CURIS INC

FORM 10-Q
(Quarterly Report)

Filed 11/03/16 for the Period Ending 09/30/16

Address	4 MAGUIRE ROAD
	LEXINGTON, MA 02421
Telephone	617-503-6500
CIK	0001108205
Symbol	CRIS
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

(Mark one)

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

FOR THE QUARTERLY PERIOD ENDED September 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 Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4 Maguire Road Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

As of October 31, 2016 , there were 140,549,019 shares of the registrant's common stock outstanding.

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)

	September 30, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,671	$ 33,091
Investments	32,684	49,100
Accounts receivable	1,857	2,106
Prepaid expenses and other current assets	1,437	1,204
Total current assets	56,649	85,501
Property and equipment, net	406	278
Long-term investment – restricted	153	153
Goodwill	8,982	8,982
Other assets	3	51
Total assets	$ 66,193	$ 94,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 5,056	$ 4,217
Accrued liabilities	2,324	1,934
Current portion of long-term debt, net	5,104	4,607
Total current liabilities	12,484	10,758
Long-term debt, net	15,798	19,558
Other long-term liabilities	41	139
Total liabilities	28,323	30,455
Commitments		
Stockholders' Equity:		
Common stock, $0.01 par value—225,000,000 shares authorized; 141,217,276 shares issued and 139,994,430 shares outstanding at September 30, 2016; 130,213,224 shares issued and 128,990,378 shares outstanding at December 31, 2015	1,412	1,302
Additional paid-in capital	925,569	903,240
Treasury stock (at cost, 1,222,846 shares)	(1,524)	(1,524)
Accumulated deficit	(887,613)	(838,536)
Accumulated other comprehensive income	26	28
Total stockholders' equity	37,870	64,510
Total liabilities and stockholders' equity	$ 66,193	$ 94,965

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Royalties	$ 1,817	$ 2,293	$ 5,403	$ 5,998
Research and development, net	(58)	(248)	(238)	(212)
Total revenues	1,759	2,045	5,165	5,786
Costs and expenses:				
Cost of royalty revenues	94	116	278	303
Research and development	6,781	4,001	22,431	14,658
In-process research and development	17,989	—	17,989	24,348
General and administrative	4,684	2,772	11,743	9,712
Total costs and expenses	29,548	6,889	52,441	49,021
Loss from operations	(27,789)	(4,844)	(47,276)	(43,235)
Other expense:				
Interest income	101	128	325	252
Interest expense	(657)	(827)	(2,126)	(2,537)
Total other expense, net	(556)	(699)	(1,801)	(2,285)
Net loss	$ (28,345)	(5,543)	$ (49,077)	$ (45,520)
Net loss per common share (basic and diluted)	$ (0.21)	$ (0.04)	$ (0.38)	$ (0.37)
Weighted average common shares (basic and diluted)	132,065,947	128,392,413	130,122,698	121,634,415
Total comprehensive loss	$ (28,376)	$ (5,488)	$ (49,079)	$ (45,456)

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)

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Cash flows from operating activities:		
Net loss	$ (49,077)	$ (45,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	141	123
Stock-based compensation expense	3,311	2,875
Amortization of debt issuance costs	36	44
Gain on disposal of assets	—	(17)
Non-cash interest expense on investments	83	119
Issuance of common stock in consideration for rights granted under collaboration agreement	17,989	23,968
Changes in operating assets and liabilities:		
Accounts receivable	249	(357)
Prepaid expenses and other assets	(265)	(339)
Accounts payable and accrued and other liabilities	1,109	76
Total adjustments	22,653	26,492
Net cash used in operating activities	(26,424)	(19,028)
Cash flows from investing activities:		
Purchase of investments	(50,485)	(95,595)
Sale of investments	66,816	73,521
Purchases of property and equipment	(269)	(48)
Decrease in restricted cash	—	14
Proceeds from sale of equipment	—	19
Net cash provided by/(used in) investing activities	16,062	(22,089)
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	1,161	203
Payments on Curis Royalty’s debt	(3,219)	(2,793)
Net cash (used in)/provided by financing activities	(2,058)	62,029
Net (decrease)/increase in cash and cash equivalents	(12,420)	20,912
Cash and cash equivalents, beginning of period	33,091	7,747
Cash and cash equivalents, end of period	$ 20,671	$ 28,659

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

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. In September 2016, the Company entered into an amendment to this agreement, pursuant to which Aurigene received 10,208,333 shares of the Company's common stock in lieu of receiving up to $24.5 million of milestone and other payments from Curis (see Note 4(b)).

The collaboration comprises multiple programs, in which Curis has the option to exclusively license each program, including data, intellectual property and compounds associated with each respective program, once a development candidate is nominated within that 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 (PD1) and V-domain Ig suppressor of T-cell activation (VISTA) pathways in the immuno-oncology field. The Company has named CA-170, a programmed death ligand-1 (PDL1)/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) enzyme 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 further development under the collaboration, the second preclinical program within the immuno-oncology field, which is focused on evaluating small molecule antagonists of PD1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM3) pathways, including small molecules that target PDL1 and TIM3. In October 2016, the Company exercised its option to license this third program, and designated CA-327 as the development candidate.

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. In addition to BCC, Roche and Genentech are separately 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, an orally-available, small molecule antagonist of Heat Shock Protein 90.

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 United States Food and Drug Administration, or 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 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 September 30, 2016 should enable it to maintain current and planned operations into the second half of 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 as filed with the Securities and Exchange Commission, or the SEC, 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 September 30, 2016 and the results of operations for the three- and nine -month periods ended September 30, 2016 and 2015 and the cash flows for the nine -month periods ended September 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. 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. Pursuant to the agreement, the Company is eligible to receive up to an aggregate of $115.0

million in contingent cash milestone payments, exclusive of royalty payments, in connection with the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this amount, the Company has received $59.0 million as of September 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 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, Odomzo ® (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 $30.0 million loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II (see 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 $1.8 million and $2.3 million in royalty revenue under the Genentech collaboration during the three months ended September 30, 2016 and 2015 , respectively, and $5.4 million and $6.0 million during the nine months ended September 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 $0.1 million and $0.1 million during the three months ended September 30, 2016 and 2015 , respectively, and $0.3 million and $0.3 million during the nine months ended September 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 $0.1 million and $0.1 million during the three months ended September 30, 2016 and 2015 , respectively, and research and development revenue of $0.2 million and $0.2 million during the nine months ended September 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 $0.1 million and $0.3 million during the three months ended September 30, 2016 and 2015 , respectively, and expenses of $0.4 million and $0.4 million during the nine months ended September 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 $6.0 million (comprised of a $3.0 million 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 $2.0 million for supplemental research, development and/or manufacturing activities in support of these two programs. The Company incurred and recognized $1.0 million of such costs in the three months ended December 31, 2015 , which was paid in the three months ended March 31, 2016. The remaining $1.0 million 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 resulting in a one-time $2.0 million payment. In October 2016, the Company licensed the program and designated CA-327 as the development candidate as described in Note 1, resulting in a one-time $1.5 million payment.

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 $7.5 million , to be paid in two equal installments, and the Company currently estimates that these payments will be due in the first and third quarters 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 PD1/VISTA and IRAK4 programs: up to $52.5 million per program, comprised of: $3.0 million for each option exercise, $3.0 million upon acceptance of each IND filing, $4.0 million 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 $2.0 million for supplemental research, development and/or manufacturing activities in support of these two programs. During the three months ended September 30, 2016 , the Company recognized and paid $3.0 million to Aurigene upon the acceptance of the IND filing for CA-170, a PDL1/VISTA antagonist. Since the inception of the agreement through September 30, 2016 , the Company has incurred costs totaling $11.0 million related to these programs under the collaboration;
- for the third and fourth programs: up to $50.0 million per program, comprised of: $2.0 million for a program selection fee, $3.0 million for an option exercise, $2.5 million 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 September 30, 2016 , the Company has made payments to Aurigene totaling $2.0 million related to the third program under this collaboration; and
- for any program thereafter: up to $140.5 million per program, comprised of: up to a total of $53.0 million 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 September 30, 2016 , no payments have been made to Aurigene related to such programs under the collaboration.

Amendment to Collaboration Agreement . On September 7, 2016, the Company and Aurigene entered into an amendment to the January 2015 collaboration agreement. Under the terms of the amendment, in exchange for the issuance by the Company to Aurigene of 10,208,333 shares of its common stock, Aurigene waived payment of up to a total of $24.5 million in milestones and other payments from the Company that may become due under the 2015 collaboration agreement. The following milestones and other payments have been waived:

- $1.0 million payment for extended exclusivity related to the IRAK4 program;
- $3.0 million payment upon acceptance of IND filing related to the IRAK4 program;
- $4.0 million payment upon dosing of the fifth patient in the Company's Phase 1 clinical trial for the IRAK4 program;
- $1.0 million payment for extended exclusivity related to the PD1/VISTA program;
- $4.0 million payment upon dosing of the fifth patient in the Company's Phase 1 clinical trial for the PD1/VISTA program;
- $1.5 million , or 50% , of the payment related to the option exercise payment of the third program;
- $2.5 million payment upon acceptance of IND filing related to the third program;
- $2.0 million payment for program selection fee of the fourth program;
- $3.0 million payment for option exercise of the fourth program;
- $2.5 million payment upon acceptance of IND filing related to the fourth program;

To the extent any of these milestone or other payments described above would not otherwise be payable by Curis, e.g. in the event one or more of the listed milestone events do not occur, the Company will have the right to deduct the unused waiver amount from any one or more of the milestone payment obligations tied to achievement of commercial milestone events. The amendment also provides that upon exercise the option for the third and fourth programs, the Company will provide up to $2.0 million of additional funding for each such licensed program provided that supplemental program activities are performed by Aurigene.

Accounting Summary. Under the terms of this amendment, the value of common stock issued to Aurigene equaled $18.0 million based on the closing share price of the Company's common stock of $1.76 per share on September 6, 2016, which was the last closing price prior to execution of the amendment. As a result, the Company recognized in-process research and development expense of $18.0 million within its condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2016 in recognition of the fact that any compounds that have been and may be licensed from Aurigene are in clinical or preclinical development and will require substantial development, regulatory and marketing approval efforts in order to reach technological feasibility.

5. <u>Fair Value Measurements</u>

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

Level 1	Quoted prices in active markets for identical assets or liabilities.
Level 2	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In accordance with the fair value hierarchy, the following table shows the fair value as of September 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 September 30, 2016:				
Cash equivalents:				
Money market funds	$ 16,521	$ —	$ —	$ 16,521
Corporate commercial paper, bonds and notes	—	1,250	—	1,250
Municipal bonds	—	330	—	330
Short-term investments:				
Corporate commercial paper, stock, bonds and notes	—	32,684	—	32,684
Total assets at fair value	$ 16,521	$ 34,264	$ —	$ 50,785

	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 September 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 September 30, 2016 are as follows:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Total Fair Value
Corporate bonds and notes – short-term	$ 32,657	$ 32	$ (5)	$ 32,684
Total investments	$ 32,657	$ 32	$ (5)	$ 32,684

Short-term investments have maturities ranging from one to 12 months with a weighted-average maturity of 2.5 months at September 30, 2016 .

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 to 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 $30.0 million loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II. In connection with the loan, Curis transferred to Curis Royalty its right to receive royalty and royalty-related payments on the commercial sales of Erivedge that it receives from Genentech (see Note 4(a)). The loan and accrued interest 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 nine months ended September 30, 2016 and 2015 , Curis Royalty made payments totaling $5.3 million and $5.3 million , respectively, of which $3.2 million and $2.8 million have been applied to the principal, respectively, with the remainder applied to accrued interest. As of September 30, 2016 , the Company recorded short- and long-term debt of $5.1 million and $15.8 million , respectively, and at December 31, 2015 , the Company recorded short- and long-term debt of $4.6 million and $19.6 million , 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. 2015-3 *, 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 $0.2 million and $0.3 million as of September 30, 2016 and December 31, 2015 , respectively, with such amounts included in the Company's accrued liabilities section of its condensed consolidated balance sheets. For the three months ended September 30, 2016 and 2015 , the Company recognized interest expense related to the loan with BioPharma-II of $0.7 million and $0.8 million , respectively, in the condensed consolidated statement of operations and comprehensive loss. For the nine months ended September 30, 2016 and 2015 , the Company recognized interest expense related to the loan with BioPharma-II of $2.1 million and $2.5 million , respectively, in the condensed consolidated statement of operations and comprehensive loss.

At September 30, 2016 , the fair value of the debt approximates its carrying value due to the expected repayment period and because the interest rate yield is near current market rate yields. Due to the assumptions required in estimating future Erivedge royalties, the expected repayment period and weighting of various royalty projection scenarios, the fair value of the debt is measured using Level 3 inputs.

8. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2016	December 31, 2015
Accrued compensation	$ 1,637	$ 1,310
Professional fees	115	123
Accrued interest on debt (Note 7)	225	252
Other	347	249
Total	$ 2,324	$ 1,934

9. Accounting for Stock-Based Compensation

As of September 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 as amended 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 nine months ended September 30, 2016 , the Company's board of directors granted options to purchase a total of 4,621,225 shares of the Company's common stock to officers and employees of the Company, both under the 2010 Plan or in the form of inducement awards pursuant to NASDAQ Marketplace Rules. 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.

During the nine months ended September 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 nine months ended September 30, 2016 and 2015 based on the assumptions noted in the following table:

	Nine Months Ended September 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	63-70%	68-70%
Dividends	None	None

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

The risk-free 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 September 30, 2016 , there were 15,487,348 stock options outstanding. The aggregate intrinsic value of employee options outstanding at September 30, 2016 was $9.2 million , of which $3.9 million related to exercisable options. The weighted average grant-date fair values of these stock options granted during the nine months ended September 30, 2016 and 2015 were $1.08 and $1.71 , respectively. As of September 30, 2016 , there was approximately $7.1 million , 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 2.84 years. The intrinsic value of employee stock options exercised during the nine months ended September 30, 2016 and 2015 was $0.5 million and $0.1 million , respectively.

Employee Stock-Based Compensation Expense

During the three months ended September 30, 2016 , Daniel Passeri resigned from his position as Vice Chairman of the Company's board of directors. In connection with the related letter agreement with the Company, the board of directors approved a modification to Mr. Passeri's vested common stock options such that the exercise period for all such options shall be twenty-four months . As a result, $0.6 million of additional stock based compensation expense was recorded to account for this modification during the three months ended September 30, 2016 .

