CURIS INC
Form 10-Q
August 02, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark one)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 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)	(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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. (Check one):

Large accelerated filer	¨	Accelerated filer	ý
Non-accelerated filer	¨	Smaller reporting company	¨
		Emerging growth company	¨

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

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

As of July 27, 2018, there were 33,181,146 shares of the registrant's common stock outstanding.

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CURIS, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q
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PART I—FINANCIAL INFORMATION

Item 1. CONDENSED FINANCIAL STATEMENTS

CURIS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$30,465	$ 38,288
Investments	9,955	21,944
Accounts receivable	2,505	3,073
Prepaid expenses and other current assets	776	989
Total current assets	43,701	64,294
Property and equipment, net	352	366
Long-term investment – restricted	153	153
Goodwill	8,982	8,982
Other assets	3	3
Total assets	$53,191	$ 73,798
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$4,275	$ 5,423
Accrued liabilities	3,263	2,793
Current portion of long-term debt, net	6,965	5,886
Total current liabilities	14,503	14,102
Long-term debt, net	31,532	35,669
Other long-term liabilities	46	34
Total liabilities	46,081	49,805
Stockholders' Equity:		
Common stock, $0.01 par value—67,500,000 shares authorized, 33,181,146 shares issued and outstanding at June 30, 2018; 45,000,000 shares authorized, 33,075,949 shares issued and 32,831,380 shares outstanding at December 31, 2017	332	331
Additional paid-in capital	978,455	977,453
Treasury stock, at cost, 0 shares at June 30, 2018 and 244,569 shares at December 31, 2017	—	(1,524)
Accumulated deficit	(971,676)	(952,265)
Accumulated other comprehensive income	(1)	(2)
Total stockholders' equity	7,110	23,993
Total liabilities and stockholders' equity	$53,191	$ 73,798

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Royalties	$2,394	$2,102	$4,868	$4,294
Research and development, net	(36)	(41)	(42)	(102)
Total revenues	2,358	2,061	4,826	4,192
Costs and expenses:				
Cost of royalty revenues	134	96	263	207
Research and development	6,451	11,255	14,717	24,795
General and administrative	3,633	3,819	7,614	7,351
Total costs and expenses	10,218	15,170	22,594	32,353
Loss from operations	(7,860)	(13,109)	(17,768)	(28,161)
Other (expense) income:				
Other (expense) income	—	—	—	(104)
Interest income	189	138	375	208
Interest expense	(993)	(1,119)	(2,018)	(1,775)
Total other expense, net	(804)	(981)	(1,643)	(1,671)
Net loss	$(8,664)	$(14,090)	$(19,411)	$(29,832)
Net loss per common share (basic and diluted)	$(0.26)	$(0.49)	$(0.59)	$(1.04)
Weighted average common shares (basic and diluted)	33,135,392	28,757,341	33,094,772	28,580,829
Total comprehensive loss	$(8,659)	$(14,087)	$(19,410)	$(29,831)

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(19,411)	$(29,832)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	99	113
Stock-based compensation expense	2,415	2,688
Amortization of debt issuance costs	16	128
Non-cash interest (income) expense on investments	(128)	(49)
Changes in operating assets and liabilities:		
Accounts receivable	568	228
Prepaid expenses and other assets	213	299
Accounts payable and accrued and other liabilities	(674)	2,056
Total adjustments	2,509	5,463
Net cash used in operating activities	(16,902)	(24,369)
Cash flows from investing activities:		
Purchase of investments	(20,932)	(27,476)
Sales and maturities of investments	33,050	21,608
Purchases of property and equipment	(77)	(126)
Net cash provided by/(used in) investing activities	12,041	(5,994)
Cash flows from financing activities:		
Proceeds from issuance of common stock associated with offerings, net of issuance costs	—	6,214
Proceeds from issuance of common stock under the Company’s share-based compensation plans	112	890
Proceeds from credit agreement with HealthCare Royalty Partners, III, L.P.	—	45,000
Payment of debt issuance costs	—	(192)
Payment on termination of credit agreement with BioPharma-II	—	(18,303)
Payments on Curis Royalty’s debt	(3,074)	(2,607)
Net cash (used in)/provided by financing activities	(2,962)	31,002
Net (decrease)/increase in cash and cash equivalents	(7,823)	639
Cash and cash equivalents, beginning of period	38,288	26,038
Cash and cash equivalents, end of period	$30,465	$26,677
Non-cash items:		
Property and equipment purchases in accounts payable	$8	$—

The accompanying notes are an integral part of these condensed consolidated financial statements.

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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), which is currently in clinical studies in patients with MYC-altered diffuse large B-cell lymphoma (DLBCL) and solid tumors; CA-170, which is currently undergoing testing in a Phase 1 study in patients with advanced solid tumors and lymphomas; and CA-4948, which is being tested in a Phase 1 trial in patients with advanced non-Hodgkin lymphomas, including those with myeloid differentiation primary response 88, or MYD88, alterations. The U.S. Food and Drug Administration, or FDA, granted fimepinostat Orphan Drug Designation in April 2015 and Fast Track Designation in May 2018 for the treatment of DLBCL. The Company's pipeline also includes CA-327, which is a pre-Investigational New Drug (IND) stage oncology drug candidate. The Company continues work to enable the filing of an IND application with the U.S. FDA for clinical testing of CA-327 in 2018. 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, programmed death ligand-1 (PDL1) and V-domain Ig suppressor of T cell activation (VISTA), 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

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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 June 30, 2018, the Company had an accumulated deficit of approximately $971.7 million. The Company anticipates that its $40.4 million of existing cash, cash equivalents and investments at June 30, 2018 should enable it to maintain its planned operations into the second half 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 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. 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 June 30, 2018 and the results of operations for the three and six-month periods ended June 30, 2018 and 2017 and the cash flows for the six-month periods ended June 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

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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

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.

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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 six months ended June 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 June 30, 2018.

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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:

1. To grant the license for its Hedgehog (Hh) antagonist programs and to provide service on both a Joint Steering Committee and Co-Development Steering Committee. This performance obligation has been satisfied and only contingent royalty revenue remains to be recognized in the future.
2. 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 $2.4 million and $2.1 million in royalty revenue under the Genentech collaboration during the three months ended June 30, 2018 and 2017, respectively, and $4.9 million and $4.3 million during the six months ended June 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 $0.1 million and $0.1 million during the three months ended June 30, 2018 and 2017, respectively, and $0.3 million and $0.2 million during the six months ended June 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 immaterial research and development revenue during the three months ended June 30, 2018 and 2017, respectively, and an immaterial amount during the six months ended June 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.

Genentech incurred expenses of an immaterial amount and $0.1 million during the three months ended June 30, 2018 and 2017, respectively, and $0.1 million and $0.1 million during the six months ended June 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.

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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 June 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.
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, an orally available small molecule antagonist of PDL1 and VISTA.
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, 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 $15.5 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.

