liquidity

Since our inception, we have funded our operations primarily through private and public placements of our equity securities, license fees, contingent cash payments, research and development funding from our corporate collaborators, debt financings and the monetization of certain royalty rights. We have never been profitable on an annual basis and have an accumulated deficit of \$978.9 million as of September 30, 2018.

We will need to generate significant revenues to achieve profitability, and do not expect to achieve profitability in the foreseeable future, if at all.

We anticipate that our existing cash, cash equivalents and investments at September 30, 2018 should enable us to maintain our planned operations into the third quarter of 2019. In order to ensure adequate cash resources for 12 months from the issuance date of the financial statements included in this Form 10-Q, we will reduce or delay spending on our research and development programs, including clinical trials, and operating expenses to the extent we are unable to raise additional capital through our current at-the-market sale agreement with Cowen or other potential financing. To the extent that we are required to implement reduced or delayed spending plans, we expect that such measures would enable us to maintain our planned operations into the first quarter of 2020. For a further discussion of our liquidity and funding requirements and related risks and uncertainties, see "Liquidity and Capital Resources - Funding Requirements."

## **Table of Contents**

**Key Drivers** 

We believe that near-term key drivers to our success will include:

our ability to successfully plan, finance and complete clinical trials for fimepinostat, CA-4948, and CA-170, and that these clinical trials generate favorable data in the near term;

Aurigene's ability to advance additional preclinical immuno-oncology, and precision oncology drug candidates, and our ability to license these programs from Aurigene and further progress them clinically;

Genentech and Roche's ability to continue to successfully commercialize Erivedge in advanced BCC in the United States and in other global territories; and

our ability to raise the substantial additional financing required to fund our operations through our at-the-market sale facility with Cowen or other potential financing.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully develop and commercialize our current and any future additional drug candidates.

# Financial Operations Overview

General. Our future operating results will largely depend on the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the cost and outcome of any preclinical development or clinical trials then being conducted. For a discussion of our liquidity and funding requirements, see "Liquidity and Capital Resources - Funding Requirements."

Debt. In December 2012, our wholly-owned subsidiary, Curis Royalty LLC, or Curis Royalty, entered into a \$30.0 million credit agreement with BioPharma II, a Luxembourg limited liability company managed by Pharmakon Advisors, at an annual interest rate of 12.25% collateralized with certain future Erivedge royalty and royalty-related payment streams.

In connection with the loan, we transferred to Curis Royalty our right to receive certain royalty and royalty-related payments from Genentech. The loan and accrued interest was an obligation of Curis Royalty, with no recourse to us, to be repaid using the royalty and royalty-related payments from Genentech. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech were first applied to pay: (i) escrow fees payable by us pursuant to an escrow agreement between us, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) our royalty obligations to university licensors, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by us enforcing our right to indemnification under the collaboration agreement with Genentech. Subsequent remaining amounts were applied first, to pay interest and second, principal on the loan. We remained entitled to receive any contingent payments upon achievement of clinical development objectives. There were no caps to the amounts Curis Royalty would be required to make to BioPharma-II. Curis Royalty retained the right to royalty payments related to sales of Erivedge following repayment of the loan.

In March 2017, we and Curis Royalty, entered into a new credit agreement, referred to as the credit agreement, with HealthCare Royalty Partners III, L.P., or HealthCare Royalty, a Delaware limited partnership managed by Healthcare Royalty Management, LLC, for the purpose of refinancing the prior loan from BioPharma-II. On the effective date of the credit agreement with Healthcare Royalty, the credit agreement with BioPharma-II was terminated in its entirety. Also in March 2017, HealthCare Royalty made a \$45.0 million loan at an annual interest rate of 9.95% to Curis Royalty, which was used to pay off the approximate \$18.4 million in remaining loan obligations to Biopharma-II under the prior loan. The remaining proceeds of the loan of \$26.6 million were distributed to us as sole equity holder of Curis Royalty.

The loan from HealthCare Royalty will be repaid from certain royalty and royalty-related payments owed by Genentech under the Genentech collaboration agreement, the rights to which were transferred from Curis to Curis

Royalty pursuant to a purchase and sale agreement in 2012, in connection with the prior credit agreement. Under the terms of the credit agreement, quarterly royalty and royalty-related payments from Genentech will first be applied to pay: (i) escrow fees payable by us pursuant to an escrow agreement, (ii) our royalty obligations to academic institutions, (iii) certain expenses incurred by HealthCare Royalty in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement, and (iv) expenses incurred by us enforcing our right to indemnification under the collaboration agreement. Subsequently, remaining amounts will be applied first, to pay interest and second, to pay principal on the loan. If Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, the unpaid interest outstanding will be added to the loan principal on a quarterly basis.

The final maturity date of the loan will be the earlier of such date as the principal is paid in full, or Curis Royalty's rights to receive royalties under the collaboration agreement with Genentech terminate. At any time before the third anniversary of the closing date, Curis Royalty may, subject to certain limitations, prepay the outstanding principal of the loan in whole or in part, at a prepayment premium equal to the amount of interest that would have accrued from the date of prepayment through and including the third anniversary of the closing date. Thereafter, any voluntary prepayments during the following periods are to be made at the following prepayment prices (calculated as a percentage of the principal amount prepaid):

- 405%, after the third anniversary of the closing date through and including the fourth anniversary of the closing date;
- 402.5%, after the fourth anniversary of the closing date through and including the fifth anniversary of the closing date;
- 101%, after the fifth anniversary of the closing date through and including the sixth anniversary of the closing date; and
- 400%, after the sixth anniversary of the closing date.

The obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated upon the occurrence of an event of default as defined in the credit agreement. As of September 30, 2018, the outstanding principal and interest due under the loan is \$37.5 million.

Revenue. We do not expect to generate any revenues from our direct sale of products for several years, if ever. Substantially all of our revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees, including royalty payments. Since the first quarter of 2012, we have recognized royalty revenues related to Genentech's sales of Erivedge and we expect to continue to recognize royalty revenue in future quarters from Genentech's sales of Erivedge in the U.S. and Roche's sales of Erivedge outside of the U.S. However, we expect that all of such royalty revenues will be used by our wholly-owned subsidiary, Curis Royalty, to pay principal and interest under the loan that Curis Royalty received from HealthCare Royalty, until such time as the loan is fully repaid. We currently estimate that all Erivedge royalties will be applied to the loan from HealthCare Royalty for the foreseeable future. The repayment period is highly uncertain and could vary materially to the extent that royalty payments received are higher or lower than our current estimates, which could arise due to factors beyond our control, such as the sale of competing products that result in a lowering of the royalty rates we are entitled to receive, decreased market acceptance, a failure by Genentech and/or Roche to obtain required regulatory approvals, and other factors described under "Part II, Item 1A—Risk Factors," We could receive additional milestone payments from Genentech, provided that contractually-specified development and regulatory objectives are met. Our only source of revenues and/or cash flows from operations for the foreseeable future will be royalty payments that are contingent upon the continued commercialization of Erivedge under this collaboration, and contingent cash payments for the achievement of clinical, development and regulatory objectives, if any, are met, under our existing collaboration with Genentech. Our receipt of additional payments under our existing collaboration with Genentech cannot be assured, nor can we predict the timing of any such payments, as the case may

Cost of Royalty Revenues. Cost of royalty revenues consists of all expenses incurred that are associated with royalty revenues that we record as revenues in our consolidated statements of operations and comprehensive loss. These costs currently consist of payments we are obligated to make to university licensors on royalties that Curis Royalty receives from Genentech on net sales of Erivedge. In all territories other than Australia, our obligation is equal to 5% of the royalty payments that we receive from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. In addition, for royalties that Curis Royalty receives from Roche's sales of Erivedge in Australia, we will be obligated to make payments to university licensors of 2% of Roche's direct net sales in Australia until expiration of the patent in April 2019. After April 2019, the amount we are obligated to pay will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech through February 2022. Research and Development. Research and development expense consists of costs incurred to develop our drug candidates. These expenses consist primarily of: salaries and related expenses for personnel, including stock-based compensation expense, costs of conducting clinical trials, including amounts paid to clinical centers, clinical research organizations and consultants, among others, other outside service costs including costs of contract manufacturing, sublicense payments, the costs of supplies and reagents, consulting, and occupancy and depreciation charges.

Research and development expenses also include certain payments that we make to Aurigene under our collaboration agreement, including, for example, option exercise fees and milestone payments. We expense research and development costs as incurred. We are currently incurring research and development costs under our Hedgehog signaling pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. In addition, we record research and development expense for payments that we are obligated to make to certain third-party university licensors upon our receipt of

## **Table of Contents**

payments from Genentech related to the achievement of clinical development and regulatory objectives under our collaboration agreement.

The following graphic outlines the current status of our programs:

Our programs are in early stages of clinical or preclinical development. Therefore, our ability and that of our collaborators and licensees to successfully complete preclinical studies and clinical trials of these drug candidates, as appropriate, and the timing of completion of such programs, is highly uncertain.

There are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators' future results, including:

the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;

the results of future preclinical studies and clinical trials;

the cost and timing of regulatory approvals and maintaining compliance with regulatory requirements;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;

the effect of competing technological and market developments; and

the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which, material net cash inflows are expected to commence from any of our drug candidates. Any failure to complete the development of our drug candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

A further discussion of some of the risks and uncertainties associated with completing our research and development programs on schedule, or at all, and some consequences of failing to do so, are set forth under "Part II, Item 1A-Risk Factors."

General and Administrative. General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs

include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by us.

# Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the value of certain liabilities, debt classification and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We set forth our critical accounting policies and estimates in our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 8, 2018. Refer to Note 3, Revenue Recognition, in the accompanying Notes to condensed consolidated financial statements included in Item 1 of Part I of this Form 10-Q for updates to our critical accounting policies and estimates.

