CURIS INC
Form 10-Q
August 04, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

FOR THE QUARTERLY PERIOD ENDED June 30, 2016

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	**(I.R.S. Employer**
Incorporation or Organization)	**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. x 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). x Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

As of July 29, 2016, there were 129,472,012 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

(Unaudited)

(In thousands, except share data)

	June 30, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,643	$ 33,091
Investments	53,028	49,100
Accounts receivable	1,869	2,106
Prepaid expenses and other current assets	975	1,204
Total current assets	64,515	85,501
Property and equipment, net	451	278
Long-term investment restricted	153	153
Goodwill	8,982	8,982
Other assets	3	51
Total assets	$ 74,104	$ 94,965
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 3,875	$ 4,217
Accrued liabilities	2,012	1,934
Current portion of long-term debt, net	5,429	4,607
Total current liabilities	11,316	10,758
Long-term debt, net	16,539	19,558
Other long-term liabilities	62	139
Total liabilities	27,917	30,455
Commitments		
Stockholders Equity:		
	1,307	1,302

Common stock, $0.01 par value 225,000,000 shares authorized; 130,685,068 shares issued and 129,462,222 shares outstanding at June 30, 2016; 130,213,224 shares issued and 128,990,378 shares outstanding at December 31, 2015		
Additional paid-in capital	905,614	903,240
Treasury stock (at cost, 1,222,846 shares)	(1,524)	(1,524)
Accumulated deficit	(859,267)	(838,536)
Accumulated other comprehensive income	57	28
Total stockholders equity	46,187	64,510
Total liabilities and stockholders equity	$ 74,104	$ 94,965

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

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Royalties	$ 1,842	$ 2,034	$ 3,586	$ 3,705
Research and development, net	(162)	49	(180)	36
Total revenues	1,680	2,083	3,406	3,741
Costs and Expenses:				
Cost of royalty revenues	95	103	184	187
Research and development	8,822	5,938	15,650	10,657
In-process research and development				24,348
General and administrative	3,443	3,411	7,059	6,940
Total costs and expenses	12,360	9,452	22,893	42,132
Loss from operations	(10,680)	(7,369)	(19,487)	(38,391)
Other Expense:				
Interest income	119	84	224	124
Interest expense	(729)	(843)	(1,468)	(1,710)
Total other expense, net	(610)	(759)	(1,244)	(1,586)
Net loss	$ (11,290)	(8,128)	$ (20,731)	$ (39,977)
Net loss per common share (basic and diluted)	$ (0.09)	$ (0.06)	$ (0.16)	$ (0.34)
Weighted average common shares (basic and diluted)	129,270,639	128,351,482	129,142,989	118,199,388

Total comprehensive loss	$ (11,293)	$ (8,128)	$ (20,702)	$ (39,967)

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

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,731)	$ (39,977)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	90	82
Stock-based compensation expense	1,680	1,974
Amortization of debt issuance costs	24	31
Gain on disposal of assets		(16)
Non-cash interest expense (income) on investments	9	(47)
Issuance of common stock in consideration for rights granted under collaboration agreement		23,968
Changes in operating assets and liabilities:		
Accounts receivable	237	(132)
Prepaid expenses and other assets	196	(274)
Accounts payable and accrued and other liabilities	(346)	(154)
Total adjustments	1,890	25,432
Net cash used in operating activities	(18,841)	(14,545)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investments	(48,744)	(66,296)
Sale of investments	44,836	41,443
Purchases of property and equipment	(256)	(15)
Decrease in restricted cash		14
Net cash used in investing activities	(4,164)	(24,854)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock associated with offerings, net of issuance costs		64,619
Proceeds from issuance of common stock under the Company s share-based compensation plans	698	195
Payments on Curis Royalty s debt	(2,141)	(1,677)
Net cash (used in)/provided by financing activities	(1,443)	63,137

NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(24,448)	23,738
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	33,091	7,747
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 8,643	$ 31,485

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 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 most advanced drug candidate is CUDC-907, which is being investigated in clinical studies in patients with diffuse large B-cell lymphoma and solid tumors.

In January 2015, the Company entered into an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets with Aurigene Discovery Technologies Limited, or Aurigene (Note 4(b)). The collaboration comprises multiple programs, in which Curis has the option to exclusively license compounds once a development candidate is nominated within each respective program. In October 2015, the Company exercised options to license the first two programs under this collaboration. The first licensed program is focused on the development of orally-available small molecule antagonists of programmed death-1 (PD-1) and V-domain Ig suppressor of T-cell activation (VISTA) in the immuno-oncology field. The Company has named CA-170, a programmed death ligand-1 (PD-L1)/VISTA antagonist, as the development candidate from this program. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field and the Company has named CA-4948 as the development candidate from this program. In addition, in October 2015, the Company selected a third program for potential further development under the collaboration, the second preclinical program within the immuno-oncology field, which is focused on evaluating small molecule antagonists of PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) pathways, including small molecules that target PD-L1 and TIM-3. The Company has not yet exercised its option to license this third program.

The Company is also 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® (vismodegib), a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor, in advanced basal cell carcinoma, or BCC. Roche and Genentech are continuing to develop Erivedge in less severe forms of BCC and are conducting studies of Erivedge in other diseases, including in idiopathic pulmonary fibrosis and myelofibrosis.

The Company s proprietary small molecule compounds also include CUDC-427, an orally-available, small molecule antagonist of inhibitor of apoptosis, or IAP proteins, and CUDC-305, a Heat Shock Protein 90, or HSP90, inhibitor.

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 health care 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 Genentech and Roche 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 s wholly owned subsidiary, Curis Royalty, LLC, or Curis Royalty, to satisfy the terms of its loan agreement with BioPharma Secured Debt Fund II Sub, S.à.r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II; the Company s ability to obtain and maintain necessary intellectual property protection; development by the Company s competitors of new or better technological innovations; dependence on key personnel; the Company s ability to comply with regulatory requirements; 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 receives and makes under its current and potential future collaborations. The results of the Company s operations may 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

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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; positive results in Roche and Genentech s ongoing clinical trials.