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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 $0.8 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.
Level 2	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted 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 June 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 Inputs (Level 2)	Unobservable Inputs (Level 3)	Total Fair Value
As of June 30, 2018:				
Cash equivalents:				
Money market funds	$ 26,813	$ —	$ —	$ 26,813
Corporate commercial paper, bonds and notes	—	1,399	—	1,399
Municipal and government securities	—	190	—	190
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	—	9,955	—	9,955
Total assets at fair value	$ 26,813	$ 11,544	$ —	$ 38,357

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total Fair Value
As of December 31, 2017:				
Cash equivalents:				
Money market funds	$ 35,308	$ —	$ —	$ 35,308
Municipal bonds	—	260	—	260
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	—	21,944	—	21,944
Total assets at fair value	$ 35,308	$ 22,204	$ —	$ 57,512

No investments held at June 30, 2018 were transferred between levels.

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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 June 30, 2018 are as follows:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Total Fair Value
Corporate bonds and notes – short-term	$ 9,956	$ —	$ (1)	$ 9,955
Total investments	$ 9,956	$ —	$ (1)	$ 9,955

Short-term investments have maturities ranging from one to 12 months with a weighted-average maturity of 0.1 years at June 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 Cost	Unrealized Gain	Unrealized Loss	Total Fair Value
Corporate bonds and notes – short-term	$ 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.

At June 30, 2018, the Company held 2 debt securities that had been in an unrealized loss position for less than 12 months. The aggregate fair value of these securities was $2.9 million at June 30, 2018. The Company held no investments that have been in a continuous unrealized loss position for 12 months or longer. The Company evaluated its securities for other-than-temporary impairments based on quantitative and qualitative factors, and considered the decline in market value for the 2 debt securities held as of June 30, 2018 to be primarily attributable to current economic and market conditions. The Company will likely not be required to sell these securities, and the Company does not intend to sell these securities before the recovery of their amortized cost bases, which recovery is expected within the next 12 months. Based on this analysis, the Company does not consider these investments to be other-than-temporarily impaired as of June 30, 2018.

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

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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 six months ended June 30, 2018 and 2017, Curis Royalty made payments totaling $5.1 million and $4.4 million, respectively, of which $3.1 million and $2.6 million have been applied to the principal, respectively, with the remainder applied to accrued interest. As of June 30, 2018, the Company recorded short- and long-term debt of $7.0 million and $31.5 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 June 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 June 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 six months ended June 30, 2018 and 2017, the Company recognized interest expense related to its debt of $2.0 million and $1.8 million, respectively, in the condensed consolidated statement of operations and comprehensive loss.

At June 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.

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During the six months ended June 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:

	June 30, 2018	December 31, 2017
Accrued compensation	$ 2,548	$ 2,187
Professional fees	332	148
Accrued interest on debt (Note 7)	169	193
Other	214	265
Total	$ 3,263	$ 2,793

9. Accounting for Stock-Based Compensation

As of June 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 six months ended June 30, 2018, the Company’s board of directors granted options to purchase a total of 1,220,596 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 783,596 shares were granted to non-officer 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 six months ended June 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 six months ended June 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

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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 six months ended June 30, 2018 and 2017 based on the assumptions noted in the following table:

	Six Months Ended June 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	2.5-2.8%	2.0-2.1%
Volatility	66-72%	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	1,220,596	3.19		
Exercised	—	—		
Canceled	(357,742)	11.59		
Outstanding, June 30, 2018	4,069,712	$ 9.46	7.49	$ —
Exercisable at June 30, 2018	1,894,027	$ 12.47	5.77	$ —
Vested and unvested expected to vest at June 30, 2018	3,811,106	$ 9.74	7.36	$ —

The weighted average grant-date fair values of these stock options granted during the six months ended June 30, 2018 and 2017 were $1.73 and $7.25, respectively. As of June 30, 2018, there was approximately $7.5 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 2.83 years. There

were no options exercised

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during the six months ended June 30, 2018. The intrinsic value of employee stock options exercised during the six months ended June 30, 2017 was $0.9 million.

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

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2017	—	$ —
Awarded	294,250	3.45
Vested	—	—
Forfeited	—	—
Outstanding, June 30, 2018	294,250	$ 3.45

As of June 30, 2018, there were 294,250 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 June 30, 2018, there were approximately $0.6 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 1.67 years.

Employee Stock-Based Compensation Expense

The Company recorded a total of $1.2 million and $2.4 million, respectively, in compensation expense for the three and six months ended June 30, 2018 and $1.6 million and $2.7 million, respectively, for the three and six months ended June 30, 2017 related to employee and director stock option grants. The total fair values of vested stock options for each of the six months ended June 30, 2018 and 2017 was $1.8 million and $2.1 million, respectively.

The Company recorded $0.2 million and $0.3 million in compensation expense during the three and six months ended June 30, 2018, net of expected forfeitures, related to officer and director restricted stock awards.

Total Stock-Based Compensation Expense

For the three and six months ended June 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development expenses	$436	$414	$849	$703
General and administrative expenses	753	1,171	1,566	1,985
Total stock-based compensation expense	$1,189	$1,585	$2,415	$2,688

10. Accumulated Other Comprehensive Income (Loss)

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

	Unrealized Gain on Securities Available-for-Sale
Balance, as of December 31, 2017	$ (2)
Unrealized loss on marketable securities	1
Amounts reclassified from accumulated other comprehensive income (loss)	—
Net current period other comprehensive income	1
Balance, as of June 30, 2018	$ (1)

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

	Unrealized Losses and Gain on Securities Available-for-Sale
Balance, as of December 31, 2016	$ (4)
Unrealized loss on marketable securities	1
Amounts reclassified from accumulated other comprehensive income (loss)	—
Net current period other comprehensive income	1
Balance, as of June 30, 2017	$ (3)

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 Nasdaq 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 June 30, 2018 and 2017, because the effect of the potential

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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 4,069,712 and 3,714,413 as of June 30, 2018 and 2017, respectively.

13. New Accounting Pronouncements

In June 2018, the FASB issued Accounting Standard Update (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 does not have any outstanding nonemployee awards as of June 30, 2018, and has 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 February 2016, the FASB issued ASU 2016-02, Leases. 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.

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

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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.

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 Phase 2 study in patients with relapsed refractory DLBCL including those with MYC alterations is ongoing, was granted Orphan Drug Designation in April 2015 and Fast Track Designation in May 2018 by the U.S. FDA. We are currently in ongoing discussions with the U.S. FDA that we anticipate will facilitate our determination of the most appropriate regulatory path;
- CA-170, for which we are currently conducting a Phase 1 study in patients with advanced solid tumors and lymphomas; and
- CA-4948, for which, in January 2018 we initiated a Phase 1 study in patients with advanced non-Hodgkin lymphomas including those with MYD88 alterations.

Our pipeline also includes CA-327, which is a pre-Investigational New Drug, or IND, stage oncology drug candidate. We continue work to enable the filing of an IND application with the FDA for clinical testing of CA-327 in 2018. 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 June 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.

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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-170, CA-4948 and CA-327 in collaboration with Aurigene in the near term.

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 $971.7 million as of June 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 June 30, 2018 should enable us to maintain our planned operations into the second half 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 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. For a further discussion of our liquidity and funding requirements and related risks and uncertainties, see “Liquidity and Capital Resources - Funding Requirements.”

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-170, and CA-4948, and that these clinical trials generate favorable data;
- our and Aurigene’s ability to complete preclinical development and IND-enabling studies for CA-327 and a fourth immuno-oncology program, and for us to then finance and complete planned Phase 1 clinical trials for this development candidate;
- 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 additional financing 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.”