#### **Results of Operations**

Three and Nine Months Ended September 30, 2018 and September 30, 2017

The following table summarizes our results of operations for the three and nine months ended September 30, 2018 and 2017:

	For the Three Months Ended September 30,		Incre		For the Nin Ended Sep	Percentage Increase/ (Decrease)		
	2018	2017			2018	2017		
	(in thousa			(in thousar				
Revenues	\$2,847	\$2,444	16	%	\$7,673	\$6,636	16	%
Costs and expenses:								
Cost of royalty revenues	154	124	24	%	417	331	26	%
Research and development	4,983	13,382	(63	)%	19,700	38,177	(48	)%
General and administrative	4,127	3,409	21	%	11,741	10,760	9	%
Other expense, net	806	986	(18	)%	2,449	2,657	(8	)%
Net loss	(7,223)	\$(15,457)	(53	)%	\$(26,634)	\$(45,289)	(41	)%

Revenues. Total revenues are summarized as follows:

	For the Three				For the I	Vine		
	Months	Percent	tage	Months	Percentage			
	Ended Se	Increase/		Ended S	Increase/			
	30,	(Decrea	ase)	30,	(Decrease)			
	2018	2017			2018	2017		
	(in thous			(in thous				
Revenues:								
Royalties	\$ 2,781	\$ 2,412	15	%	\$7,649	\$6,706	14	%
Research and development, net	66	32	106	%	24	(70)	(134	)%
Total revenues	\$ 2,847	\$ 2,444	16	%	\$7,673	\$6,636	16	%

Total revenues increased by \$0.4 million to \$2.8 million for the three months ended September 30, 2018 as compared to \$2.4 million for the same period in 2017, related to an increase in royalty revenues arising from Genentech and

Roche's net sales of Erivedge during the three months ended September 30, 2018 as compared to the prior year period.

Total revenues increased by \$1.1 million to \$7.7 million for the nine months ended September 30, 2018 as compared to \$6.6 million for the same period in 2017, related to an increase in royalty revenues arising from Genentech and Roche's net sales of Erivedge during the nine months ended September 30, 2018 as compared to the prior year period. Cost of Royalty Revenues. Cost of royalty revenues increased by \$0.1 million to \$0.2 million for the three months ended September 30, 2018 as compared to \$0.1 million for the same period in 2017. Cost of royalty revenues increased by \$0.1 million to \$0.4 million for the nine months ended September 30, 2018 as compared to \$0.3 million for the same period in 2017. We are obligated to make payments to two university licensors on royalties that Curis Royalty earns from Genentech on net sales of Erivedge.

Research and Development Expenses. The following table summarizes our research and development expenses incurred during the periods indicated:

	For the '	Three			For the N			
	Months	Perc	entage	Months	Percentage			
	Ended S	Increase/ (Decrease)		Ended September 30,		Increase/ (Decrease)		
	30,							
	2018	2017			2018	2017		
	(in thou			(in thousands)				
Direct research and development expenses	\$ 2,057	\$10,087	(80	)%	\$8,901	\$27,637	(68	)%
Employee-related expenses	2,439	2,780	(12	)%	9,150	9,189		%
Facilities, depreciation and other expenses	487	515	(5	)%	1,649	1,351	22	%
Total research and development expenses	\$4,983	\$13,382	(63	)%	\$19,700	\$38,177	(48	)%

Research and development expenses were \$5.0 million for the three months ended September 30, 2018, as compared to \$13.4 million in the same period in 2017, a decrease of \$8.4 million, or 63%. Direct research and development expenses decreased by \$8.0 million for the three months ended September 30, 2018 as compared to the same period in 2017, primarily due to decreased costs related to clinical activities and manufacturing for fimepinostat, CA-170 and CA-4948 and due to a payment to Aurigene of \$3.8 million for an exclusivity option in September 2017.

Research and development expenses were \$19.7 million for the nine months ended September 30, 2018, as compared to \$38.2 million in the same period in 2017, a decrease of \$18.5 million, or 48%. Direct research and development expenses decreased by \$18.7 million for the nine months ended September 30, 2018 as compared to the same period in 2017, primarily due to two payments to Aurigene of \$3.8 million each for an exclusivity option in January and September 2017, as well as decreased costs related to clinical activities and manufacturing for fimepinostat and CA-170, partially offset by increased costs related to CA-4948.

We expect that a majority of our research and development expenses for the foreseeable future will be incurred in connection with our efforts to advance our programs, including clinical and preclinical development costs, option exercise fees, exclusivity option payments, and potential milestone payments upon achievement of certain milestones. General and Administrative Expenses. General and administrative expenses are summarized as follows:

	For the Three				For the N			
	Months Ended September 30,			ntage	Months	Percentage Increase/ (Decrease)		
				ase/				
				ease)				
	2018	2017			2018	2017		
	(in thousands)				(in thousands)			
Personnel	\$ 1,789	\$ 1,025	75	%	\$4,281	\$3,699	16	%
Occupancy and depreciation	133	115	16	%	426	329	29	%
Legal services	773	667	16	%	2,234	1,513	48	%
Professional and consulting services	535	393	36	%	1,693	1,401	21	%

Insurance costs	102	99	3	%	304	300	1	%
Stock-based compensation	600	923	(35	)%	2,166	2,908	(26	)%
Other general and administrative expenses	195	187	4	%	637	610	4	%
Total general and administrative expenses	\$4,127	\$ 3,409	21	%	\$11,741	\$10,760	9	%

## **Table of Contents**

General and administrative expenses were \$4.1 million for the three months ended September 30, 2018, as compared to \$3.4 million in the same period in 2017, an increase of \$0.7 million, or 21%. The increase in general administrative expense was driven primarily by higher personnel and professional and consulting services partially offset by lower stock-based compensation for the period.

General and administrative expenses were \$11.7 million for the nine months ended September 30, 2018, as compared to \$10.8 million in the same period in 2017, an increase of \$0.9 million, or 9%. The increase in general administrative expense was driven primarily by higher personnel, legal, professional and consulting services partially offset by lower stock-based compensation costs for the period.