The Company recorded a total of $1.6 million and $3.3 million in compensation expense for the three and nine months ended September 30, 2016 , respectively and $1.0 million and $2.7 million in compensation expense for the three and the nine months ended September 30, 2015 , respectively, related to employee and director stock option grants. The total fair values of vested stock options for the nine months ended September 30, 2016 and 2015 were $2.8 million and $2.1 million , 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 $0.1 million and reversed expense of less than $0.1 million during the three and nine months ended September 30, 2016 , respectively, and reversed expense of $0.1 million and recognized expense of $0.2 million during the three and nine months ended September 30, 2015 , respectively.

Total Stock-Based Compensation Expense

For the three and nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expenses	$ 205	$ 170	$ 531	$ 771
General and administrative expenses	1,425	731	2,780	2,104
Total stock-based compensation expense	$ 1,630	$ 901	$ 3,311	$ 2,875

10. Accumulated Other Comprehensive Income (Loss)

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

		Unrealized Gain on Securities Available-for-Sale
Balance, as of December 31, 2015	$	28
Unrealized gain on marketable securities		(2)
Amounts reclassified from accumulated other comprehensive income (loss)		—
Net current period other comprehensive income		(2)
Balance, as of September 30, 2016	$	26

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		65
Amounts reclassified from accumulated other comprehensive income (loss)		—
Net current period other comprehensive income		65
Balance, as of September 30, 2015	$	54

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 nine months ended September 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 15,487,348 and 13,678,899 as of September 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 $30,000 per month. During the nine months ended September 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.

On September 2, 2016, the Company and Mr. Passeri entered into a letter agreement pursuant to which Mr. Passeri resigned as director and Vice Chairman of the Company's board of directors, which became effective on September 14, 2016. Pursuant to the terms of the Letter Agreement, and in recognition of his many years of service to the Company in varying roles, including as a director and Vice Chairman of the Board, and formerly as Chief Executive Officer, President, and as a consultant, the Board authorized a $250,000 recognition bonus payment to Mr. Passeri and also approved a modification to Mr. Passeri’s vested common stock options such that the exercise period for all such options shall be 24 months . Mr. Passeri agreed to provide continued assistance to the Company, without further remuneration, for up to two years , if and when requested by the Board or the Chief Executive Officer. The letter agreement also contains other customary terms and conditions relating to Mr. Passeri's end of service with the Company.

The Company recognized expenses related to the consulting and letter agreements of $0.3 million and $0.1 million during the three months ended September 30, 2016 and 2015 , respectively, and expenses of $0.4 million and $0.1 million during the nine months ended September 30, 2016 and 2015 , respectively.

13. New Accounting Pronouncements

In March 2016, the Financial Accounting Standard Board (FASB) issued Accounting Standard Update (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 February 2016, the FASB issued ASU 2016-02, *Leases* . The standard requires organizations that lease assets to recognize on the balance sheet assets or liabilities, as applicable, for the rights and obligations created by those leases. Additionally, the guidance modifies current guidance for lessor accounting and leveraged leases, and is effective for fiscal years beginning after December 15, 2018, and interim periods within such years. Early adoption is permitted, but the Company does not anticipate electing early adoption. The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial statements.

In January 2016, the FASB issued ASU, 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities,* which amends prior guidance on accounting for equity investments and financial liabilities. The new standard amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in results of operations. The new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. The guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within such years. 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 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 ending 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 collectability, 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.

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 our 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 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, or PD1, and V-domain Ig suppressor of T-cell activation, or VISTA, pathways in the immuno-oncology field, including the development candidate designated CA-170, which targets programmed death ligand-1, or PDL1, and VISTA. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4, or 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 PD1 and T-cell immunoglobulin and mucin domain containing protein-3, or TIM3, pathways, including small molecules that target PDL1 and TIM3. In October 2016, we exercised our option to license this third program, and designated CA-327 as the development candidate.

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 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, as well as CA-170, CA-4948 and CA-327 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. In September 2016, we entered into an amendment to this agreement, pursuant to which Aurigene received 10,208,333 shares of our common stock in lieu of receiving up to $24.5 million in milestone and other payments from Curis. There are currently three licensed programs 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 .

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 $887.6 million as of September 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 September 30, 2016 should enable us to maintain current and planned operations into the second half of 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 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 CA-327, and for us to then finance and complete planned Phase 1 clinical trials for each of these development candidates;
- Aurigene's ability to advance additional preclinical immuno-oncology, and precision oncology drug candidates, and our ability to license these programs from Aurigene and further progress them clinically;
- Genentech and Roche's ability to 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 September 30, 2016 should enable us to maintain current and planned operations into the second half of 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 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 September 30, 2016 , the outstanding principal and interest due under the loan is $21.3 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 and as amended in September 2016, including, for example, option exercise fees and milestone payments. We expense research and development costs as incurred. We are currently incurring research and development costs under our Hedgehog signaling pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. In addition, we record research and development expense for payments that we are obligated to make to certain third

-party university licensors upon our receipt of payments from Genentech related to the achievement of clinical development and regulatory objectives under our collaboration agreement.

The following graphic outlines the current status of our programs:

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.

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 , which was filed with the SEC on February 29, 2016 .

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015 :

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues	$ 1,759	$ 2,045	(14)%
Costs and expenses:			
Cost of royalty revenues	94	116	(19)%
Research and development	6,781	4,001	69 %
In-process research and development	17,989	—	— %
General and administrative	4,684	2,772	69 %
Other expense, net	556	699	(20)%
Net loss	$ (28,345)	$ (5,543)	411 %

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues:			
Royalties	$ 1,817	$ 2,293	(21)%
Research and development, net	(58)	(248)	(77)%
Total revenues	$ 1,759	$ 2,045	(14)%

Total revenues decreased by $0.3 million to $1.8 million for the three months ended September 30, 2016 as compared to $2.0 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 September 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 September 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 September 30, 2016	For the Three Months Ended September 30, 2015	Percentage Increase/ (Decrease)
	(in thousands)		
Direct research and development expenses	$ 3,970	$ 2,053	93 %
Employee-related expenses	2,378	1,481	61 %
Facilities, depreciation and other expenses	433	467	(7)%
Total research and development expenses	$ 6,781	$ 4,001	69 %

Research and development expenses were $6.8 million for the three months ended September 30, 2016 , as compared to $4.0 million in the same period in 2015, an increase of $2.8 million , or 69% . Direct research and development expenses increased $1.9 million for the three months ended September 30, 2016 as compared to the same period in 2015, which 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. Employee-related expenses increased $0.9 million for the three months ended September 30, 2016 as compared to the same period in 2015, which was primarily due to additional headcount.

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 three months ended September 30, 2016 , we recognized in-process research and development expenses of $18.0 million , which represented the consideration we paid as part of our amendment to the collaboration agreement with Aurigene. No such expense was recorded for the three months ended September 30, 2015 .

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

	For the Three Months Ended September 30, 2016	For the Three Months Ended September 30, 2015	Percentage Increase/ (Decrease)
	(in thousands)		
Personnel	$ 1,088	$ 784	39%
Occupancy and depreciation	105	99	6%
Legal services	953	267	257%
Professional and consulting services	574	553	4%
Insurance costs	100	98	2%
Other general and administrative expenses	439	240	83%
Stock-based compensation	1,425	731	95%
Total general and administrative expenses	$ 4,684	$ 2,772	69%

General and administrative expenses were $4.7 million for the three months ended September 30, 2016 , as compared to $2.8 million in the same period in 2015, an increase of $1.9 million , or 69% . The increase in general administrative expense was driven primarily by higher personnel costs and stock-based compensation due to increased headcount and an increase in legal service costs related to our intellectual property.

Other Expense. For the three months ended September 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 September 30, 2016 and 2015 , respectively.

Nine Months Ended September 30, 2016 and September 30, 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015 :

	Nine Months Ended September 30, 2016		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues	$ 5,165	$ 5,786	(11)%
Costs and expenses:			
Cost of royalty revenues	278	303	(8)%
Research and development	22,431	14,658	53 %
In-process research and development	17,989	24,348	(26)%
General and administrative	11,743	9,712	21 %
Other expense, net	1,801	2,285	(21)%
Net loss	$ (49,077)	$ (45,520)	8 %

Revenues. Total revenues are summarized as follows:

	Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Revenues:			
Royalty revenues from Genentech	$ 5,403	$ 5,998	(10)%
Research and development, net	(238)	(212)	12 %
Total Revenues	$ 5,165	$ 5,786	(11)%

Total revenues decreased by $0.6 million to $5.2 million for the nine months ended September 30, 2016 as compared to $5.8 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 nine months ended September 30, 2016 as compared to the prior year period.

Cost of Royalty Revenues. Cost of royalty revenues remained unchanged at $0.3 million for the nine months ended September 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:

	Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Direct research and development expenses	$ 14,710	$ 8,658	70%
Employee-related expenses	6,379	4,714	35%
Facilities, depreciation and other expenses	1,342	1,286	4%
Total research and development expenses	$ 22,431	$ 14,658	53%

Research and development expenses were $22.4 million for the nine months ended September 30, 2016 , as compared to $14.7 million in the same period in 2015 , an increase of $7.8 million , or 53% . Direct research and development expenses increased $6.1 million for the nine months ended September 30, 2016 , which 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 nine months ended September 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 nine months ended September 30, 2015 includes a $2.0 million milestone payment to Aurigene for selection of the third program under the collaboration. Employee-related expenses increased $1.7 million for the nine months ended September 30, 2016 , which was primarily due to additional headcount, offset by a decrease in stock-based compensation of $0.2 million. Facilities, depreciation and other expenses have increased by $0.1 million for the nine months ended September 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 nine months ended September 30, 2016 , we recognized in-process research and development expenses of $18.0 million , which represented the consideration we paid as part of our amendment to the collaboration agreement with Aurigene. For the nine months ended September 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.

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

	Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2016	2015	
	(in thousands)		
Personnel	$ 3,399	$ 2,825	20%
Occupancy and depreciation	326	294	11%
Legal services	2,098	1,690	24%
Professional and consulting services	1,724	1,717	—%
Insurance costs	292	271	8%
Other general and administrative expenses	1,124	811	39%
Stock-based compensation	2,780	2,104	32%
Total general and administrative expenses	$ 11,743	$ 9,712	21%

General and administrative expenses increased by $2.0 million , or 21% , for the nine months ended September 30, 2016 as compared to the same period in the prior year. The increase in general administrative expense was driven primarily by higher personnel costs and stock-based compensation due to increased headcount and an increase in legal service costs related to our intellectual property.

Other Expense. For the nine months ended September 30, 2016 and 2015 , interest expense was $2.1 million and $2.5 million , respectively, related to interest accrued on Curis Royalty's outstanding debt with BioPharma-II. Interest income was $0.3 million and $0.3 million for the nine months ended September 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 September 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 nine months ended September 30, 2016 totaled $5.3 million, of which $3.2 million has been applied to the principal, and the remainder satisfying interest obligations. As of September 30, 2016 , Curis Royalty owed a total of $21.3 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 September 30, 2016 , our principal sources of liquidity consisted of cash, cash equivalents, and investments of $53.4 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.

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 $26.4 million during the nine months ended September 30, 2016 was primarily the result of our net loss for the period of $49.1 million , offset by non-cash charges consisting of the stock issuance to Aurigene as consideration for the amendment to our collaboration agreement with Aurigene, stock-based compensation, non-cash interest expense, amortization of debt issuance costs and depreciation, totaling $21.6 million . In addition, accounts payable and accrued liabilities increased $1.1 million , accounts receivable decreased $0.2 million and prepaid assets increased $0.3 million related to deposits made with vendors.

Net cash used in operating activities of $19.0 million during the nine -month period ended September 30, 2015 was primarily the result of our net loss for the period of $45.5 million , offset by non-cash charges consisting of the stock issuance to

Aurigene 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 $27.1 million . In addition, accounts receivable increased $0.4 million related to an increase in Erivedge royalties 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 three programs under our collaboration agreement with Aurigene. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and other specified objectives.

Investing activities provided cash of $16.1 million and accounted for cash expenditures of $22.1 million for the nine months ended September 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 $2.1 million for the nine months ended September 30, 2016 as a result of principal payments on Curis Royalty’s loan with BioPharma-II of $3.2 million , offset by $1.2 million in proceeds from the exercise of stock options. Financing activities provided cash of $62.0 million for the nine months ended September 30, 2015 . During the nine months ended September 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 were offset by the principal payment on Curis Royalty’s loan with BioPharma-II of $2.8 million .

Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2016 , we had an accumulated deficit of approximately $887.6 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.

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. In September 2016, we entered into an amendment to our license agreement with Aurigene, pursuant to which Aurigene received 10,208,333 shares of common stock in lieu of receiving up to $24.5 million of milestones and other payments from Curis. In October 2016, we exercised our option related to the third program, upon which we paid a $1.5 million payment to Aurigene. 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, to be paid in two equal installments, we currently estimate that these payments will be due in the first and third quarters 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.

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 September 30, 2016 should enable us to maintain current and planned operations into the second half of 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 September 30, 2016 .

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Our marketable securities and long-term investments are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, marketable securities since September 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 September 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 September 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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 $49.1 million for the nine months ended September 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 September 30, 2016 , we had an accumulated deficit of $887.6 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 revenues other than those related to Erivedge unless and until we are, or any collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our 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 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 and CA-170, 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, CA-170 and other 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 September 30, 2016 should enable us to maintain current and planned operations into the second half of 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.

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.

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 (Odomzo ®) 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 sonidegib 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 BioPharma 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 and CA-170, 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 U.S. and Europe for the treatment of locally advanced BCC and is marketed and sold by Novartis in the U.S.;
- 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.

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 in October 2016 we exercised our option to exclusively license a third program, which is focused on evaluating small molecule antagonists of PD1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM3) pathways, including small molecules that target PDL1 and TIM3. 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 CA-170 as well as 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;
- 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 approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, or the EMA, impose similar requirements. We, and any collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of product development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or we may mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

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

- incur additional unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

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

Adverse events or undesirable side effects caused by, or other unexpected properties of, product candidates that we develop may be identified during development and could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, any product candidates that we may develop could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

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

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

- regulators or institutional review boards may not authorize us, any collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or any collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we, or any collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we, or any collaborators, anticipate, patient enrollment in these clinical trials may be slower than we, or any collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or any collaborators, anticipate;
- our estimates of the patient populations available for study may be higher than actual patient numbers and result in our inability to sufficiently enroll our trials;
- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- our third-party contractors or those of any collaborators, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any collaborators in a timely manner or at all;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we, or any collaborators, may have to delay, suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we, or any collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our, or any collaborators', clinical trial designs or our or their interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

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

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

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

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

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

Enrollment delays in our clinical trials, including for the additional clinical trials of CUDC-907 and CA-170, may result in increased development costs for our drug candidates, which could cause the value of our stock price to decline.