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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):

- 105%, after the third anniversary of the closing date through and including the fourth anniversary of the closing date;
- 102.5%, 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

- 100%, 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 June 30, 2018, the outstanding principal and interest due under the loan is $38.8 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

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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 be.

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 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:

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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

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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 Six Months Ended June 30, 2018 and June 30, 2017

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

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)		For the Six Months Ended June 30,		Percentage Increase/ (Decrease)	
	2018	2017			2018	2017		
	(in thousands)				(in thousands)			
Revenues	$2,358	$2,061	14	%	$4,826	$4,192	15	%
Costs and expenses:								
Cost of royalty revenues	134	96	40	%	263	207	27	%
Research and development	6,451	11,255	(43	)%	14,717	24,795	(41	)%
General and administrative	3,633	3,819	(5	)%	7,614	7,351	4	%
Other expense, net	804	981	(18	)%	1,643	1,671	(2	)%
Net loss	$(8,664)	$(14,090)	(39	)%	$(19,411)	$(29,832)	(35	)%

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)		For the Six Months Ended June 30,		Percentage Increase/ (Decrease)	
	2018	2017			2018	2017		
	(in thousands)				(in thousands)			
Revenues:								
Royalties	$2,394	$2,102	14	%	$4,868	$4,294	13	%
Research and development, net	(36)	(41)	(12	)%	(42)	(102)	(59	)%
Total revenues	$2,358	$2,061	14	%	$4,826	$4,192	15	%

Total revenues increased by $0.3 million to $2.4 million for the three months ended June 30, 2018 as compared to $2.1 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 June 30, 2018 as compared to the prior year period.

Total revenues increased by $0.6 million to $4.8 million for the six months ended June 30, 2018 as compared to $4.2 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 June 30, 2018 as compared to the prior year period.

Cost of Royalty Revenues. Cost of royalty revenues remained unchanged at $0.1 million for the three months ended June 30, 2018 as compared to the same period in 2017. Cost of royalty revenues increased by $0.1 million to $0.3 million for the six months ended June 30, 2018 as compared to $0.2 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:

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	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)		For the Six Months Ended June 30,		Percentage Increase/ (Decrease)	
	2018	2017			2018	2017		
	(in thousands)				(in thousands)			
Direct research and development expenses	$2,673	$7,546	(65	)%	$6,844	$17,550	(61	)%
Employee-related expenses	3,238	3,272	(1	)%	6,711	6,409	5	%
Facilities, depreciation and other expenses	540	437	24	%	1,162	836	39	%
Total research and development expenses	$6,451	$11,255	(43	)%	$14,717	$24,795	(41	)%

Research and development expenses were $6.5 million for the three months ended June 30, 2018, as compared to $11.3 million in the same period in 2017, a decrease of $4.8 million, or 43%. Direct research and development expenses decreased by $4.9 million for the three months ended June 30, 2018 as compared to the same period in 2017, primarily due to decreased costs related to clinical activities for fimepinostat and CA-170, partially offset by increased costs related to CA-4948.

Research and development expenses were $14.7 million for the six months ended June 30, 2018, as compared to $24.8 million in the same period in 2017, a decrease of $10.1 million, or 41%. Direct research and development expenses decreased by $10.7 million for the six months ended June 30, 2018 as compared to the same period in 2017, primarily due to a payment to Aurigene of $3.8 million for an exclusivity option in January 2017, as well as decreased costs related to clinical activities 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 Months Ended June 30,		Percentage Increase/ (Decrease)		For the Six Months Ended June 30,		Percentage Increase/ (Decrease)	
	2018	2017			2018	2017		
	(in thousands)				(in thousands)			
Personnel	$1,166	$1,287	(9	)%	$2,492	$2,674	(7	)%
Occupancy and depreciation	132	114	16	%	293	214	37	%
Legal services	719	436	65	%	1,460	846	73	%
Professional and consulting services	566	488	16	%	1,158	1,008	15	%
Insurance costs	98	101	(3	)%	202	201	—	%
Stock-based compensation	753	1,171	(36	)%	1,566	1,985	(21	)%
Other general and administrative expenses	199	222	(10	)%	443	423	5	%
Total general and administrative expenses	$3,633	$3,819	(5	)%	$7,614	$7,351	3	%

General and administrative expenses were $3.6 million for the three months ended June 30, 2018, as compared to $3.8 million in the same period in 2017, a decrease of $0.2 million, or 5%. The decrease in general administrative expense was driven primarily by lower personnel and stock-based compensation costs offset by higher legal services for the period.

General and administrative expenses were $7.6 million for the six months ended June 30, 2018, as compared to $7.4 million in the same period in 2017, an increase of $0.3 million, or 3%. The increase in general administrative expense was driven primarily by higher legal, professional and consulting services offset by lower personnel and stock-based compensation costs for the period.

Other Expense. For the three months ended June 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 June 30, 2018 and 2017, respectively.

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For the six months ended June 30, 2018 and 2017, interest expense was $2.0 million and $1.8 million, respectively, related to interest accrued on Curis Royalty's debt obligations. Interest income was $0.4 million and $0.2 million for the six months ended June 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 June 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. 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 six months ended June 30, 2018 totaled $5.1 million, of which $3.1 million has been applied to the principal, and the remainder satisfying interest obligations. As of June 30, 2018, Curis Royalty owed a total of $38.8 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.

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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 June 30, 2018, our principal sources of liquidity consisted of cash, cash equivalents, and investments of $40.4 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 $16.9 million during the six months ended June 30, 2018 was primarily the result of our net loss for the period of $19.4 million, offset by non-cash charges consisting of stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling $2.4 million. In addition, accounts payable and accrued liabilities decreased by $0.7 million and accounts receivable decreased by $0.6 million related to a decrease in Erivedge royalties.

Net cash used in operating activities of $24.4 million during the six-month period ended June 30, 2017 was primarily the result of our net loss for the period of $29.8 million, offset by non-cash charges consisting of stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling $2.9 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 $12.0 million and used cash of $6.0 million for the six months ended June 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 $3.0 million for the six months ended June 30, 2018 as a result of principal payments on Curis Royalty's loan from HealthCare Royalty of $3.1 million.

Financing activities provided cash of $31.0 million for the six months ended June 30, 2017 as a result of $45.0 million in gross proceeds from the credit agreement with HealthCare Royalty, $6.2 million in net proceeds from our at-the-market sales pursuant to our sales agreement with Cowen and $0.9 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 $2.6 million, respectively.

Funding Requirements

We have incurred significant losses since our inception. As of June 30, 2018, we had an accumulated deficit of approximately $971.7 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 research and development activities for fimepinostat, CA-170, CA-4948 and CA-327, and to fund our general and administrative costs and expenses. We anticipate that our existing

cash, cash equivalents and investments at June 30, 2018 should enable us to maintain our planned operations into the second half 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 and operating expenses to the extent we are unable to raise

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additional capital through our current at-the-market sale agreement with Cowen or other potential financing. 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 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 13, “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

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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 June 30, 2018.

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Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our current cash balances in excess of operating requirements are invested in cash equivalents, short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year. All marketable securities are considered available-for-sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the volatile business environment and continued unpredictable and unstable market conditions.