Other Expense. For the three months ended September 30, 2018 and 2017, interest expense was \$1.0 million and \$1.1 million, respectively, related to interest accrued on Curis Royalty's debt obligations. Interest income was \$0.2 million and \$0.1 million for the three months ended September 30, 2018 and 2017, respectively.

For the nine months ended September 30, 2018 and 2017, interest expense was \$3.0 million and \$2.9 million, respectively, related to interest accrued on Curis Royalty's debt obligations. Interest income was \$0.5 million and \$0.3 million for the nine months ended September 30, 2018 and 2017, respectively.

#### Liquidity and Capital Resources

We have financed our operations primarily through private and public placements of our equity securities, license fees, contingent cash payments, and research and development funding from our corporate collaborators, debt financings and the monetization of certain royalty rights.

# Public Offering of Common Stock

On September 18, 2017, we entered into an underwriting agreement with Robert W. Baird & Co. Incorporated as underwriter, under which we issued and sold 4,000,000 shares of our common stock in a public offering. The offering price to the public was \$9.25 per share, and the underwriter agreed to purchase the shares from us pursuant to the underwriting agreement at a price of \$8.90 per share. We received net proceeds from the sale of the shares, after deducting the underwriting discounts and commissions and estimated offering expenses, of \$35.3 million. We incurred other offering expenses of \$0.3 million related to this transaction.

# Placement of Equity Securities

On July 2, 2015, we entered into a sales agreement with Cowen and Company, or Cowen, for up to \$30.0 million of our common stock through an "at-the-market" equity offering program, under which Cowen acts as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. We are not obligated to sell any of the common stock under this sales agreement. Either Cowen or we may at any time suspend solicitations and offers under the sales agreement upon notice to the other party. The sales agreement may be terminated at any time by either party upon written notice to the other party, in the manner specified in the sales agreement. The aggregate compensation payable to Cowen will be 3% of the gross sales price of the common stock sold pursuant to the sales agreement. The shares sold under the sales agreement have been sold pursuant to our universal shelf registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on September 2, 2015. As of September 30, 2018, we sold 420,796 shares of common stock under this sales agreement for net proceeds of \$6.2 million. The remaining shares that may be sold under the sales agreement are expected to be issued and sold, if at all, pursuant to our universal shelf registration statement on Form S-3, filed with the Securities and Exchange Commission on May 3, 2018 and declared effective on May 17, 2018.

# **Debt Financing**

In December 2012, our wholly owned subsidiary, Curis Royalty, received a \$30.0 million loan, at an interest rate of 12.25%, pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments from Genentech. The loan and accrued interest was an obligation of Curis Royalty, with no recourse to us, to be repaid using the royalty and royalty-related payments from Genentech. The final maturity date of the loan was the earlier of such date that the principal was paid

in full, or Curis Royalty's right to receive royalties under the collaboration agreement with Genentech was terminated.

## **Table of Contents**

On March 6, 2017, we and Curis Royalty entered into a new credit agreement with HealthCare Royalty Partners, for the purpose of refinancing the prior loan from BioPharma-II. Accordingly, HealthCare Royalty made a \$45.0 million loan at an interest rate of 9.95% to Curis Royalty, of which proceeds of \$18.4 million were used to pay off the then-remaining loan obligations to Biopharma-II and the remaining proceeds of \$26.6 million were distributed to us as sole equity holder of Curis Royalty.

Payments to HealthCare Royalty for the nine months ended September 30, 2018 totaled \$7.4 million, of which \$4.4 million has been applied to the principal, and the remainder satisfying interest obligations. As of September 30, 2018, Curis Royalty owed a total of \$37.5 million, gross of issuance costs, to HealthCare Royalty, including accrued interest.

Milestone Payments and Monetization of Royalty Rights

We have received aggregate milestone payments totaling \$59.0 million under our collaboration with Genentech. In addition, we began receiving royalty revenues in 2012 in connection with Genentech's sales of Erivedge in the U.S. and Roche's sales of Erivedge outside of the U.S. Erivedge royalty revenues received after December 2012 have been used to repay Curis Royalty's outstanding principal and interest under the loan due to BioPharma-II, subject to specified quarterly caps. Erivedge royalty revenues will continue to be used to repay Curis Royalty's outstanding principal and interest under the loan due to HealthCare Royalty. We also remain entitled to receive any contingent payments upon achievement of clinical development objectives and royalty payments related to sales of Erivedge following repayment of the loan. Upon receipt of any such payments, as well as on royalties received in any territory other than Australia, we are required to make payments to certain university licensors totaling 5% of these amounts. In addition, for royalties that Curis Royalty receives from Roche's sales of Erivedge in Australia, we are obligated to make payments to university licensors of 2% of Roche's direct net sales in Australia until the expiration of the patent in April 2019. After April 2019, the amount we are obligated to pay will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech through February 2022.

At September 30, 2018, our principal sources of liquidity consisted of cash, cash equivalents, and investments of \$30.8 million. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, as well as short-term commercial paper and government obligations. We maintain cash balances with financial institutions in excess of insured limits.

#### Cash Flows

Cash flows for operations have primarily been used for salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical and clinical studies, laboratory supplies, consulting fees and legal fees. We expect that costs associated with clinical studies will increase in future periods.