Results of preclinical studies and early clinical trials may not be predictive of results of future late stage clinical trials.

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

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

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

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for any of our product candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates or any companion diagnostics, generating revenues and achieving and sustaining profitability. If any of these outcomes occurs, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

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

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

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

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

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

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

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product’s convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions, contained in the product’s approved labeling;

- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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

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

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

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

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

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

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

Our drug candidates face competition from existing and new technologies and products being developed by biotechnology, medical device, and pharmaceutical companies, as well as universities and other research institutions. For example, we are aware of several biotechnology and pharmaceutical companies that have drug development programs relating to compounds that modulate the Hedgehog signaling pathway. We believe that there are currently at least four other companies that have progressed Hedgehog signaling pathway inhibitors into clinical development: Eli Lilly and Company, Exelixis, Inc. in co-development with the Bristol-Myers Squibb Company, and Pfizer Inc, or Pfizer.

During the third quarter of 2015, the FDA and CHMP approved another Hedgehog signaling pathway inhibitor, called sonidegib and marketed by Novartis, for the treatment of adults with locally advanced BCC. Under the terms of our collaboration agreement with Genentech, our royalty would be reduced in any country where another drug that binds to the same molecular target receives regulatory approval for the same indication as Erivedge and is subsequently commercialized in that country. As Novartis recorded sales of sonidegib in the U.S. during the fourth quarter of 2015, Genentech began reducing royalties on its net sales in the U.S. of Erivedge accordingly.

In addition, there are several companies developing drug candidates that target the same molecular targets that we are targeting or that are testing drug candidates in the same cancer indications that we are testing. For example, while we are not aware of other molecules in clinical testing that are designed as one chemical entity to target both PI3K and HDAC, there are commercially-available drugs that individually target PI3K or HDAC and there are multiple companies testing PI3K or HDAC inhibitors that are in various stages of clinical development.

In October 2015, we exercised options to license the first two programs under our collaboration with Aurigene. The first licensed program is focused on the development of orally-available small molecule antagonists of PD1 and VISTA pathways in the immuno-oncology field. The second licensed program is focused on orally-available small molecule inhibitors of IRAK4 in the precision oncology field. We are aware of at least three other companies that are developing IRAK4 inhibitors: Pfizer, Nimbus Discovery in collaboration with Genentech, and TG Therapeutics (in-licensed an IRAK4 inhibitor from Ligand Pharmaceuticals). In addition, there are three approved drugs on the market that target PD1/PDL1 interactions (Bristol-Myers Squibb’s Opdivo ™, Merck & Co.’s Keytruda ™ and Roche’s Tecentriq ™) and a number of drug candidates in various stages of development that target the similar interactions such as Merck KGaA / Pfizer’s avelumab, AstraZeneca/MedImmune’s MEDI4736 and MEDI0680, and others. Additionally, in October 2016, we exercised our option to license the third program under our collaboration with Aurigene, that is focused on the development of orally-available small molecule antagonists of PD1 and TIM3 pathways, including small molecules that target PDL1 within immuno-oncology. We are aware of at least two TIM3 targeting antibodies that are being investigated in clinical trials currently (Novartis’s MBG453 and Tesaro’s TSR-022) and there are several others in various stages of preclinical development.

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

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

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

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

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

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize successfully any of our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

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

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

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

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

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

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

RISKS RELATING TO OUR DEPENDENCE ON THIRD PARTIES

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

Erivedge is FDA-approved for people with advanced BCC in the United States. Erivedge is also approved in over 60 foreign countries. Genentech and/or Roche have filed regulatory submissions in additional territories seeking approval to commercialize Erivedge for this same indication. Outside of BCC, Roche and Genentech are also pursuing its potential development in other diseases including in IPF and MF. Our levels of revenue in each period and our near-term prospects substantially depend upon Genentech's ability to successfully develop and commercialize Erivedge in one or more additional indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. The development and commercialization of Erivedge could be unsuccessful if:

- Erivedge is no longer accepted as safe, efficacious, cost-effective and preferable for the treatment of advanced BCC to current therapies in the medical community and by third-party payors;
- Genentech and/or Roche fail to continue to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC, and to regulatory approvals for this indication outside of the U.S.;
- Genentech and/or Roche do not continue to develop and implement effective marketing, sales and distribution strategies and operations for development and commercialization of Erivedge for advanced BCC;
- Genentech and/or Roche do not continue to develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;
- Genentech and Roche do not obtain full approval to commercialize Erivedge in the EU based upon the results of the study of vismodegib in patients with locally advanced or metastatic BCC;
- Genentech and/or Roche do not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we, Genentech, or Roche encounter any third party patent interference, derivation, *inter partes* review, post-grant review, reexamination or patent infringement claims with respect to Erivedge;
- Genentech and/or Roche do not comply with regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;
- competing products are approved for the same indications as Erivedge, such as the FDA and CHMP approval during the third quarter of 2015 of another Hedgehog signaling pathway inhibitor, sonidegib, marketed by Novartis, for the treatment of adults with locally advanced BCC;
- new safety risks are identified; or
- Erivedge does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than advanced BCC.

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

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

Pursuant to our collaboration with Genentech, we have granted to Genentech exclusive rights to develop and commercialize products based upon our Hedgehog signaling pathway technologies. In addition, we entered into a collaboration, license and option agreement with Aurigene pursuant to which Aurigene may develop various immuno-oncology, selected precision oncology and other potential targets which we will have the option to license and advance into clinical trials.

Collaborations involving our product candidates, including our collaborations with Aurigene and Genentech, pose the following risks to us:

- Our collaborators each have significant discretion in determining the efforts and resources that they will apply to their respective collaboration with us. If a collaborator fails to allocate sufficient time, attention and resources to our collaboration, the successful development and commercialization of drug candidates under such collaboration is likely to be adversely affected. For example, we are dependent on Aurigene to successfully discover and advance preclinical programs from which we may exercise our option to license drug candidates for future development.
- Our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of our respective collaborations. For example, Genentech and Roche are involved in the commercialization of many cancer medicines and are seeking to develop several other cancer drug therapies, and Aurigene has other active cancer-focused discovery programs and has also entered into license agreements with other companies that focus on cancer therapies.
- Our collaborators may change the focus of their development and commercialization efforts or pursue higher-priority programs.
- Our collaborators may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. Any such transaction could divert the attention of our collaborative partner’s management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator’s development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates our collaboration.
- Our collaborators may, under specified circumstances, terminate their collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific, biotech, pharma and financial communities.
- Our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights, or expose us to potential liability.
- If any of our collaborators were to breach or terminate its arrangement with us, the development and commercialization of the affected drug candidate or program could be delayed, curtailed or terminated.

In addition, our collaboration agreement with Genentech has resulted in the approval of Erivedge for the treatment of advanced BCC in the United States, the European Union, and several other countries. The commercial success of Erivedge in this patient population is dependent on continued investment by Genentech and Roche, and development and market approvals in indications other than in BCC will require significant investments from Genentech and Roche. The success of the further development or commercialization of Erivedge in advanced BCC, and potentially in additional indications, is dependent on a number of factors, including the following:

- Genentech is a wholly owned member of the Roche Group, and as such, is subject to the risk that Roche could determine to re-prioritize Genentech’s commercial or development programs, which could reduce Genentech’s efforts on the development or commercialization of Erivedge or cause Genentech to terminate our collaboration.
- Genentech has the first right to maintain or defend intellectual property rights associated with the drug candidate under its agreement and, although we may have the right to assume the maintenance and defense of our intellectual property rights if Genentech does not, our ability to do so may be compromised by Genentech’s acts or failures to act.

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

We intend to seek corporate collaborators or licensees for the further development and commercialization of one or more of our drug candidates in one or more geographic territories, particularly in territories outside of the United States. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., Phase 3) or commercialization on our own, but we are seeking to build such a capacity to enable Curis to retain development and certain commercial rights to most of our programs in at least the United States. Our success will depend, in part, on either our ability to build such capacity, or our ability to enter into one or more collaborations for our drug candidates. We face significant competition in seeking appropriate collaborators and a number of recent business combinations in the biotechnology and pharmaceutical industry may result in a reduced number of potential future collaborators. In addition, collaborations are complex and time-consuming to negotiate and document. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy or as sufficiently differentiated compared to existing or emerging treatments. We are also restricted under the terms of certain of our existing collaboration agreements from entering into collaborations regarding or otherwise developing product candidates that are similar to the product candidates that are subject to those agreements, such as developing product candidates that inhibit the same molecular target. In addition, collaboration agreements that we enter into in the future may contain further restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us and such collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all.

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

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

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

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

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

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

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our and our collaborators’ control or may terminate or fail to renew a manufacturing agreement based on their own business priorities, becoming costly and/or inconvenient for us and our collaborators.

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

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

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

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

We rely on third parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. Such suppliers may not sell these raw materials to us at the times we need them or on commercially reasonable terms, or delivery of these raw materials may be delayed or interrupted. Although we generally do not begin a preclinical study or clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such study or trial, any significant delay in the supply of raw materials for our drug candidates for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which would impair our ability to generate revenues from their sale.

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

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

RISKS RELATING TO EMPLOYEE MATTERS AND MANAGING GROWTH

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

We depend upon our senior management team. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers all serve pursuant to “at will” employment arrangements and can terminate their employment with us at any time. In the future, we may be dependent on other members of our management, scientific and development team.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We may seek to acquire complementary businesses and technologies or otherwise seek to expand our operations and grow our business, which may divert management resources and adversely affect our financial condition and operating results.

We may seek to expand our operations, including through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

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

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We may not be able to obtain and maintain patent protection for our technologies and products, our licensors may not be able to obtain and maintain patent protection for the technology or products that we license from them, and the patent protection we or they do obtain may not be sufficient to stop our competitors from using similar technology.

The long-term success of our business depends in significant part on our ability to:

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

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

law does. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain.

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

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

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

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

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

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

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

- initiation of litigation or other proceedings against third parties to enforce our patent rights, to seek to invalidate the patents held by third parties or to obtain a judgment that our drug candidates do not infringe such third parties' patents;
- participation in interference and/or derivation proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;

- initiation of opposition, reexamination, post grant review or *inter partes* review proceedings by third parties that seek to limit or eliminate the scope of our patent protection;
- initiation of litigation by third parties claiming that our processes or drug candidates or the intended use of our drug candidates infringes their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

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

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

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

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

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

We rely heavily on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect this information through confidentiality and intellectual property license or assignment provisions in agreements with our employees, consultants and other third-party contractors, including our contract research agreement with a medicinal chemistry provider in China, as well as through other security measures. Similarly, our agreement with Aurigene requires Aurigene to enter into such agreements with its employees, consultants, and other third-party contractors. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

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

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

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

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

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

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Moreover, the FDA or other regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

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

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

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

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

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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

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

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

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

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

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

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

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

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;

- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures.

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

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

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

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our drug products and other materials are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

Any business that we conduct in China will expose us to risks resulting from adverse changes in political, legal and economic policies of the Chinese government.

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China’s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Recent evidence of a slowdown in the pace of growth of the Chinese economy could result in interruptions and/or delay of our development efforts in China. If our research and development efforts in China are delayed, we may not realize the reductions in costs anticipated from doing business in China. We would also have to consider moving our chemistry and/or biology research, which is currently conducted by contract research organizations in China, to providers in the U.S. or Europe. Such a move could increase our overall costs for these services, or reduce the total number of chemists and or/biologists that we could engage. In addition, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws, the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China, or by the inability to enforce applicable Chinese laws and regulations.

RISKS RELATING TO OUR COMMON STOCK

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

Our common stock is currently listed for quotation on the NASDAQ Global Market. We are required to meet specified financial requirements in order to maintain our listing on the NASDAQ Global Market. One such requirement is that we maintain a minimum bid price of at least $1.00 per share for our common stock. Although we currently comply with the minimum bid requirement, our bid price could fall below $1.00 per share in the future. If our bid price falls below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from NASDAQ advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies. If in the future we fail to satisfy the NASDAQ Global Market's continued listing requirements, we may transfer to the NASDAQ Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the NASDAQ Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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

The trading price of our common stock has been volatile and is likely to continue to be volatile in the future. For example, our stock traded within a range of a high price of $5.65 and a low price of $1.09 per share for the period January 1, 2012 through October 31, 2016 . The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical and biotechnology company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

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

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

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

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. Genentech is a wholly owned member of the Roche Group, and Roche has also made public statements regarding its expectations for the clinical development, commercialization and marketing of Erivedge, and may in the future make additional statements about its goals and expectations for Erivedge and/or its collaboration with us. The actual timing of these events can vary dramatically due to a number of factors including delays or failures in our and our current and potential future collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by all parties, and the inherent uncertainties in the regulatory approval and commercialization process. As a result:

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

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

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

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

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

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

We currently have on file with the SEC a "universal" shelf registration statement which allows us to offer and sell registered common stock, preferred stock, and warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In July 2015, we entered into a sales agreement with Cowen pursuant to which, from time to time, we may offer and sell through Cowen up to $30.0 million of the registered common stock that was on the shelf registration statement pursuant to one or more "at the market" offerings. As of September 30, 2016 , we have not had any such sales. In addition, with our prior written approval, Cowen may sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities under this registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

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

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

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

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

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

As of September 30, 2016 , we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 57.4% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could harm the market price of our common stock by:

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

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

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

A decline in our stock price may affect future fundraising efforts.

We currently have no product revenues, and depend entirely on funds raised through other sources. One source of such funding is future debt and/or equity offerings. Our ability to raise funds in this manner depends upon, among other things, our stock price, which may be affected by capital market forces, evaluation of our stock by securities analysts, product development success (or failure), and internal management operations and controls.

We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable, or prevent attempts by our stockholders to replace or remove current management, which could result in a decline in the price of our common stock.