Our marketable securities and long-term investments are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, marketable securities since June 30, 2018, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities and long-term investments owned by us. To help manage this risk, we limit our investments to investment grade securities and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls & Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 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 as of June 30, 2018, our chief executive officer and chief financial officer concluded that, as of such date, 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 June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 $19.4 million for the six months ended June 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 June 30, 2018, we had an accumulated deficit of $971.7 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

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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 research and development activities for fimepinostat, CA-170, CA-4948 and CA-327 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 June 30, 2018 should enable us to maintain our planned operations into the second half of 2019. We will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, many of which are outside of our control, and we may be unable to raise financing when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

Furthermore, there are a number of factors that may affect our future capital requirements and further accelerate our need for additional working capital, many of which are outside our control, including 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.

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

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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
- if 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.

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:

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- 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-170 and CA-4948, 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-170 and CA-4948, 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 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

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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-170 and CA-4948. 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-170, CA-4948 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 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.

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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;
- clinical 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;

- 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

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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 clinical 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;
- regulators or institutional review boards may require that we, or any collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the drug candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our, or any collaborators', clinical trial designs or our or their interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Drug development costs for us, or any collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our drug candidates. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we, or any collaborators, may have the exclusive right to commercialize our drug candidates or allow our competitors, or the competitors of any collaborators, to bring drugs to market before we, or any collaborators, do and impair our ability, or the ability of any collaborators, to successfully commercialize our drug candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our drug candidates.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the availability of approved therapeutics for the relevant disease;
- the proximity of patients to clinical sites;
- the eligibility criteria and design for the trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, many of our competitors have ongoing clinical trials for drug candidates that could be competitive with our drug candidates. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates or rely upon treatment with existing therapies that may preclude them from eligibility for our clinical trials.

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Our inability, or the inability of any future collaborators, to enroll a sufficient number of patients for our, or their, clinical trials could result in significant delays or may require us or them to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials, including for clinical trials of fimepinostat, CA-170 and CA-4948, may result in increased development costs for our drug candidates, which could cause the value of our stock price to decline.

Results of preclinical studies and early clinical trials may not be predictive of results of future late stage clinical trials. We cannot assure you that we will be able to replicate in human clinical trials the results we observed in animal models. Moreover, the outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the drug candidates. Even if we, or any collaborators, believe that the results of clinical trials for our drug candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our drug candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our drug candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced drug candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

Interim, “top-line,” initial, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and audit and verification procedures could result in material changes to the final data.

From time to time, we publish interim, “top-line,” initial, or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Initial, preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, interim, "top-line," initial, and preliminary data should be viewed with caution until the final data are available. Material adverse changes between such data and final published data could significantly harm our business prospects.

We have never obtained marketing approval for a drug candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our current drug candidates or any future drug candidates that we, or any future collaborators, may develop.

We have never obtained marketing approval for a drug candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, that we submit for our drug candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our drug candidates. If the FDA does not accept or approve our NDAs for any of our drug candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals

would prevent us from commercializing our drug candidates or any companion diagnostics, generating revenues and achieving and sustaining profitability. If any of these outcomes occurs, we may be forced to abandon our development efforts for our drug candidates, which could significantly harm our business.

Even if any drug candidates that we, or any collaborators, may develop receive marketing approval, we or others may later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any collaborators, to market the drug.

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Clinical trials of any drug candidates we may develop will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any collaborator, may indicate an apparent positive effect of a drug candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a drug candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations, and could negatively impact our stock price.

Even if our drug candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a drug, and even if one of our drug candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching drugs or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may not be successful. If any of our drug candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable.

The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the drug;
- the potential advantages of the drug compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the drug is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the drug for sale at competitive prices;
- the drug’s convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the drug;
- limitations or warnings, including distribution or use restrictions, contained in the drug’s approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the drug; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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

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Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we believe may have the best potential in certain specific indications. As a result, we may delay or forgo pursuit of certain opportunities with our other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future proprietary research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We have no sales, marketing, or distribution experience and, as such, plan to rely primarily on third parties who may not successfully market or sell any drugs we develop.

We have no sales, marketing, or drug distribution experience or capabilities. If we receive required regulatory approvals to commercialize any of our drug candidates, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech, we have granted Genentech the exclusive rights to distribute drugs resulting from such collaboration, and Genentech is currently commercializing Erivedge. We may have to enter into additional marketing and/or sales arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing, and distribution activities of these third parties, and sales through these third parties could be less profitable for us than direct sales. These third parties could sell competing drugs and may devote insufficient sales efforts or resources to our drugs. Our future revenues will be materially dependent upon the successful efforts of these third parties.

We may seek to independently market and sell drugs that are not already subject to agreements with other parties. If we undertake to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular drug; and
- our direct sales and marketing efforts may not be successful.

We face substantial competition, and our competitors may discover, develop or commercialize drugs before or more successfully than we do.

Our drug candidates face competition from existing and new technologies and drugs being developed by biotechnology, medical device, and pharmaceutical companies, as well as universities and other research institutions. For example, there are several companies developing drug candidates that target the same molecular targets that we are targeting or that are testing drug candidates in the same cancer indications that we are testing. For example, while we are not aware of other molecules in clinical testing that are designed as one chemical entity to target both PI3K and HDAC, there are commercially-available drugs that individually target PI3K or HDAC and there are multiple companies testing PI3K or HDAC inhibitors that are in various stages of clinical development.

We are aware of multiple other companies that are developing IRAK4 inhibitors for oncology indications, including: Pfizer, Nimbus Discovery, TG Therapeutics, Ligand, AstraZeneca and Bayer. In addition, there are multiple approved products on the market that inhibit PD1/PDL1, including Bristol-Myers Squibb Company's Opdivo™, Merck's Keytruda™, and Roche's Tecentriq™, Merck KGaA / Pfizer's Bavencio™, and AstraZeneca PLC's Imfinzi™ and a number of drug candidates in various stages of development (by Regeneron, Novartis AG, Tesaro Inc., and others). We are also aware of multiple other companies developing drugs to target TIM3, including Novartis AG, Tesaro Inc., Bristol-Myers Squibb, Eli Lilly and Company, and others.

We are aware of several companies that have clinical development programs relating to compounds that modulate the Hedgehog signaling pathway and may compete with Erivedge, including: Pfizer (glasdegib / PF-04449913), Eli Lilly and Company (taladegib / LY2940680), Exelixis, Inc./Bristol-Myers Squibb Company (BMS-833923 / XL139), Pelle

Pharm, Inc., (patidegib), Novartis International AG (LEQ-506) and Cyclene Pharmaceuticals Inc./Senhwa Biosciences Inc. (silmitasertib / CX-4945). Furthermore, sonidegib (Odomzo™) is marketed by Sun Pharmaceuticals, for the treatment of adults with locally

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advanced BCC. Under the terms of our collaboration agreement with Genentech, our royalty on sales of Erivedge has been reduced as a result of sales of sonidegib.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities, and more extensive experience than we have. As a result, efforts by other biotechnology, medical device and pharmaceutical companies could render our programs or drugs uneconomical or result in therapies superior to those that we develop alone or with a collaborator. For those programs that we have selected for internal development, we face competition from companies that are more experienced in drug development and commercialization, obtaining regulatory approvals and drug manufacturing. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, any of these companies may be more successful in obtaining collaboration agreements or other monetary support, approval and commercialization of their drugs and/or may develop competing drugs more rapidly and/or at a lower cost.