Net cash used in operating activities of \$25.1 million during the nine months ended September 30, 2018 was primarily the result of our net loss for the period of \$26.6 million, offset by non-cash charges consisting of stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling \$3.3 million. In addition, changes in the balances of certain of our assets and liabilities had an unfavorable effect on cash including a net decrease in accounts payable and accrued liabilities of \$1.9 million, offset slightly by a decrease in accounts receivable of \$0.2 million.

Net cash used in operating activities of \$40.9 million during the nine-month period ended September 30, 2017 was primarily the result of our net loss for the period of \$45.3 million, offset by non-cash charges consisting of stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling \$4.3 million. In addition, changes in the balances of certain of our assets and liabilities had a favorable effect on cash, including an increase in accounts payable and a decrease in accounts receivable.

We expect to continue to use cash in operations as we seek to advance our drug candidates and four programs under our collaboration agreement with Aurigene. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and other specified objectives.

Investing activities provided cash of \$16.7 million and used cash of \$1.1 million for the nine months ended September 30, 2018 and 2017, respectively, resulting primarily from net investment activity from purchases and maturities of investments for the respective periods.

Financing activities used cash of \$4.3 million for the nine months ended September 30, 2018 as a result of principal payments on Curis Royalty's loan from HealthCare Royalty of \$4.4 million.

Financing activities provided cash of \$65.7 million for the nine months ended September 30, 2017 as a result of \$45.0 million in gross proceeds from the credit agreement with HealthCare Royalty, an aggregate of \$41.8 million in net proceeds from the public offering underwritten by Baird and our at-the-market sales pursuant to our sales agreement with Cowen and \$1.0 million in proceeds from the exercise of stock options, offset by full payoff as well as principal payments on Curis Royalty's loan from BioPharma-II of \$18.4 million and \$3.6 million, respectively. Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2018, we had an accumulated deficit of approximately \$978.9 million. We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to support our current and future research and development activities for fimepinostat, CA-4948 and CA-170, and to fund our general and administrative costs and expenses. We anticipate that our existing cash, cash equivalents and investments at September 30, 2018 should enable us to maintain our planned operations into the third quarter of 2019. In order to ensure adequate cash resources for 12 months from the issuance date of the financial statements included in this Form 10-Q, we will reduce or delay spending on our research and development programs, including clinical trials, and operating expenses to the extent we are unable to raise additional capital through our current at-the-market sale agreement with Cowen or other potential financing. To the extent that we are required to implement reduced or delayed spending plans, we expect that such measures would enable us to maintain our planned operations into the first quarter of 2020. Our ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of our control, and we may be unable to raise financing in the next 12 months, or on terms favorable to us. Our inability to obtain additional funds in the next 12 months would delay, or cause us to reduce in scope or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates, and would have a negative impact on our financial condition and ability to pursue our business strategies. Factors that may affect our planned future capital requirements and accelerate our need for additional working capital include the following:

unanticipated costs in our research and development programs;

the timing and cost of obtaining regulatory approvals for our drug candidates and maintaining compliance with regulatory requirements;

the timing and amount of option exercise fees, milestone payments, royalties and other payments due to licensors, including Aurigene, for patent rights and technology used in our drug development programs;

the costs of commercialization activities for any of our drug candidates that receive marketing approval, to the extent such costs are our responsibility, including the costs and timing of establishing drug sales, marketing, distribution and manufacturing capabilities;

unplanned costs to prepare, file, prosecute, defend and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and

unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

Subject to specified exceptions, we and Aurigene have agreed to collaborate exclusively with each other on the discovery, research, development and commercialization of programs and compounds within immuno-oncology for an initial period of approximately two years from the effective date of the collaboration agreement. At our option, and subject to specified conditions, we may extend such exclusivity for up to three additional one-year periods by paying exclusivity option fees on an annual basis. We exercised the first one-year exclusivity option in the first quarter of 2017. The fee for this exclusivity option exercise was \$7.5 million, which we paid in two equal installments in the first and third quarters of 2017. We have elected not to further exercise our exclusivity option and thus will not make the \$10.0 million payment required for this additional exclusivity in 2018. As a result of our election to not further exercise our exclusivity option, we are no longer operating under the broad immuno-oncology exclusivity with Aurigene. We have, however, as provided in the agreement, elected to exercise our option to extend exclusivity on a program-by-program, year-by-year, basis for the IRAK4 Program and the PD1/VISTA Program, both of the licensed programs currently in clinical trials.

We have historically derived a portion of our operating cash flow from our receipt of milestone payments under collaboration agreements with third parties. However, we cannot predict whether we will receive additional milestone payments under existing or future collaborations.

To become and remain profitable, we, either alone or with collaborators, must develop and eventually commercialize one or more drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling those drugs for which we may obtain marketing approval and

## **Table of Contents**

satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. Other than Erivedge, which is being commercialized by Genentech and Roche, our most advanced drug candidates are currently only in early clinical testing.

For the foreseeable future, we will need to spend significant capital in an effort to develop and commercialize products and we expect to incur substantial operating losses. Our failure to become and remain profitable would, among other things, depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

#### **New Accounting Pronouncements**

For detailed information regarding recently issued accounting pronouncements and the expected impact on our condensed consolidated financial statements, see Note 14, "New Accounting Pronouncements," in the accompanying Notes to Condensed Consolidated Financial Statements included in Item 1. of Part I of this Form 10-Q.

# **Contractual Obligations**

There have been no material changes to our contractual obligations set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations" in our Annual Report on Form 10-K for the year ended December 31, 2017.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2018.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK Not required.

#### Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls & Procedures

Our management, with the participation of our chief executive officer, who is also our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act") means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Table of Contents**

#### PART II—OTHER INFORMATION

#### Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this Form 10-Q and in other documents we file with the SEC, in evaluating Curis and our business. If any of the scenarios described in the following risk factors occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede the risk factors previously disclosed in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2017.

# RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have incurred substantial losses, expect to continue to incur substantial losses for the foreseeable future and may never generate significant revenue or achieve profitability.

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. Our net losses were \$26.6 million for the nine months ended September 30, 2018, and \$53.3 million, \$60.4 million and \$59.0 million for the years ended December 31, 2017, 2016, and 2015, respectively. As of September 30, 2018, we had an accumulated deficit of \$978.9 million. We have not completed the development of any drug candidate on our own. Other than Erivedge®, which is being commercialized and further developed by Genentech and Roche under our June 2003 collaboration with Genentech, we may never have a drug candidate approved for commercialization. We have financed our operations to date primarily through public offerings and private placements of our common stock, other debt financings and amounts received through various licensing and collaboration agreements. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital.

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

continue to develop and conduct clinical trials with respect to drug candidates;

seek to identify and develop additional drug candidates;

acquire or in-license other drug candidates or technologies;

seek regulatory and marketing approvals for our drug candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution, and other commercial infrastructure in the future to commercialize various drugs for which we may obtain marketing approval, if any;

require the manufacture of larger quantities of drug candidates for clinical development and, potentially, commercialization;

maintain, expand, and protect our intellectual property portfolio;

hire and retain additional personnel, such as clinical, quality control and scientific personnel; and

add equipment and physical infrastructure as may be required to support our research and development programs. Our ability to become and remain profitable depends on our ability to generate significant revenue. Our only current source of revenues is comprised of licensing and royalty revenues that we earn under our collaboration with Genentech related to the development and commercialization of Erivedge. In addition, all future royalty payments related to Erivedge will service the outstanding debt and accrued interest owed by Curis Royalty to HealthCare Royalty Partners III until the debt is fully repaid. The final maturity date of the loan will be the earlier of such date that the principal is paid in full, or Curis Royalty's right to receive royalties under the collaboration agreement with Genentech is terminated.

We do not expect to generate significant revenues other than those related to Erivedge unless and until we are, or any collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our drug candidates other than Erivedge. Successful commercialization will require achievement of key milestones, including initiating and successfully completing clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing, and selling those drugs for which we, or any of our collaborators, may

obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our drugs from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues and whether or when we might achieve profitability. We and any collaborators may never succeed in these activities

#### **Table of Contents**

and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of drug candidates, or continue our operations and cause a decline in the value of our common stock.

We will require substantial additional capital, which may be difficult to obtain, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our drug development programs or commercialization efforts.

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. Our planned operating and capital requirements currently include the support of our current and future research and development activities for fimepinostat, CA-4948 and CA-170 as well as development candidates we have and may continue to license under our collaboration with Aurigene. We will require substantial additional capital to fund the further development of these programs, as well as to fund our general and administrative costs and expenses. Moreover, under our collaboration, license and option agreement with Aurigene, we are required to make milestone, royalty and option fee payments for discovery, research and preclinical development programs that will be performed by Aurigene, which impose significant potential financial obligations on us. The collaboration includes multiple programs, and we have the option to exclusively license compounds once a development candidate is nominated within each respective program.

We anticipate that our existing cash, cash equivalents and investments at September 30, 2018 should enable us to maintain our planned operations into the third quarter of 2019. In order to ensure adequate cash resources for 12 months from the issuance date of the financial statements included in this Form 10-Q, we will reduce or delay spending on our research and development programs, including related clinical trials, and operating expenses to the extent we are unable to raise additional capital through our current at-the-market sale agreement with Cowen or other potential financing. To the extent that we are required to implement reduced or delayed spending plans, we expect that such measures would enable us to maintain our planned operations into the first quarter of 2020. Our ability to raise additional funds will depend, among other factors, on financial, economic and market conditions, many of which are outside of our control, and we may be unable to raise financing in the next 12 months, or on terms favorable to us. Our inability to obtain additional funds in the next 12 months would delay, or cause us to reduce in scope or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates, and would have a negative impact on our financial condition and ability to pursue our business strategies. Furthermore, there are a number of factors that may affect our future capital requirements and further accelerate our

unanticipated costs in our research and development programs;

the timing and cost of obtaining regulatory approvals for our drug candidates and maintaining compliance with regulatory requirements;

need for additional working capital, many of which are outside our control, including the following:

the timing and amount of option exercise fees, milestone payments, royalties and other payments due to licensors, including Aurigene, for patent rights and technology used in our drug development programs;

the costs of commercialization activities for any of our drug candidates that receive marketing approval, to the extent such costs are our responsibility, including the costs and timing of establishing drug sales, marketing, distribution and manufacturing capabilities;

unplanned costs to prepare, file, prosecute, defend and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and

unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

We transferred and encumbered certain royalty and royalty-related payments on the commercial sales of Erivedge in connection with our credit agreement with HealthCare Royalty Partners III and, as a result, we could lose all rights to future royalty and royalty-related payments.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a \$30.0 million loan pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on commercial sales of Erivedge that we receive from Genentech. In March 2017, Curis Royalty received a \$45.0 million loan pursuant to a new credit agreement with HealthCare Royalty Partners III, or HealthCare Royalty the proceeds of which were first used to pay off \$18.4 million in remaining loan obligations to BioPharma-II and the

remaining proceeds were then distributed to Curis as sole equity holder of Curis Royalty. The loan and accrued interest is being repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the new loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to HealthCare Royalty in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is non-recourse to Curis, except that (i) Curis agreed, as a post-closing matter, to use reasonable best efforts to obtain Genentech's consent to a pledge of Curis' equity interest in Curis Royalty, which has since been obtained, and (ii) under certain circumstances arising from the breach of certain covenants and representations, HealthCare Royalty may proceed directly against Curis.