The Company anticipates that its existing cash, cash equivalents and investments at June 30, 2016 should enable it to maintain current and planned operations into 2017. The Company s ability to continue funding its planned operations beyond this period is dependent upon, among other things, its ability to control expenses and its ability to raise additional funds through equity or debt financings, the success of its collaboration with Genentech, including its receipt of additional contingent cash payments under this collaboration, new collaborations or other sources of financing. The Company may not be able to successfully raise additional funds or enter into or continue any corporate collaborations and the timing, amount and likelihood of such events is highly uncertain. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

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 United States, 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, 2015, or the Annual Report, as filed with the Securities and Exchange Commission on February 29, 2016.

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, 2016 and the results of operations for the three- and six-month periods ended June 30, 2016 and 2015 and the cash flows for the six-month periods ended June 30, 2016 and 2015. The condensed consolidated balance sheet at December 31, 2015, was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements.

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 is currently a party to a collaboration agreement with Genentech, the terms of which provide for Genentech to make a non-refundable license fee payment, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives, and royalties on product

sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its 2015 Annual Report on Form 10-K.

4. Collaboration Agreements

(a) Genentech, Inc.

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 United States and by Genentech s parent company, Roche, in several other countries for the treatment of advanced BCC. Roche is also conducting additional exploratory clinical studies in patients with less severe forms of BCC. Pursuant to the agreement, the Company is eligible to receive up to an aggregate of $115,000 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 $59,000 as of June 30, 2016.

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

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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, or CHMP, approved another Hedgehog signaling pathway inhibitor, sonidegib, which is marketed by Novartis, for use in locally advanced BCC. Beginning in the fourth quarter of 2015, Genentech applied the 2% royalty reduction on United States sales of Erivedge as a result of the first commercial sale of sonidegib in the United States.

In December 2012, Curis formed a wholly owned subsidiary, Curis Royalty, which received a $30,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II (Note 7). 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. The loan and accrued interest is being repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty and is non-recourse to Curis.

The Company recognized $1,842 and $2,034 in royalty revenue under the Genentech collaboration during the three months ended June 30, 2016 and 2015, respectively, and $3,586 and $3,705 during the six months ended June 30, 2016 and 2015, 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 $95 and $103 during the three months ended June 30, 2016 and 2015, respectively, and $184 and $187 during the six months ended June 30, 2016 and 2015, respectively. For each of these periods, these amounts are comprised of 5% of the royalties earned by Curis Royalty that the Company is obligated to pay to university licensors. As further discussed in Note 7, the Company expects that all royalty revenues received by Curis Royalty from Genentech on net sales of Erivedge will be used by Curis Royalty to pay principal and interest under the loan that Curis Royalty received from BioPharma-II, subject to specified quarterly caps, until such time as the loan is fully repaid.

The Company recorded research and development revenue of $56 and $84 during the three months ended June 30, 2016 and 2015, respectively, and research and development revenue of $109 and $140 during the six months ended June 30, 2016 and 2015, 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 $218 and $46 during the three months ended June 30, 2016 and 2015, respectively, and expenses of $289 and $114 during the six months ended June 30, 2016 and 2015, respectively, under this collaboration, for which the Company is obligated to reimburse to Genentech, and which the Company has recorded as contra-revenues in its condensed consolidated statements of operations and comprehensive loss.

b) Aurigene Agreement

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.

For each program, Aurigene has granted the Company an exclusive option, exercisable within 90 days after Aurigene delivers the relevant data regarding a development candidate, to obtain an exclusive, royalty-bearing license to develop, manufacture and commercialize compounds from such program, including the development candidate and products containing such compounds, anywhere in the world, except for India and Russia. For the development, manufacture, and commercialization of compounds from a particular program and products containing such

compounds in India and Russia, Aurigene will grant the Company the royalty-bearing license described above for such program, and the Company will grant Aurigene an exclusive, royalty-free, fully paid license under the Company s relevant technology upon exercise of the relevant option.

During 2015, the Company exercised options to license the first two programs under this collaboration, resulting in an aggregate one-time payment of $6,000 (comprised of a $3,000 option exercise fee for each program) by the Company to Aurigene. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000 for supplemental research, development and/or manufacturing activities in support of these two programs. The Company incurred and recognized $1,000 of such costs in the three months ended December 31, 2015, which was paid in the three months ended March 31, 2016. The remaining $1,000 was incurred and recognized in the three months ended March 31, 2016 and paid in the three months ended June 30, 2016.

Also in 2015, the Company selected a preclinical program for potential further development within the immuno-oncology part of the collaboration, as described in Note 1. The Company has not yet exercised its option to license this third program under the collaboration.

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The Company anticipates that it will select additional programs under this collaboration in the future, and the Company intends to have the collaboration s steering committee recommend such additional programs in order for Aurigene to initiate or continue the relevant preclinical activities described in each program s written plan.

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 United States, 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 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 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 exclusivity option fees on an annual basis. The first of such option fees will be $7,500, and the Company currently estimates that this payment will be due in the first quarter of 2017.

In addition, beyond the up-to five years of exclusivity described above, and subject to specified exceptions and payment by the Company of an annual exclusivity fee on a program-by-program basis, Aurigene and the Company have agreed to collaborate exclusively with each other on each program for which there are ongoing activities in research or development, or for which the Company has exercised its option to acquire an exclusive license (as described above) and the Company or its affiliates or sublicensees are actively developing or commercializing a compound or product from such program in a major market.

For each product that may be commercialized, the Company has granted Aurigene the right, subject to certain conditions, to nominate one global drug substance or drug product supplier to provide up to 50% of the total requirements in the Company s territory.

Research Payments, Option Exercise Fees and Milestone Payments. The Company has agreed to make the following research, option exercise fees and milestone payments to Aurigene:

- for the PD-1/VISTA and IRAK4 programs: up to $52,500 per program, comprised of: $3,000 for each option exercise, $3,000 upon acceptance of each IND filing, $4,000 upon dosing of the fifth patient in the Company s first Phase 1 clinical trial in each program, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000 for supplemental research, development and/or manufacturing activities in support of these two programs. During the three months ended June 30, 2016, the Company recognized and paid $3,000 to Aurigene upon the acceptance of the IND filing for CA-170, a PD-L1/VISTA antagonist. Since the inception of the agreement through June 30, 2016, the Company has incurred costs totaling $11,000 related to these programs under the collaboration;

- for the third and fourth programs: up to $50,000 per program, comprised of: $2,000 for a program selection fee, $3,000 for an option exercise, $2,500 upon acceptance of an IND filing, as well as development, approval and commercial milestones, plus specified additional payments for approvals for additional

indications, if any. Since the inception of the agreement through June 30, 2016, the Company has made payments to Aurigene totaling $2,000 related to the third program under this collaboration; and

for any program thereafter: up to $140,500 per program, comprised of: up to a total of $53,000 for research fees, an option exercise fee, a preclinical milestone and development milestones, as well as specified filing, approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any. As of June 30, 2016, no payments have been made to Aurigene related to such programs under the collaboration.