If we are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our drug candidates, which would adversely affect our ability to grow our business and become profitable.

Even if we, or any collaborators, are able to commercialize any drug candidate that we, or they, develop, the drug may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm our business.

The commercial success of our drug candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our drug candidates will be paid by third-party payors, including government health care programs and private health insurers. If coverage is not available, or reimbursement is limited, we, or any collaborators, may not be able to successfully commercialize our drug candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payors and coverage and reimbursement levels for drugs can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our drugs to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or drug licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay commercial launch of the drug, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize successfully any of our drug candidates will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the U.S. and elsewhere. Government authorities and other third-party

payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell our drug candidates profitably. These payors may not view our drugs, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our drugs, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for drugs, which could result in lower than anticipated drug revenues. If the prices for our drugs, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

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There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our drug candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any drugs that we may develop.

Product liability claims are inherent in the process of researching, developing and commercializing human healthcare drugs and could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Regardless of their merit or eventual outcome, such liability claims would require us to spend significant time, money and other resources to defend such claims, and could result in:

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

Although we currently have product liability insurance for our clinical trials, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful drug liability claim. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we commercialize any drug that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our drug candidates, which could harm our business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR DEPENDENCE ON THIRD PARTIES

We are reliant on Genentech and Roche for the successful development and commercialization of Erivedge. If Genentech and Roche do not successfully commercialize Erivedge for advanced BCC or develop Erivedge for other indications, our future prospects may be substantially harmed.

Erivedge is FDA-approved for people with advanced BCC in the U.S. Erivedge is also approved in over 60 foreign countries. Genentech and/or Roche have filed regulatory submissions in additional territories seeking approval to commercialize Erivedge for this same indication. Our levels of revenue in each period and our near-term prospects substantially depend upon Genentech’s ability to successfully develop and commercialize Erivedge in one or more

additional indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. The development and commercialization of Erivedge could be unsuccessful if:

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- Erivedge becomes no longer accepted as safe, efficacious, cost-effective and preferable for the treatment of advanced BCC to current therapies in the medical community and by third-party payors;
- Genentech and/or Roche fail to continue to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC, and to regulatory approvals for this indication outside of the U.S.;
- Genentech and/or Roche do not continue to develop and implement effective marketing, sales and distribution strategies and operations for development and commercialization of Erivedge for advanced BCC;
- Genentech and/or Roche do not continue to develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;
- Genentech and/or Roche do not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we, Genentech, or Roche encounter third-party patent interference, derivation, inter partes review, post-grant review, reexamination or patent infringement claims with respect to Erivedge;
- Genentech and/or Roche do not comply with regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;
- competing drug products are approved for the same indications as Erivedge, such as is the case with sonidegib, which is being marketed and sold by Sun Pharmaceutical, both in the U.S. and abroad for the treatment of adults with locally advanced BCC;
- new safety risks are identified;
- Erivedge does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than advanced BCC;
- Genentech and/or Roche determine to re-prioritize Genentech's commercial or development programs and reduce or terminate Genentech's efforts on the development or commercialization of Erivedge; or
- Genentech does not exercise its first right to maintain or defend intellectual property rights associated with Erivedge.

In addition, pursuant to the terms of our credit agreement with HealthCare Royalty, we expect that all royalties that Curis Royalty receives under our collaboration agreement with Genentech will, for the foreseeable future, be remitted to HealthCare Royalty in repayment of our loan.

We depend on third parties for the research and, as applicable, development and commercialization of certain programs. If one or more of our collaborators fails or delays in developing or, as applicable, commercializing drug candidates based upon our technologies, our business prospects and operating results would suffer and our stock price would likely decline.

Pursuant to our collaboration with Genentech, we have granted to Genentech exclusive rights to develop and commercialize drugs based upon our Hedgehog signaling pathway technologies. In addition, pursuant to our collaboration agreement with Aurigene, Aurigene may develop various immuno-oncology, selected precision oncology and other potential targets which we will have the option to license and advance into clinical trials. Collaborations involving our drug candidates, including our collaborations with Aurigene and Genentech, pose the following risks to us:

- Our collaborators each have significant discretion in determining the efforts and resources that they will apply to their respective collaboration with us. If a collaborator fails to allocate sufficient time, attention and resources to our collaboration, the successful development and commercialization of drug candidates under such collaboration is likely to be adversely affected. For example, we are dependent on Aurigene to successfully discover and advance preclinical programs from which we may exercise our option to license drug candidates for future development.
- Our collaborators may develop and commercialize, either alone or with others, drugs that are similar to or competitive with the drug candidates that are the subject of our respective collaborations. For example, Genentech and Roche are involved in the commercialization of many cancer medicines and are seeking to develop several other cancer drug therapies, and Aurigene has other active cancer-focused discovery programs and has also entered into license agreements with other companies that focus on cancer therapies.

- Our collaborators may change the focus of their development and commercialization efforts or pursue higher-priority programs.
- Our collaborators may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. Any such transaction could

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divert the attention of our collaborative partner's management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator's development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates our collaboration.

- Our collaborators may, under specified circumstances, terminate their collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific, biotech, pharma and financial communities.
- Our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights, or expose us to potential liability.
- Disputes may arise between collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations.
- If any of our collaborators were to breach or terminate its arrangement with us, the development and commercialization of the affected drug candidate or program could be delayed, curtailed or terminated.

If Genentech and other third parties are not successful in commercializing products that reach successful development, our revenues and business will suffer.

As development of certain of our drug candidates advance, we must begin to plan for their launch and commercial distribution. Potential competitors may have substantially greater financial and other resources and may be able to expend more funds and effort than Genentech or other third parties engaged by us in marketing competing products. There can be no assurance that Genentech or other third parties will succeed in commercializing our products, or that the pricing of our products will allow us to generate significant revenues. There can be no assurance that Genentech or other third parties engaged to commercialize our products will devote sufficient resources to marketing and commercialization of our products. Genentech's or third party's failure to successfully commercialize our products will have a material adverse effect on our business and financial condition.

We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize drug candidates.

We intend to seek corporate collaborators or licensees for the further development and commercialization of one or more of our drug candidates in one or more geographic territories, particularly in territories outside of the U.S. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., Phase 3) or commercialization on our own, but we are seeking to build such a capacity to enable us to retain development and certain commercial rights to most of our programs in at least the U.S., should we elect to do so. Our success will depend, in part, on either our ability to build such capacity, or our ability to enter into one or more collaborations for our drug candidates. We face significant competition in seeking appropriate collaborators and a number of recent business combinations in the biotechnology and pharmaceutical industry may result in a reduced number of potential future collaborators. In addition, collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy or as sufficiently differentiated compared to existing or emerging treatments. We are also restricted under the terms of certain of our existing collaboration agreements from entering into collaborations regarding or otherwise developing drug candidates that are similar to the drug candidates that are subject to those agreements, such as developing drug candidates that inhibit the same molecular target. In addition, collaboration agreements that we enter into in the future may contain further restrictions on our ability to enter into

potential collaborations or to otherwise develop specified drug candidates. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us and such collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all.