Under the terms of the credit agreement, neither Curis nor Curis Royalty guaranteed any level of future royalty or royalty-related payments or the value of such payments as collateral to the loan. However, in certain circumstances, the obligations of Curis Royalty to repay the loan may be accelerated under the credit agreement with HealthCare Royalty, including:

if any payment of principal is not made within three days of when such payment is due and payable or otherwise made in accordance with the terms of the credit agreement;

if any representations or warranties made in the credit agreement or any other related transaction document prove to be incorrect or misleading in any material respect when made;

if there occurs a default in the performance of affirmative and negative covenants set forth in the credit agreement or under certain ancillary transaction documents;

the failure by Genentech to pay material amounts owed under the collaboration agreement with Genentech because of an actual breach or default by Curis under the collaboration agreement;

a material breach or default by Curis Royalty under certain ancillary transaction documents with HealthCare Royalty, in each case, which such breach or default is not cured within 30 days after written demand thereof by HealthCare Royalty;

the voluntary or involuntary commencement of bankruptcy proceedings by either Curis or Curis Royalty and other insolvency-related defaults;

any materially adverse effect on the binding nature of any of the transaction documents or the Genentech collaboration agreement;

if any person shall be designated an independent director of Curis Royalty other than in accordance with its limited liability company operating agreement; or

•ff Curis shall at any time cease to own, of record and beneficially, 100% of the equity interests in Curis Royalty. If any of the above were to occur, Curis Royalty may not have sufficient funds to pay the accelerated obligation and HealthCare Royalty could foreclose on the secured royalty and royalty-related payment stream. In such an event, we could lose our right to royalty and royalty-related payments not transferred to HealthCare Royalty, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to HealthCare Royalty under the credit agreement.

The amount of royalty revenue we received from sales of Erivedge has been adversely affected by a competing drug, and may further be affected in the future.

Pursuant to the terms of our collaboration agreement with Genentech, our subsidiary Curis Royalty is entitled to receive royalties on net sales of Erivedge that range from 5% to 7.5% based upon global Erivedge sales by Roche and Genentech. The royalty rate applicable to Erivedge may be decreased in certain specified circumstances, including when a competing drug product that binds to the same molecular target as Erivedge is approved by the applicable country's regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge, or when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded. During the third quarter of 2015, the FDA and the Committee for Medicinal Products for Human Use, or CHMP, approved an additional Hedgehog signaling pathway inhibitor marketed by Sun Pharmaceuticals, sonidegib (Odomzo®), for the treatment of adults with locally advanced BCC.

Sales of sonidegib (Odomzo®) were first recorded in the U.S. during the fourth quarter of 2015 and, accordingly, Genentech has reduced royalties on its net sales in the U.S. of Erivedge from 5–7.5% to 3–5.5%. We also believe that sales of sonidegib have, and are likely to, adversely affect sales of Erivedge, including those in the U.S. and ex-U.S. countries, and the resulting revenue we may receive from Genentech. A decrease in sales of Erivedge, or in the royalty rate that we receive for sales of Erivedge could adversely affect our operating results and the ability of our wholly-owned subsidiary, Curis Royalty, to satisfy its royalty-secured loan obligation to HealthCare Royalty.

#### **Table of Contents**

Fluctuations in our quarterly and annual operating results could adversely affect the price of our common stock. Our quarterly and annual operating results may fluctuate significantly. Some of the factors that may cause our operating results to fluctuate on a period-to-period basis include:

payments we may be required to make to collaborators such as Aurigene to exercise license rights and satisfy milestones and royalty obligations;

the status of, and level of expenses incurred in connection with, our programs, including development costs relating to fimepinostat, CA-4948 and CA-170, as well as funding programs that we have licensed or may in the future license and develop under our collaboration with Aurigene;

fluctuations in sales of Erivedge and related royalty payments, including fluctuations resulting from the sales of competing drug products such as sonidegib, which is approved in the U.S. and Europe for the treatment of locally advanced BCC and is now being marketed and sold by Sun Pharmaceuticals Industries Ltd., or Sun Pharmaceuticals; any intellectual property infringement lawsuit or other litigation in which we may become involved; the implementation of restructuring and cost-savings strategies;

the occurrence of an event of default under the credit agreement by and among Curis, Curis Royalty and HealthCare Royalty;

the implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, and non-recurring revenue or expenses under any such agreement; and compliance with regulatory requirements.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us, and disclosures related thereto. Such estimates and judgments include the carrying value of our property, the value of equipment and intangible assets, revenue recognition, and the value of certain liabilities, the repayment term of our loan from HealthCare Royalty, and stock-based compensation expense. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, and their underlying assumptions, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" set forth in this report.

# RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR DRUGS

The therapeutic efficacy of our drug candidates is unproven in humans, and we may not be able to successfully develop and commercialize drug candidates pursuant to these programs.

Our drug candidates, including fimepinostat, CA-4948 and CA-170, are novel chemical entities, and their potential benefit as therapeutic cancer drugs is unproven. Our ability to generate revenues from these drug candidates, which we do not expect will occur in the short term, if ever, will depend heavily on their successful development and commercialization, which is subject to many potential risks. For example, our drug candidates may not prove to be effective inhibitors of the molecular targets they are being designed to act against, and may not demonstrate in patients any or all of the pharmacological benefits that may have been demonstrated in preclinical studies. These drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If the FDA determines that any of our drug candidates are associated with significant side effects or have characteristics that are unexpected, we may need to delay or abandon their development or limit development to certain 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.

Moreover, many drug candidates that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound or resulted in their removal from the market. As a result of these and other risks described herein that are inherent in the development and commercialization of novel therapeutic agents, we may not successfully maintain third party licensing or collaboration transactions with respect to, or

#### **Table of Contents**

successfully commercialize, drug candidates, in which case we will not achieve profitability and the value of our stock may decline.

We depend heavily on the success of our most advanced drug candidates. All of our drug candidates are still in early clinical or preclinical development. Preclinical studies and clinical trials of our drug candidates may not be successful. If we are unable to commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed.

Our ability to generate drug candidate(s) and/or drug product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our most advanced drug candidates, including fimepinostat, CA-4948 and CA-170. The success of our drug candidates will depend on many factors, including the following:

• successful enrollment in, and completion of, ongoing and future clinical trials of fimepinostat, CA-4948, CA-170 and other compounds that we may develop under our collaboration agreement with Aurigene; Aurigene's ability to successfully discover and preclinically develop other drug candidates under the collaboration agreement;

a safety, tolerability and efficacy profile that is satisfactory to FDA or any comparable foreign regulatory authority for marketing approval;

receipt of requisite marketing approvals from applicable regulatory authorities;

the extent of any required post marketing approval commitments to applicable regulatory authorities;

establishment of supply arrangements with third party raw materials suppliers and manufacturers; establishment of arrangements with third party manufacturers to obtain finished drug products that is appropriately packaged for sale;

adequate ongoing availability of raw materials and drug products for clinical development and any commercial sales; obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;

protection of the rights in our intellectual property portfolio;

successful launch of commercial sales following any marketing approval;

a continued acceptable safety profile following any marketing approval;

commercial acceptance by patients, the medical community and third-party payors; and

our ability to compete with other therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully market, commercialize, or distribute our most advanced drug candidate, which would materially harm our business.

If clinical trials of any future drug candidates that we, or any collaborators, may develop fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we, or any collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these drug candidates.

We, and any collaborators, are not permitted to commercialize, market, promote or sell any drug candidate in the U.S. without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, or the EMA, impose similar requirements. We, and any collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our drug candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our drug candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events or undesirable side effects that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or

any comparable foreign regulatory authority that a drug candidate may not continue development or is not approvable. It is possible that even if one or more of our drug candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a

#### **Table of Contents**

variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a drug candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our drug candidates, or we may mistakenly believe that our drug candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, or any collaborators, and impair our ability to generate revenues from drug sales, regulatory and commercialization milestones and royalties. Moreover, if we, or any collaborators, are required to conduct additional clinical trials or other testing of our drug candidates beyond the trials and testing that we or they contemplate, if we, or they, are unable to successfully complete clinical trials of our drug candidates or other testing, or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our drug candidates, we, or any future collaborators, may:

incur additional unplanned costs;

be delayed in obtaining marketing approval for our drug 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 significant safety warnings, including boxed warnings;

be subject to additional post-marketing testing or other requirements; or

be required to remove the drug from the market after obtaining marketing approval.

Our failure to successfully initiate and complete clinical trials of our drug candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our drug candidates would significantly harm our business.

Adverse events or undesirable side effects caused by, or other unexpected properties of, drug candidates that we develop may be identified during development and could delay or prevent their marketing approval or limit their use. Adverse events or undesirable side effects caused by, or other unexpected properties of, any drug candidates that we may develop could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our drug candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If any of our drug candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of that drug candidate to certain 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. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

If we, or any collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of our drug candidates, potential clinical development, marketing approval or commercialization of our drug candidates could be delayed or prevented.

We, or any collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent clinical development, marketing approval or commercialization of our current drug candidates or any future drug candidates that we, or any collaborators, may develop, including:

regulators or institutional review boards may not authorize us, any collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

we, or any collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

elinical trials of our drug candidates may produce unfavorable or inconclusive results;

we, or any collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon drug development programs;

the number of patients required for clinical trials of our drug candidates may be larger than we, or any collaborators, anticipate, patient enrollment in these clinical trials may be slower than we, or any collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or any collaborators, anticipate;

## **Table of Contents**

our estimates of the patient populations available for study may be higher than actual patient numbers and result in our inability to sufficiently enroll our trials;

the cost of planned clinical trials of our drug candidates may be greater than we anticipate;

our third-party contractors or those of any collaborators, including those manufacturing our drug candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any collaborators in a timely manner or at all;

patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the elinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;

we, or any collaborators, may have to delay, suspend or terminate clinical trials of our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the drug candidate;