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:

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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, 2016 and December 31, 2015 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, 2016:				
Cash equivalents:				
Money market funds	$ 7,313	$	$	$ 7,313
Corporate commercial paper, bonds and notes		390		390
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	7,469	45,559		53,028
Total assets at fair value	$ 14,782	$ 45,949	$	$ 60,731

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total Fair Value
As of December 31, 2015:				
Cash equivalents:				
Money market funds	$ 13,568	$	$	$ 13,568
Corporate commercial paper, bonds and notes	2,001	7,998		9,999
Municipal bonds		7,850		7,850
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	2,644	46,456		49,100
Total assets at fair value	$ 18,213	$ 62,304	$	$ 80,517

No investments held at June 30, 2016 were transferred between levels.

6. Investments

The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of June 30, 2016 are as follows:

		Amortized Cost	Unrealized Gain	Unrealized Loss	Total Fair Value
Corporate bonds and notes	short-term	$ 52,971	$ 66	$ (9)	$ 53,028
Total investments		$ 52,971	$ 66	$ (9)	$ 53,028

Short-term investments have maturities ranging from one and twelve months with a weighted average maturity of 3.81 months at June 30, 2016.

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The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of December 31, 2015 are as follows:

		Amortized Cost	Unrealized Gain	Unrealized Loss	Total Fair Value
Corporate bonds and notes	short-term	$ 49,072	$ 44	$ (16)	$ 49,100
Total investments		$ 49,072	$ 44	$ (16)	$ 49,100

Short-term investments have maturities ranging from one and 12 months with a weighted average maturity of 4.2 months at December 31, 2015.

7. Debt

In December 2012, Curis wholly owned subsidiary, Curis Royalty, received a $30,000 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 (Note 4(a)). The loan and accrued interest is 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 constitutes an obligation of Curis Royalty, and is non-recourse to Curis. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis royalty obligations to university licensors, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts are applied first to pay interest and second, principal on the loan. Curis remains entitled to receive any contingent payments upon achievement of clinical development objectives. Curis Royalty retains its right to royalty payments related to sales of Erivedge following repayment of the loan.

The final maturity date of the loan will be the earlier of the date when the principal is 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 is contingent upon the level of Erivedge royalties received, the short- and long-term classification of the debt is based on the Company s estimate of the timing of amounts to be repaid. The Company cannot estimate when the loan will be repaid as repayment is impacted by numerous factors, all of which are beyond the Company s control. The repayment term may be shortened or extended depending on the actual level of Erivedge royalties received. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, any unpaid interest outstanding will be added to the principal on a quarterly basis. The length of the actual repayment period could vary materially to the extent that royalty payments Curis Royalty receives are lower than the Company s current estimates, which could arise due to factors beyond the Company s control, such as the sale of competing products that result in a lowering of the royalty rates that Curis Royalty is entitled to receive, decreased market acceptance or a failure by Genentech and/or Roche to successfully commercialize Erivedge in territories where it has received regulatory approval. At any time after January 1, 2017, Curis Royalty may, subject to certain limitations, 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 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.

During the six months ended June 30, 2016 and 2015, Curis Royalty made payments totaling $3,585 and $3,356, respectively, of which $2,141 and $1,677 have been applied to the principal, respectively, with the remainder applied to accrued interest. As of June 30, 2016, the Company recorded short- and long-term debt of $5,429 and $16,539, respectively (net of unamortized issuance costs of $48 and $94, respectively), and at December 31, 2015, the Company recorded short- and long-term debt of $4,607 and $19,558, respectively (net of unamortized issuance costs of $12 and $73, respectively), related to the loan, with such amounts recorded within the Company s condensed consolidated balance sheets. In the three months ended March 31, 2016, the Company adopted ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. In accordance with the updated standard, the Company reclassified certain of its debt issuance costs, related to the loan, from assets to a direct deduction from the carrying amount of the related debt liability. The adoption of this guidance did not impact the consolidated statement of operations and comprehensive loss and the impact to the balance sheet was not material.

In addition, the Company recorded related accrued interest on the debt of $252 as of both June 30, 2016 and December 31, 2015, with such amounts included in the Company s accrued liabilities section of its condensed consolidated balance sheets. For

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the three months ended June 30, 2016 and 2015, the Company recognized interest expense related to the loan with BioPharma-II of $729 and $843, respectively, in the condensed consolidated statement of operations and comprehensive loss. For the six months ended June 30, 2016 and 2015, the Company recognized interest expense related to the loan with BioPharma-II of $1,468 and $1,710, respectively, in the condensed consolidated statement of operations and comprehensive loss.

At June 30, 2016, the fair value of the debt approximates its carrying value due to the expected repayment period and 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.

8. Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2016	December 31, 2015
Accrued compensation	$ 1,237	$ 1,310
Professional fees	297	123
Accrued interest on debt (Note 7)	252	252
Other	226	249
Total	$ 2,012	$ 1,934

9. Accounting for Stock-Based Compensation

As of June 30, 2016, the Company had two shareholder-approved, share-based compensation plans: (i) the Amended and Restated 2010 Stock Incentive Plan, or the 2010 Plan, adopted by the board of directors in March 2015 and approved by shareholders in May 2015 and (ii) the 2010 Employee Stock Purchase Plan, or the ESPP, adopted by the board of directors in April 2010 and approved by shareholders in June 2010.

During the six months ended June 30, 2016, the Company s board of directors granted options to purchase 2,400,225 shares of the Company s common stock to officers and employees of the Company under the 2010 Plan. These options 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.

On March 29, 2016, the Company s board of directors appointed James E. Dentzer to the position of chief financial officer, chief administrative officer, secretary and treasurer of the Company. As a material inducement to his employment, the compensation committee of the Company s board of directors granted Mr. Dentzer a stock option to purchase 1,700,000 shares of the Company s common stock with an exercise price equal to the fair market value of $1.51 per share. The option was granted as an inducement equity award under NASDAQ Listing Rule 5635(c)(4) outside of the 2010 Plan. The option will vest as to 25% of the shares underlying the option on the first anniversary of

the grant date, and as to an additional 6.25% of the shares underlying the option on each successive three-month period thereafter, subject to Mr. Dentzer s continued service with the Company.