Moreover, if we fail to establish and maintain additional collaborations related to our drug candidates:

- the development of certain of our current or future drug candidates may be terminated or delayed;

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- our cash expenditures related to development of certain of our current or future drug candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop additional expertise, such as clinical, regulatory, sales and marketing expertise, for which we have not budgeted;
- we will have to bear all of the risk related to the development of any such drug candidates; and
- our future prospects may be adversely affected and our stock price could decline.

We rely in part on third parties to conduct clinical trials of our internally-developed drug candidates, and if such third parties perform inadequately, including failing to meet deadlines for the completion of such trials, research or testing, then we will not be able to successfully develop and commercialize drug candidates and grow our business.

We rely heavily on third parties such as consultants, clinical investigators, contract research organizations and other similar entities to complete certain aspects of our preclinical testing and clinical trials and provide services in connection with such clinical trials, and expect to continue to do so for the foreseeable future. Despite having contractual remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. These third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with the established clinical trial protocol or design. In addition, the FDA and its foreign equivalents require us to comply with certain standards, referred to as “good clinical practices,” and applicable regulatory requirements, for conducting, recording and reporting the results of clinical trials. These requirements assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If any of our third party contractors do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the applicable trial. Any failure by a third party to conduct our clinical trials as planned or in accordance with regulatory requirements could delay or otherwise adversely affect our efforts to obtain regulatory approvals for and commercialize our drug candidates.

We depend on third parties to produce our drug candidates, and if these third parties do not successfully formulate or manufacture these drug candidates, our business will be harmed.

We have no internal manufacturing experience or capabilities, and therefore cannot manufacture any of our drug candidates on either a clinical or commercial scale. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize drugs, we or any collaborators must be able to manufacture drug candidates in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our drug candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and low yields of quality drugs. The cost of manufacturing some of our drug candidates may make them prohibitively expensive.

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. We may be unable to establish any agreements with contract manufacturers or to
do so on acceptable terms. Contract manufacturers may breach their manufacturing agreements because of factors beyond our and our collaborators’ control or may terminate or fail to renew a manufacturing agreement based on their own business priorities, becoming costly and/or inconvenient for us and our collaborators. Even if we are able to establish agreements with contract manufacturers, reliance on contract manufacturers entails additional risks, including:

- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them, or if unforeseen events in the manufacturing process arise;
- the failure of third-party contractors to comply with applicable regulatory requirements;

- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

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Any manufacturing problem, the loss of a contract manufacturer or any loss of storage could be disruptive to our operations, delay our clinical trials and, if our products are approved for sale, result in lost sales.

Any contract manufacturers with whom we or our collaborators enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by contract manufacturers, collaborators, or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, denial by regulatory authorities of marketing approval for drug candidates, delays, suspension or withdrawal of approvals, imposition of clinical holds, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we or a collaborator need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

- we, and any collaborators, may not be able to initiate or continue certain preclinical and/or clinical trials of our drug candidates under development;
- we, and any collaborators, may be delayed in submitting applications for regulatory approvals for our drug candidates; and
- we, and any collaborators, may not be able to meet commercial demand for any approved drug products.

Because we rely on a limited number of suppliers for the raw materials used in our drug candidates, any delay or interruption in the supply of such raw materials could lead to delays in the manufacture and supply of our drug candidates.

We rely on third parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Although we generally do not begin a preclinical study or clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such study or trial, any significant delay in the supply of raw materials for our drug candidates for a preclinical study or an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which would impair our ability to generate revenues from their sale.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Any contamination could materially adversely affect our ability to produce drug candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. A material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our drug candidates, could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

RISKS RELATING TO EMPLOYEE MATTERS AND MANAGING GROWTH

If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

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We depend upon our senior management team. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of drug development and other business objectives. Our officers all serve pursuant to "at will" employment arrangements and can terminate their employment with us at any time. In the future, we may be dependent on other members of our management, scientific and development team.
Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to successfully implement our business strategy could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, market and commercialize drugs successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similarly qualified personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.
We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our drug candidates will be limited.
We may seek to acquire complementary businesses and technologies or otherwise seek to expand our operations and grow our business, which may divert management resources and adversely affect our financial condition and operating results.
We may seek to expand our operations, including through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

- a diversion of management attention from our existing operations;
- increased operating complexity of our business, requiring greater personnel and resources;
- significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;
- unanticipated expenses and potential delays related to integration of the operations, technology and other resources of any acquired companies;
- uncertainty related to the value, benefits or legitimacy of intellectual property or technologies acquired;
- retaining and assimilating key personnel and the potential impairment of relationships with our employees;
- incurrence of debt, other liabilities and contingent liabilities, including potentially unknown contingent liabilities; and
- dilutive stock issuances.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY
We may not be able to obtain and maintain patent protection for our technologies and drugs, our licensors may not be able to obtain and maintain patent protection for the technology or drugs that we license from them, and the patent protection we or they do obtain may not be sufficient to stop our competitors from using similar technology.
The long-term success of our business depends in significant part on our ability to:

- obtain patents to protect our technologies and discoveries;
- protect trade secrets from disclosure to competitors;
- operate without infringing upon the proprietary rights of others; and

- prevent others from infringing on our proprietary rights.

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The patent positions of pharmaceutical and life science companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The laws, procedures and standards that the U.S. Patent and Trademark Office and various foreign intellectual property offices use to grant and maintain patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and have changed in significant ways and are expected to continue to change. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U.S. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficient to protect our technology from exploitation by our competitors. Our patents also may not afford us protection against competitors with similar technology. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Prior to March 16, 2013, in the U.S., patent applications were subject to a “first to invent” rule of law. Applications filed on or after March 16, 2013 (with the exception of certain applications claiming priority to applications filed prior to March 16, 2013, such as continuations and divisionals) are subject to new laws including a “first to file” rule of law. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Additionally, how the U.S. Patent & Trademark Office and U.S. courts will interpret the new laws remains significantly uncertain at this time. We cannot be certain that any existing or future application will be subject to the “first to file” or “first to invent” rule of law, that we were the first to make the inventions claimed in our existing patents or pending patent applications subject to the prior laws, or that we were the first to file for patent protection of such inventions subject to the new laws.

We may not have rights under patents that may cover one or more of our drug candidates. Patents of others may overlap with our own patents regarding one or more of our drug candidates. In some cases, these patents may be owned or controlled by third-party competitors and may prevent or impair our ability to exploit our technology. As a result, we or our current or potential future collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our drug candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners may not be able to develop and commercialize the affected drug candidate or candidates.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or drugs that we license from third parties and are reliant on our licensors. For example, while under our collaboration with Aurigene we have established a joint patent team to coordinate efforts on patent filing, prosecution, maintenance and other patent matters, we do not control the patent process until we have exercised our option to obtain an exclusive license on a program-by-program basis. If we do not control the filing, prosecution of certain patent rights, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business.

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

We may become involved in expensive and unpredictable patent litigation or other contentious intellectual property proceedings, which could result in liability for damages or require us to cease our development and commercialization efforts.