Provisions of our certificate of incorporation, our bylaws, and Delaware law may deter unsolicited takeovers or delay or prevent changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized “blank check” preferred stock, and our stockholders are limited in their ability to call special stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control.

Item 6. Exhibits

(a) Exhibits.

See exhibit index.

SIGNATURE

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

CURIS, INC.

Dated:	November 3, 2016	By:	/s/ JAMES E. DENTZER
			James E. Dentzer
			Chief Financial Officer and Chief Administrative Officer
			(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1	Letter Agreement, dated September 2, 2016, by and between Curis, Inc. and Daniel R. Passeri
†10.2	First Amendment to Collaboration, License and Option Agreement, dated September 7, 2016, by and between Curis, Inc. and Aurigene Discovery Technologies Limited
10.3	Stock Purchase Agreement, dated September 7, 2016, by and between Curis, Inc. and Aurigene Discovery Technologies Limited
10.4	Registration Rights Agreement, dated September 7, 2016, by and between Curis, Inc. and Aurigene Discovery Technologies Limited
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

⑥ Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

Exhibit 10.1

CURIS, INC.
4 Maguire Road
Lexington, MA 02421

Daniel R. Passeri
c/o Curis, Inc.
4 Maguire Road
Lexington, MA 02421

Dear Dan:

Curis, Inc. (the "Company") appreciates your many years of service in varying roles including as Chief Executive Officer, President, Vice-Chairman of the Board of Directors (the "Board") and as a consultant. In recognition of such service, this letter agreement will memorialize certain arrangements between the Company and you, as well as resolve any outstanding issues there may be. This Agreement may be accepted by you by providing an executed agreement which is received by the Company by no later than August 31, 2016, after which time the Agreement and the offer embodied within it, shall be effectively withdrawn.

Recognition Bonus – In recognition of your service, the Board has authorized a $250,000 recognition bonus (the "Recognition Bonus"). This bonus will be paid in a lump sum on the tenth (10 th) day after your execution of this Agreement (the "Execution Date") provided you have met your obligations under this Agreement. The Company will issue federal tax form 1099 – MISC to you with respect to the Recognition Bonus.

Extension of Options' Exercise Period – All outstanding options to purchase shares of the Company's common stock in which you have vested as of the Execution Date (as set forth on Exhibit A) shall be amended to extend the exercise period until such date that is twenty-four (24) months following the Execution Date (but in no event shall such exercise period be extended later than the Final Exercise Date (as defined in the applicable option agreement)). You understand that any option that is so amended to extend the exercise period shall cease to be treated for tax purposes as an incentive stock option. You also understand that the aforementioned extension of option exercise period is contingent on your having met your obligations under this Agreement.

Resignation as a Director and All Other Offices and Capacities – Effective as of September 14, 2016, and without the need for any further action on the part of you or the Company, you have voluntarily resigned as a member of the Board of Directors and any other offices and any other capacities with the Company.

Continued Assistance – You agree that for two (2) years after the Execution Date, if requested by the Board or the Chief Executive Officer, you will provide reasonable assistance at mutually agreeable times to the Company in connection with business matters and perform any other tasks as reasonably requested by the Company ("Assistance") and cooperate in assisting the Company in defending against and/or prosecuting any litigation or threatened litigation, and, in each case without further remuneration by the Company. The Company agrees to indemnify you and hold you harmless against any and all losses, claims, damages or liabilities to which you become subject in connection with your performance of Assistance pursuant to this Section 4, except to the extent that any loss, claim, damage or liability results from your gross negligence, willful misconduct or bad faith. If any action, suit, or proceeding (each an "Action") is brought against you pursuant to which indemnification may be sought pursuant to this Section 4, you will promptly notify the Company in writing of the institution of such Action. The Company will be entitled to assume the defense of such Action, including the employment of counsel and the payment of expenses in connection with such Action. You will have the right to employ your own counsel at your own expense if (a) the Company authorizes the employment of such counsel, (b) the Company has failed in its obligation to employ counsel to take charge of such defense, or (c) in the reasonable opinion of the Company's counsel, the use of joint counsel presents an unavoidable conflict of interest. You agree not to settle any Action without the written consent of the Company.

Option Repayment – On December 18, 2015 you exercised an option purportedly pursuant to your 2000 Incentive Stock Option Agreement, to purchase 45,742 shares at a strike price of $1.57 a share, with a $2.99 value per share, yielding a $64,954 gain on that exercise. The exercise was more than 90 days after your separation from employment and should not have been processed. Accordingly, you agree that upon the Execution Date you shall remit a check to the Company for the aforementioned $64,954.

Release – In consideration of the Recognition Bonus and the extended exercise period of your options, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your engagement as a consultant, your service as a Board member and your past employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act., Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102 and Mass. Gen. Laws ch. 214, § 1C, the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Maternity Leave Act, Mass. Gen. Laws ch. 149, § 105D, the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, and the Cambridge Human Rights Ordinance, Municipal Code Ch. 2.76.010 et seq. (City of Cambridge anti-discrimination law), all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract, including but not limited to, any claim concerning your right to exercise stock options; all claims to any non-vested ownership interest in the Company, contractual or otherwise; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this letter agreement prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding).

Continuing Obligations – You acknowledge and reaffirm your obligation to keep confidential and not to use or disclose any and all non-public information concerning the Company that you acquired during the course of your engagement as a consultant or service as a board member or past employment with the Company, including, but not limited to, any non-public information concerning the Company's business affairs, business prospects, and financial condition.

Non-Disparagement – You understand and agree that you will not, in public or private, make any false, disparaging, derogatory or defamatory statements to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the Company's business affairs, business prospects, or financial condition; provided that the foregoing shall not apply to any statements made by you at a meeting of the Board while you remain a member thereof.

Return of Company Property – You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, tablets, etc.), Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those that you developed or helped to develop during your consulting, past employment and service on the Board. You further confirm that you have cancelled (or will cancel by the Effective Date) all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or wireless data accounts, and computer accounts.

Business Expenses and Other Compensation – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your consulting, service on the Board and past employment and that no other reimbursements or other compensation is owed to you except as provided herein.

Amendment and Waiver – This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

Validity – Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.

Confidentiality – To the extent permitted by law, and except as required by disclosure requirements under applicable securities laws, you understand and agree that as a condition for payment to you of the consideration herein described, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company.

Nature of Agreement – You and the Company understand and agree that this letter agreement does not constitute an admission of liability or wrongdoing on the part of either you or the Company.

Acknowledgments and Voluntary Assent – You acknowledge that you have been given twenty-one (21) days to consider this letter agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement. You agree that changes to this Agreement, whether material or immaterial, do not restart the 21 day consideration period. You understand that you may revoke this letter agreement for a period of seven (7) days after you sign this letter agreement by notifying me in writing, and the letter agreement shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this letter agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

Applicable Law – This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.

Entire Agreement – This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to benefits provided to you, your repayment obligation and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements, and commitments in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede your obligations set forth in paragraph 4 above.

Tax Acknowledgement – In connection with the benefits provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such benefits under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the consideration set forth in paragraphs 1 and 2 of this letter agreement.

If you have any questions about the matters covered in this letter agreement, please contact me.

Very truly yours,

By: /s/ Marc Rubin
Marc Rubin, M.D.
Chair, Compensation Committee

Date: September 2, 2016

I hereby agree to the terms and conditions set forth above. I intend that this letter agreement become a binding agreement between me and the Company.

/s/ Daniel R. Passeri	August 30, 2016
Daniel R. Passeri	Date

To be signed in a timely manner as set forth in paragraph 15 of this letter agreement.

Exhibit 10.2

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

FIRST AMENDMENT TO
COLLABORATION, LICENSE AND OPTION AGREEMENT

THIS FIRST AMENDMENT TO COLLABORATION, LICENSE AND OPTION AGREEMENT (the ***"Amendment"***) is entered into as of September 7, 2016 (the ***"Amendment Date"***), by and between **AURIGENE DISCOVERY TECHNOLOGIES LIMITED** , a company organized under the laws of India, having an address of 39-40, KIADB Industrial Area, Phase II, Electronic City Hosur Road, Bangalore - 560100 Karnataka, India (***"Aurigene"***), and **CURIS, INC.** , a corporation organized under the laws of Delaware, USA, having an address of 4 Maguire Road, Lexington, Massachusetts 02421-3112, USA (***"Curis"***).

RECITALS

WHEREAS, Aurigene and Curis are parties to that certain Collaboration, License and Option Agreement dated January 18, 2015, as amended by that certain letter agreement dated November 4, 2015 (the ***"Agreement"***);

WHEREAS, concurrently with the execution of this Amendment, and subject to the terms and conditions of a Stock Purchase Agreement dated as of the Amendment Date (the ***"Second Stock Purchase Agreement"***), Curis is issuing the "Initial Shares" (as such term is defined in the Second Stock Purchase Agreement) to Aurigene; and

WHEREAS, the Parties now wish to amend the Agreement to, among other things: (i) provide for the issuance to Aurigene of additional shares of common stock of Curis; (ii) provide for the waiver by Aurigene of certain milestone and other payments under the Agreement; (iii) modify the conditions under which the option to extend the exclusivity of the Parties' collaboration for the Additional Exclusivity Periods may be exercised; (iv) agree upon additional terms applicable to selection of the Program Target Profile for PTP4; and (v) if Curis exercises the Option for PTP3 and/or PTP4, provide for the funding of additional research, development and/or manufacturing funding for the Licensed Programs for PTP3 and/or PTP4; in each case, on the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Aurigene and Curis agree as follows:

1. Defined Terms. Capitalized terms used but not otherwise defined in this Amendment shall have the meanings provided in the Agreement, except that the terms "Initial Shares" and "Top-Up Shares" shall have the respective meanings provided in the Second Stock Purchase Agreement.

2. Issuance of Curis Common Stock. On the Amendment Date, and subject to the terms and conditions set forth in the Second Stock Purchase Agreement, Curis shall issue to Aurigene the Initial Shares. For the avoidance of doubt, the Parties hereby agree that, for purposes of Section 6.6(d) of the Agreement, the Initial Shares and any Top-up Shares purchased by Aurigene (in each case, as adjusted for stock splits, stock dividends, combinations, recapitalizations, redemptions, reverse stock splits, share buybacks and the like) shall be excluded from both the numerator and the denominator of the fraction described in the definition of Current POI. Section 7.3(b) of the Agreement shall apply with respect to the issuance of the Initial Shares and any Top-Up Shares as if such section was set forth in full in this Amendment.

3. Payment Waivers. As of the Amendment Date, and subject to the consummation of the issuance of the Initial Shares to Aurigene in accordance with the Second Stock Purchase Agreement, Aurigene hereby waives payment of the following amounts under the Agreement totaling $24,500,000 (the ***"Aggregate Waiver Amount"***):

(a) the first 12-month period of Extended Exclusivity Fees under Section 6.2(b) for each of Licensed Program 1 and Licensed Program 2 to the extent Curis elects to extend the exclusivity of the Parties' collaboration contemplated by Sections 4.7(b) and 4.8(b) of the Agreement;

(b) the R&D Program selection milestone payment for PTP4 under Section 6.3 of the Agreement;

(c) 50% of the Option exercise fee for Licensed Program 3 (but only if Licensed Program 3 is either PTP3 or PTP4) under Section 6.5(a) of the Agreement;

(d) the Option exercise fee for Licensed Program 4 (but only if Licensed Program 4 is either PTP3 or PTP4) under Section 6.5(a) of the Agreement; or

(e) the Acceptance for Filing of first IND milestone payment under Section 6.6(a) of the Agreement, but only with respect to Licensed Program 1 (the IRAK4 program);

(f) the Initiation of first Phase 1 Trial milestone payment under Section 6.6(a) of the Agreement, but only with respect to Licensed Program 1 (the IRAK4 program) and Licensed Program 2 (the PD-1/VISTA program); and

(g) the Acceptance for Filing of first IND milestone payment under Section 6.6(b) of the Agreement, but only with respect to PTP3 (the PD-1/Tim3 program) and PTP4 (*i.e.,* to the extent PTP3 or PTP4 constitutes Licensed Program 3 or Licensed Program 4 (in either order)).

To the extent any of the milestone or other payments set forth in paragraphs 3(a) through 3(g) above in this Amendment would not otherwise be payable by Curis, *e.g.* in the event one or more of the listed milestone events do not occur (the aggregate amount of such non-payable payment(s), collectively, the ***"Unused Waiver Amount"***), Curis shall have the right to deduct the Unused Waiver Amount from any one or more of the milestone payment obligations under Sections 6.6(a), 6.6(b) or 6.6(c) of the Agreement for the following milestone events until the Unused Waiver Amount has been fully utilized: (i) "First time cumulative Net Sales of a Product throughout the Curis Territory equal or exceed $[**]"; and (ii) "First time cumulative Net Sales of a Product throughout the Curis Territory equal or exceed $[**]".

4. Collaboration Exclusivity.

(a) First Additional Exclusivity Period. Curis and Aurigene hereby agree that if Curis elects to extend the exclusivity of the Parties' collaboration contemplated by Section 4.7(a) (***"Collaboration Exclusivity"***) for the first Additional Exclusivity Period, then notwithstanding Section 4.8(a) or Section 6.2(a) of the Agreement or any other provision of the Agreement to the contrary, the Exclusivity Option Fee for the first Additional Exclusivity Period under Section 6.2(a)(i) of the Agreement shall be payable on the following schedule:

(i) 50% of such Exclusivity Option Fee (*i.e.* , $3,750,000) shall be payable no later than the expiration of the Initial Exclusivity Period. The payment of this amount shall result in a first Additional Exclusivity Period extending to September 30, 2017; and

(ii) the remaining 50% of such Exclusivity Option Fee (*i.e.* , $3,750,000) shall be payable on or before the earlier of (x) September 30, 2017, and (y) 10 days after the closing of the Next Curis Financing. For purposes hereof, ***"Next Curis Financing"*** shall mean a financing or series of related financings (including without limitation in which Curis receives consideration in stages or at multiple closings or in separate stand-alone financings that occur that contain substantially similar terms) entered into by Curis primarily for financing/capital raising purposes, in which the Company issues and sells shares of its Common Stock or Preferred Stock or any securities conferring the right to purchase, or exercisable or exchangeable for (with or without additional consideration), its Common Stock or Preferred Stock, to any third party, whether in an underwritten public offering or otherwise. Payment of the remaining 50% of such Exclusivity Option Fee shall result in continuation of the first Additional Exclusivity Period for its full 12-month duration.