During the six months ended June 30, 2016, the Company s board of directors also granted options to its non-employee directors to purchase 470,000 shares of common stock under the 2010 Plan, which will vest and become exercisable in equal monthly installments over a period of one year from the date of grant. These options were granted at an exercise price of $1.76 per share, which equals the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date.

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. As discussed below, for employee stock options with market performance conditions, the Company uses a Monte Carlo simulation valuation 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, 2016 and 2015 based on the assumptions noted in the following table:

	Six Months Ended June 30,	
	2016	**2015**
Expected life (years) - employees	6	6
Expected life (years) officers and directors	7	7
Risk-free interest rate	1.4-1.8%	1.5-1.9%
Volatility	69-70%	68-70%
Dividends	None	None

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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 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.

As of June 30, 2016, there were 16,196,884 stock options outstanding. The aggregate intrinsic value of employee options outstanding at June 30, 2016 was $836, of which $726 related to exercisable options. The weighted average grant-date fair values of these stock options granted during the six months ended June 30, 2016 and 2015 were $1.07 and $1.71, respectively. As of June 30, 2016, there was approximately $7,636, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding that is expected to be recognized as expense over a weighted average period of 2.75 years. The intrinsic values of employee stock options exercised during the six months ended June 30, 2016 and 2015 was $159 and $75, respectively.

Employee Stock-Based Compensation Expense

The Company recorded a total of $894 and $1,779 in compensation expense for the three and six months ended June 30, 2016, respectively and $895 and $1,726 in compensation expense for the three and the six months ended June 30, 2015, respectively, related to employee and director stock option grants. The total fair values of vested stock options for the six months ended June 30, 2016 and 2015 were $2,194 and $1,529, respectively.

Non-Employee Grants

The Company has periodically granted stock options to consultants for services pursuant to the Company s stock plans at the fair market value on the respective dates of grant. Should the Company terminate any of its consulting agreements, the unvested options underlying the agreements would also be cancelled.

The Company recognized expense related to non-employee stock options of $14 during the three months ended June 30, 2016 and reversed expense of $99 during the six months ended June 30, 2016, respectively, and recognized expense related to non-employee stock options of $128 and $248 during the three and six months ended June 30, 2015, respectively.

Total Stock-Based Compensation Expense

For the three months ended June 30, 2016 and 2015, 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,	
	2016	2015	2016	2015
Research and development expenses	$ 204	$ 314	$ 326	$ 602
General and administrative expenses	704	709	1,354	1,372
Total stock-based compensation expense	$ 908	$ 1,023	$ 1,680	$ 1,974

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10. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss) as of June 30, 2016 and 2015:

	Unrealized Gain on Securities Available-for-Sale
Balance, as of December 31, 2015	$ 28
Unrealized gain on marketable securities	29
Amounts reclassified from accumulated other comprehensive income (loss)	
Net current period other comprehensive income	29
Balance, as of June 30, 2016	$ 57

The above amounts do not reflect a tax effect because the Company expects to record a net loss for 2016.

	Unrealized Losses and Gain on Securities Available-for-Sale
Balance, as of December 31, 2014	$ (11)
Unrealized gain on marketable securities	9
Amounts reclassified from accumulated other comprehensive income (loss)	
Net current period other comprehensive income	9
Balance, as of June 30, 2015	$ (2)

11. 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 and six months ended June 30, 2016 and 2015, because the effect of the potential common stock equivalents would be antidilutive due to the Company s net loss position for these periods. Antidilutive securities consist only of stock options outstanding of 16,196,884 and 13,552,649 as of June 30, 2016 and 2015, respectively.

12. Related Party Transactions

Consulting agreement with Daniel R. Passeri

On June 2, 2014, Daniel R. Passeri resigned as Chief Executive Officer of the Company and the Company s board of directors appointed Mr. Passeri to serve as the Vice Chairman of the board of directors. Also on June 2, 2014, the Company and Mr. Passeri entered into a consulting agreement. The agreement was for an initial term of one year, subject to renewal or earlier termination by the parties. The agreement was renewed by the parties through May 31, 2016, after which the agreement between Mr. Passeri and the Company was terminated. Pursuant to the terms of the agreement, Mr. Passeri was paid an hourly fee or a monthly retainer as consideration for the services rendered by Mr. Passeri to the Company. During the five months ended May 31, 2016, Mr. Passeri provided consulting services to the Company on intellectual property, corporate and strategic matters in exchange for payments of $30 per month. During the six months ended June 30, 2015, Mr. Passeri had full-time employment with a third party and was paid an hourly fee for services rendered to the Company during this time. The Company recognized expenses of $60 and $12 during the three months ended June 30, 2016 and 2015, respectively, and expenses of $150 and $17 during the six months ended June 30, 2016 and 2015, respectively.

13. New Accounting Pronouncements

In January 2016, the FASB issued Accounting Standards Update, or 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,

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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. Early adoption is permitted but the Company does not anticipate electing early adoption. The Company does not expect the adoption of this guidance to have a 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 25, 2018, and interim periods within such years. Early adoption is permitted, but the Company does not anticipate electing early adoption. The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies share-based payment accounting through a variety of amendments. The standard will be effective for annual reporting periods and interim periods within those annual periods, beginning after December 15, 2016, and early adoption is permitted. The Company does not expect the impact of this guidance to be material to its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to continue as a Going Concern.* This update is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements and to provide related footnote disclosures. This guidance is effective for fiscal years beginning after December 15, 2016, and early adoption is permitted. The Company is currently evaluating what effect, if any, the adoption of this guidance will have on the disclosures included in its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The Company is

currently evaluating the method of adoption and the potential impact that these standards may have on its consolidated financial statements.

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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 report 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.