There are substantial threats of litigation and other adversarial opposition proceedings regarding patent and other intellectual property rights in the pharmaceutical and life science industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Situations that may give rise to patent litigation or other disputes over the use of our intellectual property include:

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- initiation of litigation or other proceedings against third parties to enforce our patent rights, to seek to invalidate the patents held by third parties or to obtain a judgment that our drug candidates do not infringe such third parties' patents;
- participation in interference and/or derivation proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;
- initiation of opposition, reexamination, post grant review or inter partes review proceedings by third parties that seek to limit or eliminate the scope of our patent protection;
- initiation of litigation by third parties claiming that our processes or drug candidates or the intended use of our drug candidates infringes their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

Any patent litigation or other proceeding, even if resolved favorably, will likely require us to incur substantial costs and be a distraction to management. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. In addition, our collaborators and licensors may have rights to file and prosecute claims of infringement of certain of our intellectual property, and we are reliant on them. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or any collaborative partners may be enjoined from manufacturing or selling our future drugs without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable, and we or any collaborative partner may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace.

We face risks relating to the enforcement of our intellectual property rights in China and India that could adversely affect our business.

We have conducted chemical development work through contract research agreements with contract research organizations, or CROs, in China and India. We seek to protect our intellectual property rights under this arrangement through, among other things, non-disclosure and assignment of invention covenants. Enforcement of intellectual property rights and confidentiality protections in China may not be as effective as in the U.S. or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation vary, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

In addition, we collaborate with Aurigene, an Indian company, in the development of new therapeutic compounds. Some or all of the intellectual property arising from this collaboration may be developed by Aurigene's employees, consultants, and third-party contractors, and we have an option right under the collaboration agreement to obtain exclusive licenses to Aurigene's rights in this intellectual property. Accordingly, our rights depend in part on Aurigene's contracts with its employees and contractors and Aurigene's ability to protect its trade secrets and other confidential information in India, both before and after we exercise our option to obtain exclusive license rights on a program-by-program basis. Enforcement of intellectual property rights and confidentiality protections in India may not be as effective as in the U.S. or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we or Aurigene might need to resort to litigation to protect our trade secrets and confidential information. The experience and capabilities of Indian courts in handling intellectual property litigation vary, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any

such litigation would impair our intellectual property rights and may harm our business, prospects and reputation.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by competitors.

We rely heavily on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect this information through confidentiality and intellectual property license

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or assignment provisions in agreements with our employees, consultants and other third-party contractors, including our contract research agreements with CROs in China and India, as well as through other security measures. Similarly, our agreement with Aurigene requires Aurigene to enter into such agreements with its employees, consultants, and other third-party contractors. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we or they may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.

We are party to agreements that provide us licenses of intellectual property or sharing of rights to intellectual property that is important to our business, and we may enter into additional agreements in the future that provide us licenses to valuable technology. These licenses, including our agreement with Aurigene, impose, and future licenses may impose, various commercialization, milestone and other obligations on us, including the obligation to terminate our use of licensed subject matter under certain contingencies. If a licensor becomes entitled to, and exercises, termination rights under a license, we would lose valuable rights and could lose our ability to develop our drugs. We may need to license other intellectual property to commercialize future drugs. Our business may suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid, or if we are unable to enter into necessary licenses on acceptable terms.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our current and potential competitors. Although no claims against us are currently pending, we may be subject to claims that such employees, or as a result, we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATING TO REGULATORY APPROVAL AND MARKETING OF OUR DRUG CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERS

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our drug candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a drug candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drugs are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We, and any future collaborators, are not permitted to market our drug candidates in the U.S. or in other countries until we, or they, receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the U.S. Our drug candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our drug candidates in the U.S. or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of an NDA.

The process of obtaining marketing approvals, both in the U.S. and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that our drug candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Moreover, the FDA

or other regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

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In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborator to generate revenue from the particular drug candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad. Any approval we are granted for our drug candidates in the U.S. would not assure approval of our drug candidates in foreign jurisdictions.

In order to market and sell our drugs in the European Union and other foreign jurisdictions, we, and any future collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., a drug must be approved for reimbursement before the drug can be approved for sale in that country. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive the necessary approvals to commercialize our drugs in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our drug candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing drugs.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. We, or any future collaborators, may seek orphan drug designations for drug candidates and may be unable to obtain such designations.

Even if we, or any future collaborators, obtain orphan drug designation for a drug candidate, we, or they, may not be able to obtain orphan drug exclusivity for that drug candidate. Generally, a drug with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years

if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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Even if we, or any future collaborators, obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Even if we, or any future collaborators, obtain marketing approvals for our drug candidates, the terms of approvals and ongoing regulation of our drugs may limit how we manufacture and market our drugs, which could impair our ability to generate revenue.

Once marketing approval has been granted, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our drug candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug's approved labeling. Thus, we and any future collaborators will not be able to promote any drugs we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved drugs and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our drug candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, drug surveillance and quality control.

If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the marketing approvals for our drugs withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any of our drug candidates for which we, or any future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our drugs following approval.

Any of our drug candidates for which we, or any future collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such drug, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement an FDA-sanctioned Risk Evaluation and Mitigation Strategy.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our drug candidates for which we, or they, receive marketing approval for only

their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the U.S. Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

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

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

We may seek a Breakthrough Therapy designation for one or more of our drug candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for one or more of our drug candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drug candidates that have been designated Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated Breakthrough Therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

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

Receipt of Fast Track designation for one or more of our drug candidates, such as fimepinostat, may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a drug sponsor may apply for FDA Fast Track designation. We have received Fast Track designation for the development of fimepinostat in adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. However, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe for fimepinostat or any other product candidate that may receive Fast Track designation. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. The FDA may withdraw Fast Track designation for fimepinostat, or any other product candidate that may receive Fast Track designation, if it believes that the designation is no longer supported by data

from our clinical development program. Fast Track designation alone for fimepinostat or any other product candidate does not guarantee qualification for the FDA's priority review procedures.

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Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, certain policies of the Trump Administration may impact our business and industry. Namely, the Trump Administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval and commercialize our drug candidates and affect the prices we, or they, may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any drugs for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved drugs.

Among the provisions of the Patient Protection and Affordable Care Act, or ACA, of potential importance to our business and our drug candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

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- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a “skinny” version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other

legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

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It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions.

Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The costs of prescription pharmaceuticals in the U.S. has also been the subject of considerable discussion in the U.S., and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the U.S. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

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

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

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

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

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

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program;

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HIPAA and HITECH. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the U.S. Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We have adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third party intermediaries will comply with this code or such

anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement

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authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our drug products and other materials are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our drugs and solutions outside of the U.S. must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges, fines, which may be imposed on us and responsible employees or managers, and, in extreme cases, the incarceration of responsible employees or managers. In addition, changes in our drugs or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our drugs and solutions in international markets, prevent customers from using our drugs and solutions or, in some cases, prevent the export or import of our drugs and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our drugs and solutions could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication

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and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our drug candidates could be delayed.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

RISKS RELATING TO OUR COMMON STOCK

If we fail to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed on the Nasdaq Global Market. We are required to meet specified requirements to maintain our listing on the Nasdaq Global Market, including, among other things, a minimum bid price of $1.00 per share for our common stock and minimum stockholders' equity of $10 million.