(b) Additional Exclusivity Periods. Notwithstanding the provisions of Sections 4.8(a) and 6.2(a) of the Agreement to the contrary, and subject to the provisions of Section 14.5 of the Agreement, in the event of a Change in Control (as defined below) of Curis during the Exclusivity Period, then, following such Change in Control, the extension of Collaboration Exclusivity for any Additional Exclusivity Period shall be subject to the mutual written agreement of Aurigene and Curis (or its successor); *provided, however,* that if, prior to the consummation of such Change in Control:

(i) Curis paid the initial installment of the Exclusivity Option Fee for the first Additional Exclusivity Period as specified in paragraph 4(a)(i) of this Amendment, then the first Additional Exclusivity Period shall continue in full force and effect following consummation of such Change in Control until September 30, 2017 (*i.e.* , without any requirement that Aurigene and Curis (or its successor) reach mutual written agreement with respect to such period); and

(ii) Curis paid both the first and second installments of the Exclusivity Option Fee for the first Additional Exclusivity Period as specified in paragraphs 4(a)(i) and 4(a)(ii), respectively, of this Amendment, then the first Additional Exclusivity Period shall continue in full force and effect following consummation of such Change in Control until expiration of the full 12-month first Additional Exclusivity Period (*i.e.* , without any requirement that Aurigene and Curis (or its successor) reach mutual written agreement with respect to such period); and

(iii) Curis elected to extend Collaboration Exclusivity for any subsequent Additional Exclusivity Period and paid the corresponding Exclusivity Option Fee to Aurigene as specified in Section 6.2(a), then such Additional Exclusivity Period shall continue in full force and effect in accordance with the terms of the Agreement following consummation of such Change in Control (*i.e.* , without any requirement that Aurigene and Curis (or its successor) reach mutual written agreement with respect to such Additional Exclusivity Period).

(iv) For purposes of this paragraph 4(b), a ***"Change in Control"*** of Curis shall be deemed to have occurred upon the happening of any of the following events:

(1) any "person" or "group" within the meaning of Section 13(d) or Section 14(d)(2) of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***), becomes, is discovered to be, or files a report on Schedule 13D or 14D-1 (or any successor schedule, form or report) disclosing that such person is, a beneficial owner (as defined in Rule 13d-3 under the Exchange Act or any successor rule or regulation) of securities of Curis representing more than 50% of the total voting power of the Curis' then outstanding shares; *but excluding* any such acquisition of securities by (w) Aurigene or any of its Affiliates, (x) any employee benefit plan or related trust sponsored or maintained by Curis, (y) any "person" or "group" that acquires such securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for Curis through the issuance of equity securities, or (z) any financial investor that acquires such securities through purchases on the open market;

(2) individuals who are members of the Board of Directors of Curis as of the Amendment Date (the ***"Incumbent Board"***) cease for any reason to constitute at least a majority of the Board of Directors of Curis; *provided, however,* that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this paragraph 4(b), be considered a member of the Incumbent Board;

(3) Curis is merged, consolidated or reorganized into or with a Third Party or securities of Curis are exchanged for securities of a Third Party, unless the stockholders of Curis immediately prior to such merger, consolidation, reorganization or exchange continue to hold at least a majority of the combined voting power of the surviving entity (or, if the surviving entity is a wholly-owned subsidiary, its parent) immediately after such consolidation, merger, reorganization or exchange; or

(4) a Sale Transaction with respect to Curis.

5. PTP4 Selection. Curis agrees to select PTP4 on or before expiration of the Initial Exclusivity Period. For clarity, (a) the Parties hereby agree that the Program Target Profile for PTP4 shall be within the Immuno-oncology area, (b) Curis' selection of PTP4 shall be in accordance with the processes set forth in Section 3.1(b)(i) or Section 3.1(b)(ii) of the Agreement, as applicable, and (c) nothing in this paragraph 5 shall limit Aurigene's obligations or Curis' rights under Section 3.1(c) of the Agreement or modify the exclusivity provisions set forth in the Agreement, including Sections 4.7, 4.8, 4.9 and 4.10.

6. PTP3 and PTP4 Research Funding.

(a) PTP3. Subject to, and only after, the closing of the Next Curis Financing, and subject to Curis' exercise (if any) of the Option for PTP3, Curis shall pay up to an aggregate of $2,000,000 for Supplemental PTP3 Activities (defined below), if performed by or on behalf of Aurigene. For clarity, Curis shall not be obligated to pay any amounts under this paragraph 6(a) unless and until the later of (x) the closing of the Next Curis Financing and (y) the date such Supplemental PTP3 Activities are actually performed and Aurigene has delivered to Curis an invoice for such Supplemental PTP3 Activities. ***"Supplemental PTP3 Activities"*** shall mean specific research, development and/or manufacturing activities with respect to Program Compounds within the Licensed Program for PTP3 to be recommended by the SOC, and subject to (i) each Party's final approval of the aspects of such activities that are within such Party's final decision-making authority pursuant to Sections 2.6(a) and 2.6(b) of the Agreement and (ii) the execution by the Parties of a written supplemental development plan, including a budget of costs for each such activity, on mutually acceptable terms. Notwithstanding the foregoing, subject to Curis' payment when due of the milestone payment for Acceptance for Filing of the first IND for a Product from the Licensed Program for PTP3, the Supplemental PTP3 Activities specifically exclude Aurigene's Development Plan responsibilities and Phase 1 Trial supply obligations under Section 5.6 of the Agreement for such Licensed Program, the expenses of which are Aurigene's sole responsibility under Section 5.4(b) of the Agreement.

(b) PTP4. Subject to, and only after, the closing of the Next Curis Financing, and subject to Curis' exercise (if any) of the Option for PTP4, Curis shall pay up to an aggregate of $2,000,000 for Supplemental PTP4 Activities (defined below), if performed by or on behalf of Aurigene. For clarity, Curis shall not be obligated to pay any amounts under this paragraph 6(b) unless and until the later of (x) the closing of the Next Curis Financing and (y) the date such Supplemental PTP4 Activities are actually performed and Aurigene has delivered to Curis an invoice for such Supplemental PTP3 Activities. ***"Supplemental PTP4 Activities"*** shall mean specific research, development and/or manufacturing activities with respect to Program Compounds within the Licensed Program for PTP4 to be recommended by the SOC, and subject to (i) each Party's final approval of the aspects of such activities that are within such Party's final decision-making authority pursuant to Sections 2.6(a) and 2.6(b) of the Agreement and (ii) the execution by the Parties of a written supplemental development plan, including a budget of costs for each such activity, on mutually acceptable terms. Notwithstanding the foregoing, subject to Curis' payment when due of the milestone payment for Acceptance for Filing of the first IND for a Product from the Licensed Program for PTP4, the Supplemental PTP4 Activities specifically exclude Aurigene's Development Plan responsibilities and Phase 1 Trial supply obligations under Section 5.6 of the Agreement for such Licensed Program, the expenses of which are Aurigene's sole responsibility under Section 5.4(b) of the Agreement.

7. Corrections.

(a) Correction to Section 1.5. In Section 1.5 of the Agreement, the reference to "Section 3.1(a)" is hereby corrected to read "Section 3.1(b)(i)(2)."

(b) Correction to Section 2.6(b). In Section 2.6(b) of the Agreement, the reference to "Potential PTP" is hereby corrected to read "Proposed PTP."

(c) Correction to Sections 3.3(a) and 3.5(b). In Sections 3.3(a) and 3.5(b) of the Agreement, the phrase "Lead Candidate selection" is hereby corrected to read "Program selection."

(d) Correction to Section 5.4(b). In Section 5.4(b) of the Agreement, the phrases "subject to Section 5.5" and "under Section 5.5" are hereby corrected to read "subject to Section 5.6" and "under Section 5.6," respectively.

8. Effectiveness of Agreement. Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

9. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Amendment may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

10. Miscellaneous. For clarity, Section 8.5(b) and Articles 13 and 14 of the Agreement shall apply with respect to this Amendment.

[*Signature page follows.*]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Amendment as of the Amendment Date.

Aurigene Discovery Technologies Limited	**Curis, Inc.**
By: /s/ CSN Murthy	By: /s/ Ali Fattaey
Name: CSN Murthy	Name: Ali Fattaey
Title: Chief Executive Officer	Title: President

Exhibit 10.3

COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (this "Agreement"), dated as of September 7, 2016 (the "Effective Date") is between Curis, Inc., a Delaware corporation (the "Company"), and Aurigene Discovery Technologies Limited, a company organized under the laws of India (the "Purchaser"). Capitalized terms set forth herein and not defined shall have the meanings ascribed to such terms under the License Agreement (as defined below).

BACKGROUND

WHEREAS, the Company and the Purchaser are parties to that certain Collaboration, License and Option Agreement, dated as of January 18, 2015 (the "License Agreement"), which contains terms and conditions under which the Company and the Purchaser have agreed to enter into a relationship for the research, discovery and development of human therapeutics;

WHEREAS, in consideration for the terms of the First Amendment to the License Agreement by and between the Company and the Purchaser of even date herewith (the "License Agreement Amendment"), the Company has agreed to issue to the Purchaser shares of the Company's Common Stock, $0.01 par value per share ("Common Stock") on the terms and subject to the conditions set forth herein.

NOW THEREFORE, In consideration of the mutual promises hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereby agree as follows:

1. Issuance of the Initial Shares.

(a) In consideration of the Purchaser entering into the License Agreement Amendment, the Company agrees to issue to the Purchaser on the Initial Closing Date (as defined below) 10,208,333 shares (the "Initial Shares" and with the Top-up Shares (as defined below), the "Shares") of Common Stock.

(b) At the closing of the sale of the Initial Shares contemplated hereby ("Initial Closing"), which shall be held on the date hereof or such other date within three (3) business days of the date of this Agreement as shall be mutually agreed upon by the Company and the Purchaser remotely by facsimile transmission or other electronic means or at such location as the parties may mutually agree (the "Initial Closing Date"), (i) the Purchaser and the Company shall execute and deliver to each other the Registration Rights Agreement (the "Registration Rights Agreement") in the form of Exhibit A attached hereto and the License Agreement Amendment in the form of Exhibit B attached hereto, and (ii) the Company shall instruct the transfer agent for the Common Stock to issue and deliver to the Purchaser an original stock certificate representing the Initial Shares.

2. Additional Share Purchase Rights.

(a) Subject to Subsection 2(b) below, the first time following the Initial Closing Date that the Company proposes to offer shares of its Common Stock in an underwritten public offering (a "Subsequent Offering"), the Company shall, as soon as practicable after a determination is made by the Company to undertake such public offering (and in any event before filing a preliminary prospectus supplement with the Securities and Exchange Commission), give Purchaser written notice in accordance with Section 8 (the "Company Top-Up Notice") of such Subsequent Offering. Following receipt of the Company Top-Up Notice, Purchaser may, by written notice delivered by electronic mail to the Company's Chief Executive Officer and Chief Financial Officer at any time prior to the Pricing Time (as defined below), elect to purchase from the Company (the "Top-up Purchase"), by means of a private placement, all or a portion of such number of shares of Common Stock (the "Top-Up Shares") which, following such Top-up Purchase and the Subsequent Offering, would equal a number of shares of Common Stock that is no greater than the lesser of (i) 19.56% of the shares of Common Stock outstanding after such Top-up Purchase and the Subsequent Offering or (ii) such percentage of shares of Common Stock of the Company that is equal to the difference between 19.56% and the percentage of shares of Common Stock sold, transferred, or otherwise disposed of by Purchaser to a Person other than a Permitted Transferee on or after the Effective Date and prior to the date of such Top-up Purchase. For purposes of this Agreement, a "Permitted Transferee" shall mean any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with the Purchaser. The percentage amount derived by application of the foregoing sentence shall be referred to herein as the "Applicable Percentage," and the foregoing right to purchase the Top-up Shares in order to retain the Applicable Percentage is referred to herein as the " Top-Up Right "). The Applicable Percentage shall be subject to appropriate and equitable adjustment for any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization. If Purchaser chooses to purchase less than the maximum number of Top-Up Shares at the Subsequent Closing, it shall specify in the notice to Company which ownership percentage less than the Applicable Percentage it intends to achieve after giving effect to the purchase and Subsequent Offering. The Purchaser's exercise of its Top-up Right may be made contingent upon the closing of the applicable Subsequent Offering within a specified period of time.

(b) Notwithstanding the foregoing Subsection 2(a), (i) if the Subsequent Offering results in gross proceeds to the Company that are less than $50.0 million (with $50.0 million being defined as the "Requisite Proceeds"), then the Purchaser's Top-up Right shall continue to apply to one or more additional Subsequent Offerings until such Requisite Proceeds are received by the Company, and (ii) if a Subsequent Offering results in proceeds to the Company that exceed the Requisite Proceeds, the Top-up Right shall apply only with reference to the sale of Common Stock that results in the Requisite Proceeds, and not with reference to any sale of additional shares of Common Stock that are sold as part of the Subsequent Offering.

(c) The Company Top-up Notice shall state: (i) the Company's bona fide intention to undertake the Subsequent Offering, (ii) the estimated number of shares of Common Stock to be offered in the Subsequent Offering, if known, (iii) the expected price and terms and conditions, if any, upon which it proposes to offer its Common Stock in the Subsequent Offering, if then known and (iv) the planned date and time at which the Company expects to enter into an underwriting agreement with the underwriters for the Subsequent Offering (the " Pricing Time "), if then known. If any of the estimated number of shares of Common Stock to be offered in the Subsequent Offering, the expected price upon which the Company proposes to offer its Common Stock in the Subsequent Offering or the Pricing Time are not known at the time the Top-up Notice is delivered, then the Company shall promptly amend such Top-up Notice with such additional terms once known.

(d) Following delivery of the Company Top-Up Notice, the Company shall provide Purchaser reasonable access to enable Purchaser to conduct diligence materially equivalent to that provided to any other person that is contemplating participating in the applicable Subsequent Offering (inclusive of such person's representatives).

(e) Notwithstanding anything herein to the contrary, if Purchaser elects to exercise the Top-Up Right, then (i) the Purchaser shall have the right to purchase the same securities, and (ii) the purchase price per Top-Up Share will be the amount that is equal to the public offering price per share at which the Common Stock is sold to the public in the Subsequent Offering (the " Subsequent Offering Price " and such time, the " Top-Up Closing Date "), as, in each case, is set forth on the cover of the final prospectus filed with the Commission.