Overview

We are a biotechnology company seeking to develop and commercialize innovative and effective drug candidates for the treatment of cancers. Our most advanced drug candidate is CUDC-907, an orally-available, small molecule inhibitor of histone deacetylase, or HDAC, and phosphatidylinositol-3-kinase, or PI3K, enzymes. Based on findings of an ongoing Phase 1 clinical trial of this molecule in patients with relapsed or refractory lymphomas or multiple myeloma, we initiated an open-label Phase 2 clinical trial of CUDC-907 in patients with relapsed or refractory diffuse large B-cell lymphoma, or DLBCL, including patients with MYC-altered DLBCL. We are also conducting a Phase 1 trial in patients with solid tumors, and have recently directed our efforts in this study to enroll patients whose cancers have MYC involvement, including patients with nut midline carcinoma.

In addition, we are party to an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets with Aurigene Discovery Technologies Limited, or Aurigene, a specialized, discovery-stage biotechnology company and wholly owned subsidiary of Dr. Reddy s Laboratories. In October 2015, we exercised options to license the first two programs under this collaboration. The first licensed program is focused on the development of orally-available small molecule antagonists of programmed death-1 (PD-1) and V-domain Ig suppressor of T-cell activation (VISTA) pathways in the immuno-oncology field, including the development candidate designated CA-170, which targets programmed death ligand-1 (PD-L1) and VISTA. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field, with the lead development candidate designated CA-4948. In June 2016, we announced the FDA acceptance of the IND for CA-170 and dosed the first patient in a Phase 1 trial of CA-170. In addition, in October 2015 we selected a third program for potential development under the collaboration, which represents the second preclinical program within the immuno-oncology field. This third program in the collaboration is focused on evaluating small molecule antagonists of PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) pathways, including small molecules that target PD-L1 and TIM-3. We have not yet exercised our option to license this third program.

Our other collaborators, F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, are commercializing Erivedge® (vismodegib), a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor, in advanced basal cell carcinoma, or BCC. Roche and Genentech are also continuing Erivedge s clinical development in less severe forms of BCC, and are conducting clinical studies of Erivedge in idiopathic pulmonary fibrosis, or IPF, and myelofibrosis, or MF.

Based on our clinical development plans for our pipeline, in the near term we intend to predominantly focus our available resources on the continued development of CUDC-907, CA-170, CA-4948 as well as any development

candidates arising from the PD-1/TIM3 program in collaboration with Aurigene.

Our Collaborations and License Agreements

On January 18, 2015, we entered into a collaboration agreement with Aurigene for the discovery, development and commercialization of small molecule compounds in the areas of immuno-oncology and precision oncology, which we refer to as the Aurigene agreement. There are currently two licensed programs and one selected program, which we will have the option to license, under this collaboration as described under Overview above.

In 2003, we entered into a collaborative research, development and license agreement with Genentech, which we refer to as the collaboration agreement.

For additional information regarding our collaboration and license agreements, refer to Note 4, *Collaboration Agreements*, in the notes to the accompanying financial statements in this Quarterly Report on Form 10-Q and Items 7 and 8 of the Company s Annual Report on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on February 29, 2016.

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Liquidity

Since our inception, we have funded our operations primarily through private and public placement 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 $859.3 million as of June 30, 2016.

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 existing capital resources as of June 30, 2016 should enable us to maintain current and planned operations into 2017. Our ability to continue funding our planned operations into and beyond this point is dependent on our ability to raise additional funds through equity or debt financings, future contingent payments that we may receive from Genentech upon the achievement of development and regulatory approval objectives, through additional corporate collaborations that we may establish, or from other sources of financing.

Key Drivers

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

- our ability to successfully plan, finance and complete current and planned clinical trials for our lead proprietary drug candidate, CUDC-907, as well as for such clinical trials to generate favorable data;
- our and Aurigene s ability to successfully advance CA-170, and for us to finance and complete the current and planned Phase 1 clinical trials of this drug candidate;
- our and Aurigene s ability to complete preclinical development and IND-enabling studies for CA-4948, and for us to then finance and complete its planned Phase 1 clinical trials;
- Aurigene s ability to advance additional preclinical immuno-oncology, including the PD-1/TIM3 program, 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 successfully commercialize Erivedge in advanced BCC in the United States and in other global territories; and
- Genentech and Roche s initiation and completion of additional clinical studies of Erivedge, including in diseases other than BCC, such as IPF or MF.

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 additional product 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. We anticipate that existing capital resources as of June 30, 2016 should enable us to maintain current and planned operations into 2017.

A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under Part II, Item 1A Risk Factors.

Debt. In December 2012, our wholly owned subsidiary, Curis Royalty, entered into a $30.0 million debt transaction with BioPharma-II 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 on the commercial sales of Erivedge that we receive from Genentech. The loan and accrued interest is 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 constitutes an obligation of Curis Royalty, and is non-recourse to us. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by us pursuant to an escrow agreement between Curis, 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

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indemnification under the collaboration agreement with Genentech. Remaining amounts are applied first, to pay interest and second, principal on the loan. We remain entitled to receive any contingent payments upon achievement of clinical development objectives. Beginning in 2016, there are no quarterly caps to the amounts Curis Royalty will be required to make to BioPharma-II. Curis Royalty retains the right to royalty payments related to sales of Erivedge following repayment of the loan.

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 right to receive royalties under the collaboration agreement with Genentech terminates. At any time after January 1, 2017, Curis Royalty may, subject to certain limitations, 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 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, 2016, the outstanding principal and interest due under the loan is $22.4 million.

Revenue. We do not expect to generate any revenues from our direct sale of products for several years, if ever. Substantially all of our revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees, including royalty payments. Since the first quarter of 2012, we have recognized royalty revenues related to Genentech s sales of Erivedge, and we expect to continue to recognize royalty revenue in future quarters from Genentech s sales of Erivedge in the U.S. and Roche s sales of Erivedge outside of the U.S. However, we expect that all of such royalty revenues will be used by our wholly owned subsidiary, Curis Royalty, to pay principal and interest under the loan that Curis Royalty received from BioPharma-II, until such time as the loan is fully repaid. We currently estimate that all Erivedge royalties will be applied to the loan with BioPharma-II 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 January 2015 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.

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The following graphic outlines the current status of our programs:

With the exception of Erivedge, which is approved for sale to treat advanced BCC and marketed by Genentech/Roche, 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 other 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.

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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 United States requires that we make estimates and assumptions that affect the reported amounts and disclosures in the financial statements. Such estimates and judgments include the performance obligations under our collaboration agreements; the estimated repayment term of our debt and related short- and long-term classification; the carrying value of property and equipment and intangible assets; the assumptions used in our valuation of stock-based compensation and the value of certain investments and liabilities. 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, 2015, or the Annual Report, which was filed with the SEC on February 29, 2016.