Our stockholders’ equity as of June 30, 2018 was $7.1 million, which is below the minimum $10 million required by the Nasdaq Global Market, and as a result we expect to receive a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market. Generally, companies that receive such a deficiency letter have 45 days to submit a plan for regaining compliance to Nasdaq, although Nasdaq could require a shorter period of time in which to submit a plan. After a company submits a plan, Nasdaq determines whether the company has regained compliance, provides an extension of time up to 180 days from the date of the deficiency letter, or initiates delisting proceedings. In addition, on January 2, 2018, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market that notified us that, for the 30 consecutive business days prior to January 2, 2018, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market and provided us an initial period of 180 calendar days, or until July 2, 2018, to regain compliance with the minimum bid price requirement by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Effective as of 5:00 p.m. Eastern Time on May 29, 2018, we effected a 1-for-5 reverse stock split of our common stock. As a result of the reverse stock split, the per share market price of our common stock increased and, from May 30 to June 12, 2018 (10 consecutive business days), the closing bid price of our common stock exceeded $1.00 per share. Accordingly, on June 13, 2018, we received a notice from Nasdaq indicating that we have regained compliance with Listing Rule 5450(a)(1) as of such date.

Although we currently comply with the minimum bid requirement following the reverse stock split, our bid price could fall below $1.00 per share again in the future, in which event we would receive another deficiency notice from Nasdaq advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, Nasdaq could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies. If we fail to satisfy the Nasdaq Global Market's

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continued listing requirements, we may transfer to the Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. However, we may not be able to satisfy the initial listing requirements for the Nasdaq Capital Market. A transfer of our listing to the Nasdaq Capital Market or having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price.

Our stock price may fluctuate significantly and the market price of our common stock could drop below the price paid by our investors.

The trading price of our common stock has been volatile and is likely to continue to be volatile in the future. For example, our stock traded within a range of a high price of $28.25 and a low price of $1.57 per share for the period January 1, 2012 through July 27, 2018. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical and biotechnology company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

- the timing and result of clinical trials of our drug candidates;
- the success of, and announcements regarding, existing and new technologies and/or drug candidates by us or our competitors;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- market conditions in the biotechnology and pharmaceutical sectors;
- rumors relating to us or our collaborators or competitors;
- commencement or termination of collaborations for our development programs;
- litigation or public concern about the safety of our drug candidates;
- actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;
- the amount and timing of any royalty revenue we receive from Genentech related to Erivedge;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators;
- any intellectual property disputes or other lawsuits involving us;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;
- equity sales by us of our common stock to fund our operations;
- the loss of any of our key scientific or management personnel;
- FDA or international regulatory actions;
- limited trading volume in our common stock;
- general economic and market conditions, including recent adverse changes in the domestic and international financial markets; and
- the other factors described in this "Risk Factors" section.

While we cannot predict the individual effect that these factors may have on the price of our common stock, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources.

We and our collaborators may not achieve projected research, development, commercialization and marketing goals in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.

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We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, and clinical trials, and other developments and milestones relating to our business and our collaboration agreements. Our collaborators may also make public statements regarding their goals and expectations for their collaborations with us. The actual timing of any such events can vary dramatically due to a number of factors including delays or failures in our and our current and potential future collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by all parties, and the inherent uncertainties in the regulatory approval and commercialization process. As a result:

- our or our collaborators' preclinical studies and clinical trials may not advance or be completed in the time frames we or they announce or expect;
- we or our collaborators may not make regulatory submissions, receive regulatory approvals or commercialize approved drugs as predicted; and
- we or our collaborators may not be able to adhere to our or their current schedule for the achievement of key milestones under any programs.

If we or any collaborators fail to achieve research, development and commercialization goals as planned, our business could be materially adversely affected and the price of our common stock could decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a company undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Changes in our stock ownership, some such changes being out of our control, may have resulted or could in the future result in an ownership change. The changes of ownership will result in net operating loss and research and development credit carryforwards that we expect to expire unutilized. If additional limitations were to apply, utilization of a portion of our net operating loss and tax credit carryforwards could be further limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly

different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options or pursuant to our universal shelf registration statement could result in dilution to our stockholders and negatively affect our stock price.

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Most of our outstanding common stock can be traded without restriction at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and in the future we may issue additional options, warrants or other derivative securities convertible into our common stock. The exercise of any such options, warrants or other derivative securities, and the subsequent sale of the underlying common stock, could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We currently have on file with the SEC a “universal” shelf registration statement which allows us to offer and sell registered common stock, preferred stock, and warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In July 2015, we entered into a sales agreement with Cowen, pursuant to which, from time to time, we may offer and sell through Cowen up to $30.0 million of the common stock registered under the shelf registration statement pursuant to one or more “at the market” offerings. In addition, with our prior written approval, Cowen may sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities under this registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

If we are not able to maintain effective internal controls under Section 404 of the Sarbanes-Oxley Act, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent registered accounting firm to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

We do not intend to pay dividends on our common stock, and any return to investors will come, if at all, only from potential increases in the price of our common stock.

We have never declared nor paid cash dividends on our common stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Insiders have substantial influence over us and could delay or prevent a change in corporate control.

As of June 30, 2018, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 32.6% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- entrenching our management or the board of directors.

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

The trading market for our common stock may depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. A lack of research coverage or adverse coverage may negatively impact the market price of our common stock. In addition, if one or more of our current or potential future analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if

one or more of our current or potential

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future analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

A decline in our stock price may affect future fundraising efforts.
We currently have no drug revenues, and depend entirely on funds raised through other sources. One source of such funding is future debt and/or equity offerings. Our ability to raise funds in this manner depends upon, among other things, our stock price, which may be affected by numerous factors including without limitation capital market conditions, evaluation of our stock by securities analysts, numerous factors including without limitation development programs, and the overall status of our business, finances and operations.
We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable, or prevent attempts by our stockholders to replace or remove current management, which could result in a decline in the price of our common stock.
Provisions of our certificate of incorporation, our bylaws, and Delaware law may deter unsolicited takeovers or delay or prevent changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized "blank check" preferred stock, and our stockholders are limited in their ability to call special stockholder meetings.
In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who together with his, her, or its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control.

Item 5. Other Information
(a.)On May 24, 2018, we filed a Current Report on Form 8-K (the "Report") to announce that David Tuck, M.D., our Chief Medical Officer, provided us 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. We and Dr. Tuck entered into a letter agreement on August 1, 2018 (the "Letter Agreement") pursuant to which Dr. Tuck agreed to provide us 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, we have 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, we 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.
The foregoing summary of the Letter Agreement is qualified in its entirety by reference to the full text of the Letter Agreement, which is filed as Exhibit 10.1 to this Form 10-Q.

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Item 6. Exhibits

Exhibit Number	Description
3.1	Certificate of Amendment of Restated Certificate of Incorporation of Curis, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on May 29, 2018).
10.1	Letter Agreement, entered into on August 1, 2018, by and between Curis, Inc. and David Tuck, M.D.
10.2	Employment Agreement, dated June 1, 2018, by and between Curis, Inc. and Robert E. Martell, M.D., Ph.D.
10.3	Third Amended and Restated 2010 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed on May 18, 2018).
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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SIGNATURE

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

CURIS, INC.

Dated: August 2, 2018 By: /S/ JAMES E. DENTZER
James E. Dentzer
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)