(f) Upon any closing of the purchase of Top-Up Shares (each, a " Subsequent Closing " and with the Initial Closing, the " Closing "), Purchaser shall pay to the Company the cash purchase price for the applicable Top-Up Shares, calculated by multiplying such number of Top-Up Shares by the Subsequent Offering Price, by wire transfer of immediately available funds, and the Company shall instruct the transfer agent for the Common Stock to issue and deliver to the Purchaser an original stock certificate representing the Top-Up Shares.

(g) Each Subsequent Closing shall take place remotely by facsimile transmission or other electronic means or at such location as the parties may mutually agree, within thirty (30) calendar days after the date on which all conditions to such Subsequent Closing, as set forth in Section 5, shall been satisfied or waived (other than those conditions that by their terms are to be satisfied at the Subsequent Closing, but subject to the satisfaction or waiver of such conditions).

3. Representations and Warranties of the Company . Except as set forth in any schedules delivered herewith (the " Disclosure Schedules "), which Disclosure Schedules shall be deemed a part hereof and shall qualify

any representation made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules the Company represents and warrants to the Purchaser as of the date of this Agreement and as of the Closing:

(a) Organization and Good Standing . The Company has been duly incorporated and organized, and is validly existing in good standing, under the laws of the State of Delaware. The Company is duly qualified to transact business and is in good standing in the Commonwealth of Massachusetts and in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its business makes such qualification or licensing necessary, except where the failure to be so qualified or licensed has not had and would not reasonably be expected to have a material adverse effect on the ability of the Company to consummate the transactions contemplated hereby. The Company has the corporate power and authority to enter into and perform this Agreement and the Registration Rights Agreement (collectively, the " Agreements "), to own and operate its properties and assets and to carry on its business as currently conducted and as presently proposed to be conducted.

(b) Authorization and Binding Nature . The execution, delivery and performance by the Company of the Agreements and the issuance and delivery of the Initial Shares has been, and the issuance of any Top-up Shares will be, duly authorized by all requisite corporate action on the part of the Company. The Agreements constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except as enforceability may be limited by securities laws, bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights of creditors generally and by equitable principles, including those limiting the availability of specific performance, injunctive relief and other equitable remedies and those providing for equitable defenses.

(c) Non-Contravention . The execution, delivery and performance by the Company of the Agreements will not, with or without the giving of notice or the passage of time or both, (i) violate or conflict with the provisions of the certificate of incorporation or bylaws of the Company, (ii) violate or conflict with any judgment, decree, order or award of any court, governmental body or arbitrator applicable to the Company or (iii) violate, conflict with or cause a default under any mortgage, indenture, lease, contract or other agreement or instrument, permit, or license to which the Company is subject except, in the case of this clause (iii), any violation, conflict or default that would not reasonably be expected to have a material adverse effect on the Company's business, properties, financial position or results of operations (a " Material Adverse Effect ").

(d) Governmental Consents . No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required on the part of the Company in order to enable the Company to execute, deliver and perform its obligations under this Agreements, except for such qualifications or filings under applicable securities laws as may be required in connection with the transactions contemplated by this Agreement. All such qualifications and filings, insofar as they relate to the issuance of the Initial Shares or the Top-Up Shares at the applicable Closing, will, in the case of qualifications, be effective on such Closing and will, in the case of filings, be made within the time prescribed by law.

(e) Capitalization. The authorized capital stock of the Company consists of (i) 225,000,000 shares of Common Stock, of which, as of September 3, 2016, 130,705,427 shares were issued and 129,482,581 shares were outstanding, and (ii) 5,000,000 shares of Preferred Stock, $0.01 par value per share, of which no shares are issued or outstanding. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and nonassessable. When issued, sold and delivered in accordance with the provisions of this Agreement, the Shares will be duly authorized, validly issued, fully paid and nonassessable, and will be free of restrictions on transfer other than restrictions under this Agreement, the Registration Rights Agreement and applicable state and federal securities laws.

(f) SEC Reports. The Company has timely filed all reports, schedules and other documents required to be filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended (the " Exchange Act "). The Purchaser has had access, via the website of the Securities and Exchange Commission (" SEC "), to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and all reports filed by the Company under Section 13 of the Exchange Act with the SEC since December 31, 2015 (the " Reports "). The Reports complied in all material respects with the requirements of the Exchange Act, and the respective rules and regulations thereunder when filed. As of their respective dates, the Reports did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(g) Governmental Permits. The Company owns, possesses or has obtained all licenses, permits, certificates, consents, orders, approvals and other authorizations from, and has made all declarations and filings with, all federal, state, local and other governmental authorities (including foreign regulatory agencies), all self-regulatory organizations and all courts and other tribunals, domestic or foreign, necessary to operate its properties and to carry on its business as conducted as of the date hereof, except where the failure to own, possess, obtain or make would not, individually or in the aggregate, have a Material Adverse Effect. The Company has not received any actual notice of any proceeding relating to revocation or modification of any such license, permit, certificate, consent, order, approval or other authorization. To its knowledge, the Company is in compliance with all laws and regulations relating to the conduct of its business as conducted as of the date hereof, except where noncompliance would not reasonably be expected to have a Material Adverse Effect, and all of the descriptions in the Reports of the legal and governmental procedures and requirements of the United States Food and Drug Administration or any foreign, state or local governmental body exercising comparable authority are accurate in all material respects.

(h) Taxes. The Company has filed all material tax returns required to be filed, which returns are true and correct in all material respects, and the Company is not in default in the payment of any taxes, including penalties and interest, assessments, fees and other charges (" Tax Penalties ") shown thereon due or otherwise assessed other than those being contested in good faith and for which adequate reserves have been provided or those currently payable without which such Tax Penalties were payable pursuant to said returns or any assessments with respect thereto.

(i) Insurance. The Company maintains insurance of the type and in the amount that the Company reasonably believes is adequate for the business, including, but not limited to, liability insurance for clinical testing and insurance covering all real and personal property owned or leased by the Company against theft, damage, destruction, acts of vandalism and all other risks customarily insured against by similarly situated companies, all of which insurance is in full force and effect.

(j) Intellectual Property. The Company, to its knowledge, owns or is licensed to use all patents, patent applications, inventions, trademarks, trade names, applications for registration of trademarks, service marks, service mark applications, copyrights, know-how, manufacturing processes, formulae, trade secrets, licenses and rights in any thereof and any other intangible property and assets that are material to the business of the Company as now conducted and as, on the date hereof, proposed to be conducted (the " Proprietary Rights "), or is seeking, or will seek, to obtain rights to use such Proprietary Rights that are material to the business of the Company, on the date hereof, as proposed to be conducted. The Company does not have any knowledge of, and the Company has not given or received any notice of, any pending conflicts with or infringement of the rights of others with respect to any Proprietary Rights or with respect to any license of Proprietary Rights that are material to the business of the Company. No action, suit, arbitration, or legal, administrative or other proceeding, or investigation is pending, or, to the Company's knowledge, threatened, which involves any Proprietary Rights, nor, to the Company's knowledge, is there any reasonable basis therefor.

(k) Property. The Company has good and marketable title in fee simple to all items of real property and good and marketable title to all personal property owned by it, in each case free and clear of all liens, encumbrances and defects except such as are described or referred to in the Reports or such as do not materially affect the value of such property and do not interfere with the use made or proposed to be made of such property by the Company; and any real property and buildings held under lease by the Company are, to the knowledge of the Company, held under valid, existing and enforceable leases with such exceptions as are not material and do not interfere with the use made or proposed to be made of such property and buildings by the Company.

(l) Registration Rights. Except as described or referred to in the Reports, the Company is presently not under any obligation, and has not granted any rights, to register under the Securities Act of 1933, as amended (the " Securities Act ") any of its presently outstanding securities or any of its securities that may be subsequently issued.

(m) No Material Adverse Change. Since the filing of the Company's most recent Annual Report on Form 10-K, except as described or referred to in the Reports, there has not been any material adverse change in the assets, business, properties, financial condition or results of operations of the Company.

(n) Litigation. There is no action, suit or proceeding before or by any court or governmental agency or body, domestic or foreign, now pending, or, to the knowledge of the Company, threatened against or affecting the Company which, singly or in the aggregate, could reasonably be expected to have a Material Adverse Effect.

(o) Disclosure. To the Company's knowledge, neither this Agreement nor any certificates made or delivered in connection herewith, when read together, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements herein or therein, in light of the circumstances under which they were made, not misleading.

(p) Compliance with Laws. The Company is in material compliance with all applicable laws and, to the Company's knowledge, the Company is not under investigation with respect to, and has not been threatened to be charged with or given notice of, any material violation of any applicable laws.

4. Representations and Warranties of the Purchaser. The Purchaser represents and warrants to the Company that the statements contained in this Section 4 are true and correct as of the date of this Agreement and as of the Initial Closing and the Subsequent Closing.

(a) Investment. The Purchaser is acquiring the Initial Shares and any Top-up Shares for its own account for investment, not for resale to any other person and not with a view to or in connection with any resale or distribution. The Purchaser understands that the Initial Shares have not been, and the Top-up Shares, if applicable, will not be, registered under the securities laws of the United States or any other jurisdiction and cannot be transferred or resold except as permitted pursuant to a valid registration statement or an applicable exemption from registration. The Purchaser acknowledges that there can be no assurance that there will be any market for the Common Stock in the foreseeable future and that, as a result, the Purchaser must be prepared to bear the economic risk of its investment for an indefinite period of time.

(b) Foreign Purchaser . The Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Internal Revenue Code of 1986, as amended) and hereby represents that it has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including (a) the legal requirements within its jurisdiction for the receipt of the Shares, (b) any foreign exchange restrictions applicable to such purchase, (c) any governmental or other consents that may need to be obtained, and (d) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale, or transfer of the Shares. The Purchaser's continued beneficial ownership of the Shares will not violate any applicable securities or other laws of the Purchaser's jurisdiction as in effect on the date hereof.

(c) Regulation S Representations and Restrictions . The Purchaser makes the following additional representations, warranties and agreements:

(i) The Purchaser is not a "U.S. person" as defined in Rule 902(k) of Regulation S promulgated under the Securities Act (a " U.S. Person "). The offer and sale of the Initial Shares to the Purchaser was made in, and the offer and sale of the Top-up Shares, if applicable, will be made in an "Offshore Transaction" (as defined in Rule 902(h) of Regulation S), no "Directed Selling Efforts" (as defined in Rule 902(c) of Regulation S) were or will be made to the Purchaser in the United States, and the Purchaser is not acquiring the Shares for the account or benefit of any U.S. Person;

(ii) The Purchaser will resell the Shares only in accordance with the provisions of Regulation S, pursuant to registration under the Securities Act, or pursuant to an available exemption from registration; and the Purchaser shall not engage in hedging transactions with regard to such Shares unless in compliance with the Securities Act.

The Purchaser acknowledges and agrees that the Company shall not register any transfer or resale of the Shares not made (i) in accordance with the provisions of Regulation S, (ii) pursuant to registration under the Securities Act or (iii) or pursuant to an available exemption from registration. The Purchaser acknowledges and agrees that the certificates evidencing the Initial Shares and any Top-up Shares will bear the legend set forth below (in addition to any other legend required by applicable federal, state or foreign securities laws or provided in any other agreement with the Company:

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " ACT ") WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION. THE SHARES MAY NOT BE OFFERED FOR SALE OR SOLD EXCEPT IN ACCORDANCE WITH THE PROVISIONS OF REGULATION S OF THE ACT, PURSUANT TO REGISTRATION UNDER THE ACT, OR AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE ACT AND HEDGING TRANSACTIONS INVOLVING THESE SECURITIES MAY NOT BE CONDUCTED UNLESS IN COMPLIANCE WITH THE ACT.

(d) Authorization and Binding Nature. The execution, delivery and performance by the Purchaser of the Agreements have been duly authorized by all requisite corporate action on the part of the Purchaser. The Agreements constitute the valid and legally binding obligations of the Purchaser, enforceable against the Purchaser in accordance with their respective terms, except as enforceability may be limited by securities laws, bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights of creditors generally and by equitable principles, including those limiting the availability of specific performance, injunctive relief and other equitable remedies and those providing for equitable defenses.

(e) Non-Contravention. The execution, delivery and performance by the Purchaser of the Agreements will not, with or without the giving of notice or the passage of time or both, (i) violate or conflict with the provisions of the certificate of incorporation or bylaws of the Purchaser, (ii) violate or conflict with any judgment, decree, order or award of any court, governmental body or arbitrator applicable to the Purchaser or (iii) violate, conflict with or cause a default under any mortgage, indenture, lease, contract or other agreement or instrument, permit, or license to which the Purchaser is subject other than any violation, conflict or default which would not reasonably be expected to have a Material Adverse Effect.

(f) Access to Information. The Purchaser has substantial knowledge and experience in making investment decisions of this type and is capable of evaluating the merits and risks of its investment in the Company. The Company has made available to the Purchaser all documents and other information necessary for the Purchaser to evaluate the merits and risks of its investment in the Company. The Company has made available to the Purchaser all documents requested and has provided answers to all of its questions relating to an investment in the Company. In evaluating the suitability of an investment in the Company, the Purchaser has not relied upon any representations (whether oral or written) other than as set forth herein. The Purchaser has had an opportunity to discuss this investment with representatives of the Company and to ask questions of them. The Purchaser understands that an investment in the Company involves significant risks. The Purchaser is an "accredited investor," as defined in Rule 501 under the Securities Act.

(g) Ownership of Common Stock. Before giving effect to the issuance to the Purchaser of the Initial Shares, the Purchaser beneficially owns, directly or indirectly, 17,120,131 shares of Common Stock of the Company.

5. Conditions to Closing

(a) Conditions of the Purchaser's Obligation. The obligation of the Purchaser to consummate the transactions contemplated by this Agreement at the applicable Closing (unless otherwise indicated) is subject to the satisfaction of the following conditions, any one or more of which may be waived by the Purchaser:

(i) Documentation at Closing. The Purchaser shall have received prior to or at the Closing all of the following documents or instruments, or evidence of completion thereof, each in form and substance satisfactory to the Purchaser:

(a) (i) A copy of the certificate of incorporation of the Company, certified by the Secretary of State of the State of Delaware, (ii) (x) as of the Initial Closing Date, a copy of the resolutions of the Board of Directors of the Company evidencing the approval of this Agreement and the License Agreement Amendment, the issuance of the Shares, and the other matters contemplated hereby and (y) as of the Top-Up Closing Date, a copy of the resolutions of the Board of Directors of the Company evidencing the approval of the issuance of the Top-Up Shares and the other matters contemplated hereby, and (iii) a copy of the Bylaws of the Company, all of which shall have been certified by the Secretary of the Company to be true, complete and correct.

(b) A certificate of the Secretary of the Company which, at the Initial Closing shall certify the names of the officers of the Company authorized to sign this Agreement, and at each Closing, the certificate for the Initial Shares or Top-Up Shares, as applicable, and the other documents, instruments or certificates to be delivered pursuant to this Agreement by the Company or any of its officers.

(c) A certificate of the President and Chief Executive Officer of the Company stating that the conditions specified in Section 5(a)(ii) have been satisfied.

(d) Certificates of Good Standing for the Company from the Secretary of State of the State of Delaware and the Commonwealth of Massachusetts.

(ii) Representations and Warranties; Performance of Obligations. The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects (other than those representations that are qualified by materiality, which shall be true and correct in accordance with their terms) as of the date of the applicable Closing except for representations and warranties made as of a specific date, which shall be true and correct as of such date, and the Company shall have performed in all material respects all obligations and conditions herein required to be performed or observed by it on or prior to the applicable Closing.

(iii) Consents, Waivers, Etc. The Company shall have obtained all consents or waivers, if any, necessary to execute and deliver this Agreement, issue the Initial Shares and Top-Up Shares, as applicable, and to carry out the transactions contemplated hereby and thereby except for any which, if not obtained or effected would not have a Material Adverse Effect or a material adverse effect on the parties' ability to close the transaction contemplated by the Agreement. All corporate and other action and governmental filings necessary to effectuate the terms of this Agreement, the Initial Shares and Top-Up Shares, as applicable, and other agreements and instruments executed and delivered by the Company in connection herewith shall have been made or taken, except for any post-sale filing that may be required under federal or state securities laws except for any which, if not obtained or effected would not have a Material Adverse Effect or a material adverse effect on the parties' ability to close the transaction contemplated by the Agreement.

(iv) License Agreement Amendment . At the Initial Closing, the Purchaser and the Company shall have executed and delivered the License Agreement Amendment.

(v) Registration Rights Agreement. At the Initial Closing, Purchaser and the Company shall have executed and delivered the Registration Rights Agreement in the form attached as Exhibit A .

(b) Conditions of the Company's Obligation . The obligation of the Company to consummate the transactions contemplated by this Agreement at each Closing (unless otherwise indicated) is subject to the satisfaction of the following conditions:

(i) Representations and Warranties; Performance of Obligations. The representations and warranties made by the Purchaser in Section 4 hereof shall be true and correct in all material respects (other than those representations that are qualified by materiality, which shall be true and correct in accordance with their terms) as of the date of the applicable Closing except for representations and warranties made as of a specific date, which shall be true and correct as of such date, and the Purchaser shall have performed in all material respects all obligations and conditions herein required to be performed or observed by it on or prior to the applicable Closing.

(ii) License Agreement Amendment . At the Initial Closing, Purchaser and the Company shall have executed and delivered the License Agreement Amendment.

(iii) Registration Rights Agreement. At the Initial Closing, Purchaser and the Company shall have executed and delivered the Registration Rights Agreement in the form attached as Exhibit A .

6. Lock-Up Agreement . The Purchaser covenants and agrees that, except as specified in this Section 6, it will not, during the period beginning on the date hereof and ending on September 7, 2018, without the prior written consent of the Company, (a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, contract to dispose of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act and the rules and regulations of the SEC promulgated thereunder, with respect to any of the Initial Shares, (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such Initial Shares, in cash or otherwise, or (c) publicly announce an intention to effect any transaction specified in clause (a) or (b). Notwithstanding the foregoing, the Purchaser is permitted to take any of the actions described under Sections 6(a)-(c) with respect to (i) up to an aggregate of (A) 25% of the Initial Shares from and after March 7, 2017, (B) 50% of the Initial Shares from and after September 7, 2017, (C) 75% of the Initial Shares from and after March 7, 2018, and (ii) any or all of the Initial Shares after any public announcement with respect to the acquisition of the Company by a third

party or any change of control of the Company. For the sake of clarity, the lock-up restrictions set forth in this Section 6 shall no longer be applicable to the Initial Shares from and after September 7, 2018.

7. Restriction on Public Offering . The Company covenants and agrees that it will not, without Purchaser's prior written consent (such consent not to be unreasonably conditioned, delayed, or withheld), issue or sell any shares of its Common Stock or Preferred Stock or any securities conferring the right to purchase, or exercisable or exchangeable for (with or without additional consideration), its Common Stock or Preferred Stock, on or before December 31, 2016 at a price per share less than or equal to $2.40 (as adjusted for stock splits, combinations, recapitalizations and similar events); provided, that the foregoing shall not apply to the authorization or issuance by the Company of shares of Common Stock or options therefor to directors, officers, employees, consultants or advisors pursuant to any stock incentive or employee stock purchase plans, agreements or arrangements in consideration of services in transactions not intended for financing/capital raising purposes.

8. Notices . Any notices or other communications required or permitted hereunder shall be sufficiently given if delivered personally, via electronic mail, or via a reputable express courier, with charges prepaid, to the address set forth below or to such other address of which the parties may have given notice. Unless otherwise specified herein, such notices or other communications shall be deemed received one business day after personal delivery or electronic delivery, or three business days after being sent, if sent by reputable express courier.

If to the Company:

Curis, Inc.
4 Maguire Road
Lexington, Massachusetts 02421
Attention: President and Chief Executive Officer
Facsimile: (617) 503-6500

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 Word Trade Center
New York, NY 10007
Attn: Steven D. Singer, Esq.
Facsimile: (212) 230-8888

If to the Purchaser:

Aurigene Discovery Technologies Limited
39-40, KIADB Industrial Area
Phase II, Electronic City Hosur Road
Bangalore - 560100 Karnataka
India
Attn: CSN Murthy, Chief Executive Officer
Facsimile: (91) 80 2852 6285

9. Successors and Assigns . No party may assign its rights or obligations hereunder without the prior written consent of the other party. Subject to the foregoing, this Agreement shall be binding upon and inure to the

benefit of the parties hereto and their respective successors and assigns. Any assignment in contravention of this provision shall be void.

10. Survival of Warranties . The representations and warranties of the Company and the Purchaser contained in this Agreement shall survive the applicable Closing for a period of one year following such Closing, at which time they shall expire and have no further force or effect.

11. Entire Agreement . This Agreement represents the entire understanding and agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior oral and written and all contemporaneous oral negotiations, commitments and understandings between such parties. The parties may amend or modify this Agreement, in such manner as may be agreed upon, only by a written instrument executed by the parties hereto.

12. Expenses . Each party shall pay its own expenses in connection with this Agreement and the transactions contemplated hereby.

13. Governing Law . This Agreement shall be governed by and construed in accordance with the laws of the State of New York in the United States, without reference to conflict of laws principles, and the parties hereby consent to the jurisdiction of the courts of the State of New York.

14. Section Headings . The section headings are for the convenience of the parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the parties.

15. Severability . The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

16. Counterparts; Facsimile Signatures . This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. This Agreement may be executed by facsimile signatures.

17. Publicity and Nondisclosure . Any proposed announcement, press release or other public disclosure concerning this Agreement and/or any of the amendments, transactions or relationships contemplated hereby shall be subject to the terms of Section 8.5(a) of the License Agreement.

18. Listing of Shares. As required by the rules and regulations of any national securities exchange or automated quotation system, the Company agrees to use commercially reasonable efforts to promptly secure the listing of the Shares upon each national securities exchange or automated quotation system upon which shares of its Common Stock are listed and, so long as the Purchaser owns any of the Shares, shall use commercially reasonable efforts to maintain such listing of all the Shares.

IN WITNESS WHEREOF, this Agreement has been duly executed by the parties hereto on the date first above written.

CURIS, INC.

By: /S/ ALI FATTAEY

Ali Fattaey

President and Chief Executive Officer

AURIGENE DISCOVERY TECHNOLOGIES LIMITED

By: /S/ CSN MURTHY

CSN Murthy

Chief Executive Officer

[Signature Page to Common Stock Purchase Agreement]

Exhibit 10.4

REGISTRATION RIGHTS AGREEMENT

This REGISTRATION RIGHTS AGREEMENT (this " Agreement "), dated as of September 7, 2016, is entered into between Curis, Inc., a Delaware corporation (the " Company "), and Aurigene Discovery Technologies Limited, a company organized under the laws of India (the " Purchaser ").

BACKGROUND

WHEREAS, the Company has agreed to issue to the Purchaser 10,208,333 shares (the " Initial Shares ") of the Company's Common Stock, $0.01 par value per share (" Common Stock ") and has granted an option to purchase Top-Up Shares (as defined in the Purchase Agreement (defined below), and together with the Initial Shares, the " Shares "), each on the terms and subject to the conditions set forth in that certain Common Stock Purchase Agreement, dated as of September 7, 2016 (the " Purchase Agreement "), by and between the Company and the Purchaser, as consideration under that certain First Amendment to Collaboration, License and Option Agreement dated as of September 7, 2016; and

WHEREAS, the Company and the Purchaser desire to provide for certain arrangements with respect to the registration of the Registrable Securities (as defined below) under the Securities Act of 1933, as amended (the " Securities Act ").

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement, the parties hereto agree as follows:

1. Certain Defined Terms .

(a) " Person " means an individual, corporation, partnership, joint venture, limited liability company, governmental authority, unincorporated organization, trust, association or other entity.

(b) " Prospectus " means (i) the prospectus included in any Registration Statement contemplated by this Agreement, as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus, and (ii) any "free writing prospectus" as defined in Rule 405 promulgated under the Securities Act.

(c) " Registrable Securities " means (a) the Initial Shares, (b) the Top-Up Shares, if and at such time as such Top-Up Shares are issued to Purchaser pursuant to the terms of the Purchase Agreement, and (c) any shares of Common Stock issued or issuable with respect to the Shares by way of a stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization. As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (i) a Registration Statement covering such securities has been declared effective by the SEC and such securities have been disposed of pursuant to such effective Registration Statement, (ii) such securities are sold under circumstances in which all of the applicable conditions of Rule 144 promulgated under the Securities Act (or any similar provisions then in force) under the Securities Act are met, (iii) such securities are otherwise transferred and such securities may be resold without subsequent registration under the Securities Act, or (iv) such securities shall have ceased to be outstanding.

(d) " Registration Statement " means any registration statement of the Company which covers any of the Registrable Securities pursuant to the provisions of this Agreement, including the Prospectus, amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all materials incorporated by reference in such Registration Statement.

(e) " SEC " means the U.S. Securities and Exchange Commission.

2. Registration Statements .

(a) Resale Registration Statement . The Company, after each Closing Date (as such term is defined in the Purchase Agreement) and, in any event, on or prior to the ninetieth (90th) day following such Closing Date (and if such day falls on a Saturday, a Sunday or a national holiday, then the next business day thereafter) (the " Filing Deadline "), shall prepare and file with the SEC a Registration Statement on Form S-3 (or, if Form S-3 is not then available to the Company, on such form of Registration Statement as is then available to effect a registration for resale of all of the Registrable Securities on a continuous basis by means of a shelf registration), covering the resale of all of the Registrable Securities relating to the shares issued on such Closing Date (the " Resale Registration Statement "); provided, however, that if the Filing Deadline shall fall during a period that the Company may not file a registration statement under the Securities Act until such time as it files with the SEC its updated financial statements, then the Filing Deadline shall be no later than twenty (20) days after the filing date of such updated financial statements with the SEC. Subject to Section 4(c), the registration of the Resale Registration Statement pursuant to this Section 2(a) shall be effected by means of a shelf registration on a delayed or continuous basis in accordance with the provisions of Rule 415 promulgated under the Securities Act (" Rule 415 ").

(b) Demand Registration .

(i) At any time after six (6) months after the date of issuance of the Initial Shares or Top-up Shares, as applicable, the Purchaser may request registration under the Securities Act of all or any portion of its Registrable Securities on a Form S-3 registration statement (or any successor to such form) (or, if Form S-3 is not then available, on such form of registration statement as is then available to effect a registration of the Registrable Securities pursuant to this subsection (b)(i)) (each a " Demand Registration "), provided that , for the sake of clarity, the Company shall not be required to effect a Demand Registration with respect to any Registrable Securities that are then subject to the lock-up agreement set forth in Section 6 of the Purchase Agreement (the " Lock-up Agreement "). Each request for a Demand Registration shall specify the approximate number of Registrable Securities required to be registered. Upon receipt of a Demand Registration request, the Company shall cause a Form S-3 registration statement (or any successor to such form) (or, if Form S-3 is not then available, on such form of registration statement as is then available to effect a registration of the Registrable Securities pursuant to this subsection (b)(1)) to be filed within forty-five (45) days after the date on which such request was received by the Company. The Company shall not be required to effect a Demand Registration more than two (2) times for the Purchaser; provided, however, that a Registration Statement shall not count as a Demand Registration requested under this Section 2(b)(i) unless and until it has become effective and the Purchaser is able to register and sell at least seventy-five percent (75%) of the Registrable Securities requested to be included in such registration.

(ii) If the Purchaser requests a Demand Registration and elects to distribute the Registrable Securities covered by its request in an underwritten offering, the Purchaser shall so advise the Company as a part of its request made pursuant to Section 2(b)(i). The Company shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with such offering; provided, however, that such selection shall be subject to the consent of the Purchaser, which consent shall not be unreasonably withheld, delayed or conditioned.

(iii) The Company shall not include in any Demand Registration any securities which are not Registrable Securities without the prior written consent of the Purchaser, which consent shall not be unreasonably withheld, delayed or conditioned. If a Demand Registration involves an underwritten offering and the managing underwriter of the requested Demand Registration advises the Company and the Purchaser in writing that, in its opinion, the number of shares of Common Stock proposed to be included in the Demand Registration, including all Registrable Securities and all other shares of Common Stock proposed to be included in such underwritten offering, exceeds the number of shares of Common Stock which can be sold in such underwritten offering and/or the number of shares of Common Stock proposed to be included in such registration would adversely affect the price per share of the Registrable Securities proposed to be sold in such underwritten offering, the Company shall include in such Demand Registration (A) first, the number of shares of Common Stock that the Purchaser proposes to sell, and (B) second, the number of shares of Common Stock proposed to be included therein by any other Persons (including shares of Common Stock to be sold for the account of the Company and/or other holders of Common Stock) allocated among such Persons in such manner as they may agree. If the managing underwriter determines that less than all of the Registrable Securities proposed to be sold by the Purchaser can be included in such offering, then the Registrable Securities of the Purchaser to be included in such underwritten offer shall equal the number of securities which the Purchaser is advised by the managing underwriter can be sold in such offering.