Results of Operations

Three Months Ended June 30, 2016 and June 30, 2015

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues:			
Royalties	$ 1,842	$ 2,034	(9%)
Research and development, net	(162)	49	(431%)
Total revenues	$ 1,680	$ 2,083	(19%)

Total revenues decreased by $0.4 to $1.7 million for the three months ended June 30, 2016 as compared to $2.1 million for the same period in 2015, related to a decrease in royalty revenues arising from Genentech and Roche s net sales of Erivedge during the three months ended June 30, 2016 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, 2016 as compared to the same period in 2015. We are obligated to make payments to two university licensors on royalties that Curis Royalty earns from Genentech on net sales of Erivedge.

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

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Direct research and development expenses	$ 6,401	$ 3,743	71%
Employee-related expenses	1,990	1,790	11%
Facilities, depreciation and other expenses	431	405	6%
Total research and development expenses	$ 8,822	$ 5,938	49%

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Research and development expenses were $8.8 million for the three months ended June 30, 2016, as compared to $5.9 million in the same period in 2015, an increase of $2.9 million, or 49%. Direct research and development expenses were $6.4 million compared to $3.7 million for the comparable prior period. The increase of $2.7 million for the three months ended June 30, 2016 was primarily the result of increased costs related to ongoing clinical activities for CUDC-907, including increased clinical site, patient, clinical research organization, formulation and manufacturing and consulting costs for our ongoing Phase 1 clinical trials, as well as initial costs for our Phase 2 trial, which was initiated in January 2016. In addition, costs for programs under our Aurigene collaboration increased for the three months ended June 30, 2016, which costs include a $3.0 million milestone payment to Aurigene upon the FDA acceptance of our CA-170 IND and outside costs to support such programs, including initial costs for our CA-170 Phase 1 trial, which was initiated in June 2016. In comparison, direct research and development expense for the three months ended June 30, 2015 includes a $2.0 million milestone payment to Aurigene for selection of the third program under the collaboration. Offsetting these increases was a decrease in spending on CUDC-427 of approximately $0.4 million, related to decreases in consulting and outside services. Employee-related expenses were $2.0 million compared to $1.8 million for the comparable prior year period. The increase of $0.2 million for the three months ended June 30, 2016 was primarily due to additional headcount, offset by a decrease in stock-based compensation of $0.1 million. Facilities, depreciation and other expenses have remained consistent for the three months ended June 30, 2016 as compared to the three months ended June 30, 2015.

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)
	2016	2015	
	(in thousands)		
Personnel	$ 1,123	$ 988	14%
Occupancy and depreciation	104	97	7%
Legal services	449	697	(36%)
Professional and consulting services	549	515	7%
Insurance costs	98	87	13%
Other general and administrative expenses	416	318	31%
Stock-based compensation	704	709	(1%)
Total general and administrative expenses	$ 3,443	$ 3,411	1%

General and administrative expenses remained consistent at $3.4 million for the three months ended June 30, 2016 as compared to the prior year period. Personnel costs increased $0.1 million as compared to the prior year period, primarily due to increased headcount. This increase was offset by a decrease of $0.2 million in legal service costs.

Other Expense. For the three months ended June 30, 2016 and 2015, interest expense was $0.7 million and $0.8 million, respectively, related to interest accrued on Curis Royalty s outstanding debt with BioPharma-II. Interest income was $0.1 million and $0.1 million for the three months ended June 30, 2016 and 2015, respectively.

Six Months Ended June 30, 2016 and June 30, 2015

Revenues. Total revenues are summarized as follows:

	For the Six Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues:			
Royalty revenues from Genentech	$ 3,586	$ 3,705	(3%)
Research and development, net	(180)	36	(600%)
Total Revenues	$ 3,406	$ 3,741	(9%)

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Total revenues decreased by $0.3 million to $3.4 million for the six months ended June 30, 2016 as compared to $3.7 million for the same period in 2015, related to a decrease in royalty revenues arising from Genentech and Roche s net sales of Erivedge during the six months ended June 30, 2016 as compared to the prior year period.

Cost of Royalty Revenues. Cost of royalty revenues remained unchanged at $0.2 million for the six months ended June 30, 2016 as compared to the same period in 2015. We are obligated to make payments to two university licensors on royalties that Curis Royalty earns from Genentech on net sales of Erivedge.

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

	For the Six Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Direct research and development expenses	$ 10,740	$ 6,605	63%
Employee-related expenses	4,002	3,233	24%
Facilities, depreciation and other expenses	908	819	11%
Total research and development expenses	$ 15,650	$ 10,657	47%

Research and development expenses were $15.7 million for the six months ended June 30, 2016, as compared to $10.7 million in the same period in 2015, an increase of $5.0 million, or 47%. Direct research and development expenses were $10.7 million compared to $6.6 million for the comparable prior period. The increase of $4.1 million for the six months ended June 30, 2016 was primarily the result of increased costs related to ongoing clinical activities for CUDC-907, including increased clinical site, patient, clinical research organization, formulation and manufacturing and consulting costs for our ongoing Phase 1 clinical trials, as well as initial costs for our Phase 2 trial, which was initiated in January 2016. In addition, costs for programs under our Aurigene collaboration increased for the three months ended June 30, 2016, which costs include a $3.0 million milestone payment to Aurigene upon the FDA acceptance of our CA-170 IND and outside costs to support such programs, including initial costs for our CA-170 Phase 1 trial, which was initiated in June 2016. In comparison, direct research and development expense for the six months ended June 30, 2015 includes a $2.0 million milestone payment to Aurigene for selection of the third program under the collaboration. Offsetting these increases was a decrease in spending on CUDC-427 of approximately $1.0 million, related to decreases in consulting and outside services, and a decrease in spending on CUDC-305, primarily due to a $0.8 million payment made in the six months ended June 30, 2015 related to termination of the agreement with our collaborator for that program. Employee-related expenses were $4.0 million compared to $3.2 million for the comparable prior year period. The increase of $0.8 million for the six months ended June 30, 2016 was primarily due to additional headcount, offset by a decrease in stock-based compensation of $0.3 million. Facilities, depreciation and other expenses have increased by $0.1 million for the six months ended June 30, 2016 due to increased occupancy costs.

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.

In-process Research and Development. For the six months ended June 30, 2015, we recognized in-process research and development expenses of $24.3 million, which represented the partial consideration we paid for rights granted to us under the collaboration agreement with Aurigene. No such expense was recorded for the six months ended June 30, 2016.

General and Administrative Expenses. General and administrative expenses are summarized as follows:

	For the Six Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Personnel	$ 2,311	$ 2,041	13%
Occupancy and depreciation	221	195	13%
Legal services	1,144	1,423	(20%)
Professional and consulting services	1,151	1,164	(1%)
Insurance costs	192	173	11%
Other general and administrative expenses	686	572	20%
Stock-based compensation	1,354	1,372	(1%)
Total general and administrative expenses	$ 7,059	$ 6,940	2%

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General and administrative expenses increased by $0.1 million, or 2%, for the six months ended June 30, 2016 as compared to the same period in the prior year, primarily due to an increase of $0.3 million in personnel as compared to the prior year period. Offsetting these increases was a decrease in legal services and professional and consulting costs related to the Aurigene transaction and other business development matters that occurred during the first half of 2015.

Other Expense. For the six months ended June 30, 2016 and 2015, interest expense was $1.5 million and $1.7 million, respectively, related to interest accrued on Curis Royalty s outstanding debt with BioPharma-II. Interest income was $0.2 million and $0.1 million for the six months ended June 30, 2016 and 2015, respectively.

Liquidity and Capital Resources

We have financed our operations primarily through private and public placement 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.

Placement of Equity Securities

On July 2, 2015, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell from time to time up to $30.0 million of our common stock through an at-the-market equity offering program, under which Cowen will act 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 to be sold under the sales agreement, if any, may be issued and sold pursuant to the currently effective universal shelf registration statement on Form S-3, filed with the Securities and Exchange Commission on July 2, 2015. As of June 30, 2016, we have not sold any shares of common stock pursuant to this sales agreement.

Debt Financing

In December 2012, our wholly owned subsidiary, Curis Royalty, received a $30.0 million loan, at an annual 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 on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest is currently being repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is non-recourse to us. 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. Payments to BioPharma-II for the six months ended June 30, 2016 totaled $3.6 million, of which $2.1 million has been applied to the principal, and the remainder satisfying interest obligations. As of June 30, 2016, Curis Royalty owed a total of $22.4 million, gross of issuance costs, to BioPharma-II, including accrued interest.

Milestone Payments and Monetization of Royalty Rights

We have received aggregate milestone payments totaling $59.0 million under our collaboration with Genentech. In addition, we began receiving royalty revenues in 2012 in connection with Genentech s sales of Erivedge in the U.S. and Roche s sales of Erivedge outside of the U.S. Erivedge royalty revenues received after December 2012 have been used to repay Curis Royalty s outstanding principal and interest under the loan due to BioPharma-II, subject to specified quarterly caps. Erivedge royalty revenues will continue to be used to repay Curis Royalty s outstanding principal and interest under the loan due to BioPharma-II. 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, 2016, our principal sources of liquidity consisted of cash, cash equivalents, and investments of $61.7 million, excluding our restricted cash of $0.2 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.

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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 $18.8 million during the six months ended June 30, 2016 was primarily the result of our net loss for the period of $20.7 million, offset by non-cash charges consisting of stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling $1.8 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.

Net cash used in operating activities of $14.5 million during the six-month period ended June 30, 2015 was primarily the result of our net loss for the period of $40.0 million, offset by non-cash charges consisting of the stock issuance to Aurigene of $24.3 million as partial consideration for the collaboration agreement with Aurigene stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense and depreciation, totaling $26.0 million. In addition, accounts payable and accrued liabilities used cash of $0.2 million related to the payment of certain year-end employee benefits, and prepaid assets increased $0.3 million related to deposits made with vendors.

We expect to continue to use cash in operations as we seek to advance our drug candidates and at least two 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 used cash of $4.2 million and $24.9 million for the six months ended June 30, 2016 and 2015, respectively, resulting primarily from net investment activity from purchases and maturities of investments for the respective periods.

Financing activities used cash of $1.4 million for the six months ended June 30, 2016 as a result of principal payments on Curis Royalty s loan with BioPharma-II of $2.1 million, offset by $0.7 million in proceeds from the exercise of stock options. Financing activities provided cash of $63.1 million for the six months ended June 30, 2015. During the six months ended June 30, 2015, we received $64.6 million in net proceeds from our underwritten public offering of common stock and proceeds of $0.2 million from the exercise of stock options. These proceeds in the first half of 2015 were offset by the principal payment on Curis Royalty s loan with BioPharma-II of $1.7 million.

Funding Requirements

We have incurred significant losses since our inception. As of June 30, 2016, we had an accumulated deficit of approximately $859.3 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 CUDC-907, CA-170 and other programs under our collaboration with Aurigene, and to fund our general and administrative costs and expenses.

Contingent payments to Aurigene related to future development milestones for CA-170 and CA-4948 would total an aggregate of $11.0 million if an IND is accepted by the FDA for CA-4948 and Phase 1 clinical trial initiation milestones are achieved for both. In June 2016, we announced the FDA acceptance of the IND for CA-170, upon which we paid a $3.0 million milestone payment to Aurigene. We also initiated Phase 1 clinical testing of CA-170 in

June 2016. We currently estimate that a CA-170 Phase 1 clinical trial initiation milestone of $4.0 million will be due and payable in the fourth quarter of 2016 or the first quarter of 2017. For the PD-1/TIM-3 program, our potential additional payments to Aurigene include a $3.0 million payment upon exercise of our option to license this program, and $2.5 million upon acceptance of an IND.

In addition, 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. The first of such option fees will be $7.5 million, and we currently estimate that this payment will be due in the first quarter of 2017.

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.

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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.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at June 30, 2016 should enable us to maintain current and planned operations into 2017. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, 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 product candidates that receive marketing approval, to the extent such costs are our responsibility, including the costs and timing of establishing product 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 may seek additional funding through public or private financings of debt or equity. The market for emerging life science stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including potentially adverse general market conditions and the early-stage development status of a majority of our drug candidates and the early stage of the commercial U.S. launch of Erivedge, additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any potential financing may be dilutive or otherwise adversely affect other rights of our stockholders.