3. Piggyback Registration .

(a) Whenever the Company proposes to register any shares of its Common Stock under the Securities Act (other than a registration effected solely to implement an employee benefit plan or a transaction to which Rule 145 is applicable, or a registration statement on Form S-4, S-8 or any successor form thereto or another form not available for registering the Registrable Securities for sale to the public), whether for its own account or for the account of one or more stockholders of the Company, and the form of Registration Statement to be used may be used for the registration of Registrable Securities (each a " Piggyback Registration "), the Company shall give prompt written notice (in any event no later than thirty (30) days prior to the filing of such Registration Statement) to the Purchaser of its intention to effect such a registration and, subject to Section 3(b) and Section 3(c), shall include in such registration all Registrable Securities with respect to which the Company has received, within fifteen (15) days after the Company's notice has been given to the Purchaser, a written request from the Purchaser for inclusion; provided that , for the sake of clarity in no event shall the Company be required to include Registrable Securities in such Piggyback Registration to the extent that such Registrable Securities are then subject to the Lock-up Agreement. A Piggyback Registration shall not be considered a Demand Registration for purposes of Section 2(b) of this Agreement.

(b) If a Piggyback Registration is initiated as a primary underwritten offering on behalf of the Company and the managing underwriter advises the Company and the Purchaser (if the Purchaser has elected to include Registrable Securities in such Piggyback Registration) in writing that in its opinion the number of shares of Common Stock proposed to be included in such registration, including all Registrable Securities and all other shares of Common Stock proposed to be included in such underwritten offering, exceeds the number of shares of Common Stock which can be sold in such offering and/or that the number of shares of Common Stock proposed to be included in any such registration would adversely affect the price per share of the Common Stock to be sold in such offering, and/or any other marketing or other factors dictate that a limitation be imposed with respect to the number of shares of Common Stock proposed to be included in such registration, the Company shall include in such registration (i) first, the number of shares of Common Stock that the Company proposes to sell; (ii) second, the number of shares of Common Stock requested to be included therein by the Purchaser; and (iii) third, the number of shares of Common Stock requested to be included therein by holders of Common Stock (other than the Purchaser), allocated among such holders in such manner as they may agree.

(c) If a Piggyback Registration is initiated as an underwritten offering on behalf of a holder of Common Stock other than the Purchaser, and the managing underwriter advises the Company in writing that in its opinion the number of shares of Common Stock proposed to be included in such registration, including all Registrable Securities and all other shares of Common Stock proposed to be included in such underwritten offering, exceeds the number of shares of Common Stock which can be sold in such offering and/or that the number of shares of Common Stock proposed to be included in any such registration would adversely affect the price per share of the Common Stock to be sold in such offering, and/or any other marketing or other factors dictate that a limitation be imposed with respect to the number of shares of Common Stock proposed to be included in such registration, the Company shall include in such registration (i) first, the number of shares of Common Stock requested to be included therein by the holder(s) requesting such registration and by the Purchaser, allocated pro rata among such holders on the basis of the number of shares of Common Stock (on a fully diluted, as converted basis) and the number of Registrable Securities, as applicable, owned by all such holders or in such manner as they may otherwise agree; and (ii) second, the number of shares of Common Stock requested to be included therein by other holders of Common Stock, allocated among such holders in such manner as they may agree.

(d) The Company shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with any offering relating to any Piggyback Registration.

4. Requirements of the Company.

(a) In connection with the filing by the Company of any Registration Statement, the Company shall furnish to the Purchaser (i) a copy of the Prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and (ii) such other documents as the Purchaser may reasonably request, in order to facilitate the public sale or other disposition of the Registrable Securities.

(b) The Company shall use its reasonable best efforts to cause each Registration Statement contemplated by this Agreement to be declared effective or become effective as soon as practicable following the filing thereof with the SEC. The Company shall notify the Purchaser in writing after any Registration Statement is declared effective.

(c) If at any time the SEC takes the position that the offering of some or all of the Registrable Securities in a Registration Statement is not eligible to be made on a delayed or continuous basis under Rule 415, or requires the Purchaser to be named as an "underwriter" in such Registration Statement, if the Company believes, upon its reasonable determination and upon the advice of counsel, that the Registrable Securities are eligible for registration under Rule 415 or that the Purchaser is not an "underwriter" for the purposes of the Securities Act and the registration, as applicable, then the Company shall use its reasonable best efforts to persuade the SEC that the offering contemplated by the Registration Statement is a valid secondary offering and not an offering by or on behalf of the Company (*i.e.* , the issuer) for the purposes of Rule 415, and/or that the Purchaser is not an "underwriter," as applicable, in which event the Purchaser shall provide to the Company, in writing, all information reasonably requested by the Company to support the Purchaser's contention that it is not an "underwriter." The Purchaser shall have the right to participate or have its counsel participate in any meetings or discussions with the SEC regarding the SEC's position (unless in the reasonable opinion of the Company or its counsel, such participation will be to the detriment to the Company in that it may cause undue delays in the registration process or for other reasons) and to comment or have its counsel comment on any written submission made to the SEC with respect thereto. No such written submission regarding the foregoing specifying the Purchaser shall be made to the SEC to which the Purchaser's counsel reasonably objects. The Company shall not agree to name the Purchaser as an "underwriter" in such Registration Statement without the prior written consent of the Purchaser. In the event that, despite the Company's reasonable best efforts and compliance with the terms of this Section 4(c), the SEC refuses to alter its position that the offering of some or all of the Registrable Securities in a Registration Statement is not eligible to be made on a delayed or continuous basis under the provisions of Rule 415, or requires the Purchaser to be named as an "underwriter" in such Registration Statement, then the Company shall (i) remove from the Registration Statement such portion of the Registrable Securities (the " Cut Back Shares "); and/or (ii) agree to such restrictions and limitations on the registration and resale of the Registrable Securities, in each case as the SEC may require to assure the Company's compliance with the requirements of Rule 415. Upon the SEC's initial declaration that the Registration Statement is effective, the Company shall no longer have any obligations under this Agreement to register the Cut Back Shares.

(d) In the event of any stock split, stock dividend or transaction with respect to the Registrable Securities that increases the number of Registrable Securities, if a then-effective Registration Statement does not cover the resale of such additional number of Registrable Securities, the Company shall amend or supplement any Registration Statement to cover such additional number of Registrable Securities.

(e) The Company shall use its best efforts to register or qualify the Registrable Securities covered by any Registration Statement under the securities laws of each state of the United States; provided , however , that the Company shall not be required in connection with this Section 4(e) to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction.

(f) If the Company has delivered preliminary or final Prospectuses to the Purchaser and, after having done so, the Prospectus is amended or supplemented to comply with the requirements of the Securities Act, the Company shall promptly notify the Purchaser and, if requested by the Company, the Purchaser shall immediately cease making offers or sales of shares under the applicable Registration Statement and return all Prospectuses to the Company. The Company shall promptly provide the Purchaser with revised or supplemented Prospectuses and, following receipt of the revised or supplemented Prospectuses, the Purchaser shall be free to resume making offers and sales under the applicable Registration Statement.

(g) The Company shall advise the Purchaser promptly after it shall receive notice or obtain knowledge of the issuance of any stop order by the SEC delaying or suspending the effectiveness of any Registration Statement or of the initiation or threat of any proceeding for that purpose, and it will promptly use commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal at the earliest possible moment if such stop order should be issued.

5. Requirements of the Purchaser. The Company shall not be required to include any Registrable Securities in any Registration Statement contemplated by this Agreement unless:

(a) the Purchaser furnishes to the Company, in writing, such information regarding the Purchaser and the proposed sale of the Registrable Securities by the Purchaser as the Company may reasonably request in writing in connection with such Registration Statement or as shall be required in connection therewith by the SEC or any state securities law authorities; and

(b) the Purchaser shall have provided to the Company a written agreement to indemnify the Company and each of its directors and officers against, and hold the Company and each of its directors and officers harmless from, any losses, claims, damages, expenses or liabilities (including reasonable attorneys fees) to which the Company or such directors and officers may become subject by reason of any statement or omission in such Registration Statement made in reliance upon, or in conformity with, a written statement by the Purchaser furnished pursuant specifically for use in preparation of such Registration Statement; provided, however, that the Purchaser's obligation to indemnify the Company shall be limited to the net amount received by the Purchaser from the sale of the Registrable Securities.

6. Suspension. The Company may suspend the use of any Registration Statement or Prospectus (a " Suspension ") by the Purchaser if the Company determines in good faith that such Suspension is necessary to (A) delay the disclosure of material non-public information concerning the Company, the disclosure of which at the time, in the good faith opinion of the Company's Board of Directors, would be materially detrimental to the Company or its stockholders for a registration to be effected at such time; (B) amend or supplement the affected Registration Statement or the related Prospectus so that such Registration Statement or Prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein; or (C) amend or supplement the affected Registration Statement or Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, in each case of clauses (A) through (C), that the Company shall (a) promptly notify the Purchaser in writing of such Suspension and the reasons therefor, but shall not disclose to the Purchaser any material non-public information giving rise to a Suspension under clause (A); (b) advise the Purchaser in writing to cease all sales under the Registration Statement or Prospectus until the end of the Suspension; and (c) use its reasonable best efforts to terminate such Suspension as promptly as practicable. The Company may not exercise its rights pursuant to this Section 6 for more than ninety (90) days in the aggregate in any twelve (12) month period.

7. Expenses. Except as set forth below, the Company will pay all of the expenses incurred in connection with complying with this Agreement (whether or not any Registration Statement or Prospectus becomes final or effective), including, without limitation: all registration, filing and printing fees, the Company's counsel and accounting fees and expenses, costs and expenses associated with clearing the Registrable Securities for sale under applicable state securities laws (including, without limitation, fees, charges and disbursements of counsel in connection with such clearance), all listing fees, expenses incurred by the Company in connection with any "road show" and reasonable fees, charges and disbursements of counsel to the Purchaser. The Company shall not be required to pay or reimburse the Purchaser for any underwriting discounts or commissions and fees of underwriters, selling brokers, dealer managers or similar securities industry professionals with respect to the Registrable Securities being sold.

8. Indemnification. The Company agrees to indemnify and hold harmless the Purchaser against any losses, claims, damages, expenses or liabilities to which the Purchaser may become subject by reason of any untrue statement of a material fact contained in any Registration Statement or any omission to state therein a fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages, expenses or liabilities arise out of or are based upon information furnished to the Company by or on behalf of the Purchaser for use in such Registration Statement. The Company shall have the right to assume the defense and settlement of any claim or suit for which the Company may be responsible for indemnification under this Section 8.

9. Termination. All of the Company's obligations to register the Registrable Securities under this Agreement shall terminate on the earlier of (a) the fifth (5th) anniversary of the date of this Agreement or (b) the date on which all of the Registrable Securities have been sold by the Purchaser.

10. Assignment of Rights. This Agreement, and the rights and obligations of the Purchaser hereunder, may be assigned by the Purchaser to any affiliate of the Purchaser to whom the Registrable Securities may be transferred pursuant to the terms of the Purchase Agreement, and such transferee shall be deemed a "Purchaser" for the purposes of this Agreement; provided that such transferee provides written notice of such assignment to the Company and agrees to be bound in writing hereby.

11. Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

12. Specific Performance. In addition to any and all other remedies that may be available at law in the event of any breach of this Agreement, the parties hereto shall be entitled to specific performance of the agreements and obligations of the parties hereunder and to such other injunctive or other equitable relief as may be granted by a court of competent jurisdiction.

13. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware (without reference to the conflicts of law provisions thereof).

14. Notices. Any notices or other communications required or permitted hereunder shall be sufficiently given if delivered personally, via electronic mail, or via a reputable express courier, with charges prepaid, to the address set forth below or to such other address of which the parties may have given notice. Unless otherwise specified herein, such notices or other communications shall be deemed received one business day after personal delivery or electronic delivery, or three business days after being sent, if sent by reputable express courier.

If to the Company:

Curis, Inc.
4 Maguire Road
Lexington, Massachusetts 02421
Attention: President and Chief Executive Officer
Facsimile: (617) 503-6500

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
New York, NY 10007
Attention: Steven D. Singer, Esq.
Facsimile: (212) 230-8888

If to the Purchaser:

Aurigene Discovery Technologies Limited
39-40, KIADB Industrial Area
Phase II, Electronic City Hosur Road
Bangalore - 560100 Karnataka
India
Attention: CSN Murthy, Chief Executive Officer
Facsimile: (91) 80 2852 6285

15. Entire Agreement . This Agreement constitutes the entire agreement and understanding of the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings relating to such subject matter. The parties may amend or modify this Agreement, in such manner as may be agreed upon, only by a written instrument executed by the parties hereto.

16. Counterparts; Facsimile Signatures . This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. This Agreement may be executed by facsimile signatures.

17. Section Headings . The section headings are for the convenience of the parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the parties.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

CURIS, INC.

By: /S/ ALI FATTAEY

Ali Fattaey

President and Chief Executive Officer

AURIGENE DISCOVERY TECHNOLOGIES LIMITED

By: /S/ CSN MURTHY

CSN Murthy

Chief Executive Officer

[*Signature Page to Registration Rights Agreement*]

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 302

I, Ali Fattaey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Curis, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2016

/S/ ALI FATTAEY

Ali Fattaey
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 302

I, James E. Dentzer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Curis, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2016	/ S / JAMES E. DENTZER
	James E. Dentzer
	Chief Financial and Chief Administrative Officer
	(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Curis, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Ali Fattaey, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

Date: November 3, 2016	/s/ Ali Fattaey
	Ali Fattaey
	President and Chief Executive Officer
	(Principal Executive Officer)

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Curis, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, James E. Dentzer, Chief Financial and Administrative Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

Date: November 3, 2016	/ S / JAMES E. DENTZER
	James E. Dentzer
	Chief Financial and Chief Administrative Officer
	(Principal Financial and Accounting Officer)