We may also seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

We anticipate that we will require additional funding. If we are unable to obtain such additional funding on a timely basis, whether through sales of debt or equity or payments under existing or future collaborations or license

agreement, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our drug candidates; or

- delay, limit, reduce or prevent us from establishing sales and marketing capabilities, either internally or through third parties, or other activities that may be necessary to commercialize our drug candidates.

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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of June 30, 2016.

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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 ongoing economic downturn and 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, 2016, 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, 2016. 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, 2016, 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, 2016 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 quarterly report on Form 10-Q and in other documents we file with the SEC, in evaluating Curis and our business. If any of the following risks 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, 2015.

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 $20.7 million for the six months ended June 30, 2016 and $59.0 million, $18.7 million and $12.3 million for the years ended December 31, 2015, 2014, and 2013, respectively. As of June 30, 2016, we had an accumulated deficit of $859.3 million. We have not completed the development of any product 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 product candidate approved for commercialization. We have financed our operations to date primarily through public offerings and private placements of our common stock and amounts received through various current and past 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 our lead product candidates;
- seek to identify and develop additional product candidates;
- acquire or in-license other product candidates or technologies;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;

establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;

require the manufacture of larger quantities of product 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 source of revenues currently includes 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 BioPharma-II 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 revenue 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 product candidates other than Erivedge. Successful commercialization will require achievement of key milestones, including initiating and successfully completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the

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uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues and if or when we might achieve profitability. We and any collaborators may never succeed in these activities 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 on a quarterly or annual basis. 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 product 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 product development programs or commercialization efforts.

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our operating and capital requirements currently include the need to support our research and development activities for CUDC-907, as well as development candidates we have and may continue to license under our collaboration with Aurigene. We expect that 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 the 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 provides for inclusion of multiple programs, and we have the option to exclusively license compounds once a development candidate is nominated within each respective program.

We expect our development activity-related expenses to substantially increase in connection with CUDC-907 and the Aurigene programs. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at June 30, 2016 should enable us to maintain current and planned operations into 2017. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and 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 product candidates that receive marketing approval, to the extent such costs are our responsibility, including the costs and timing of establishing product 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through public or private financings of debt or equity. The market for emerging life science stocks in general, and the market for our common stock in particular, are highly volatile. Due to this and various other factors, including potentially adverse general market conditions and the early-stage development status of a majority of our drug candidates and the early stage of the commercial U.S. launch of Erivedge, additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any potential financing may be dilutive or otherwise adversely affect other rights of our stockholders.

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We may also seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

We anticipate that we will require additional funding. If we are unable to obtain such additional funding on a timely basis, whether through payments under existing or future collaborations or license agreement or sales of debt or equity, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our drug candidates; or

- delay, limit, reduce or prevent us from establishing sales and marketing capabilities, either internally or through third parties, or other activities that may be necessary to commercialize our drug candidates.

We transferred and encumbered certain royalty and royalty-related payments on the commercial sales of Erivedge in connection with our credit agreement with BioPharma-II 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 the commercial sales of Erivedge that we receive from Genentech. The loan and accrued interest will be 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 constitutes an obligation of Curis Royalty, and is non-recourse to 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, 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, in each case, which breach or default is not cured within 30 days after written demand thereof by BioPharma-II;

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 BioPharma-II 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 BioPharma-II, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to BioPharma-II under the credit agreement.

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The amount of royalty revenue we receive from sales of Erivedge may be adversely affected by sales of a competing drug.

Pursuant to the terms of our collaboration agreement, our subsidiary Curis Royalty 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 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 CHMP approved an additional Hedgehog signaling pathway inhibitor marketed by Novartis, sonidegib, for the treatment of adults with locally advanced BCC.

Genentech has advised us that Novartis recorded sales of sonidegib in the U.S. during the fourth quarter of 2015 and, accordingly, Genentech began reducing royalties on its net sales in the U.S. of Erivedge during the fourth quarter of 2015 from 5 7.5% to 3 5.5%. We also anticipate that sales of sonidigeb could 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 Bio-Pharm II.

Fluctuations in our quarterly and annual operating results could adversely affect the price of our common stock.

Our quarterly and annual operating results may fluctuate significantly. Some of the factors that may cause our operating results to fluctuate on a period-to-period basis include:

- payments we may be required to make to collaborators such as Aurigene to exercise license rights and satisfy milestones and royalty obligations;
- the status of, and level of expenses incurred in connection with, our programs, including development costs relating to CUDC-907, as well as funding programs that we have and may continue to license and develop under our collaboration with Aurigene;
- fluctuations in sales of Erivedge and related royalty payments, including those resulting from the sales of competing products such as Hedgehog signaling pathway inhibitor sonidegib, which is approved in the US and Europe for the treatment of locally advanced BCC and is marketed and sold by Novartis in the US;
- 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 BioPharma-II;

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 with BioPharma-II, 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.

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RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

Except for Erivedge, 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 are novel chemical entities and, except for Erivedge, which is approved and being commercialized for advanced BCC in several territories, 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.

In addition, in connection with our collaboration with Aurigene, we are seeking to discover, develop and commercialize small molecule antagonists for immuno-oncology targets such as immune checkpoint proteins and precision oncology targets, and such efforts may not prove to be successful. As such, outside of our collaboration with Aurigene, we are not aware of any small molecules that target the same immune checkpoint protein interactions in late preclinical or clinical development and we may never be able to successfully develop such drug candidates.

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 never successfully develop, enter into or 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 product candidates. Other than Erivedge, all of our product candidates are still in early clinical or preclinical development. Preclinical studies and clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates other than Erivedge or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources on our most advanced product candidate, CUDC-907. In addition, under our agreement with Aurigene, we have the option to license specified programs from Aurigene, and in October 2015, we exercised options to exclusively license two programs under this agreement, and selected a third program. Our ability to generate 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 product candidates. The success of our product candidates will depend on many factors, including the following:

- successful enrollment in, and completion of, ongoing and future clinical trials of CUDC-907 and potential 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 parties collaboration agreement;

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

receipt of 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 product that is appropriately packaged for sale;

adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;

obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;

protection of our rights in our intellectual property portfolio;

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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;

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 product candidate, which would materially harm our business.

If clinical trials of any future product 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 product candidates.

We, and any collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing