CURIS INC
Form 10-Q
November 09, 2015
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark one)**

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015**

**OR**

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

**Commission File Number: 000-30347**

**CURIS, INC.**

**(Exact Name of Registrant as Specified in Its Charter)**

| | |
|---|---|
| **Delaware** | **04-3505116** |
| **(State or Other Jurisdiction of** | **(I.R.S. Employer** |
| **Incorporation or Organization)** | **Identification No.)** |
| **4 Maguire Road** | |
| **Lexington, Massachusetts** | **02421** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

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

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

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

As of November 5, 2015, there were 128,394,655 shares of the registrant s common stock outstanding.

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

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**Item 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**CURIS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(unaudited)**

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 28,658,916 | $ 7,747,411 |
| Investments | 64,811,477 | 42,002,782 |
| Short-term investment restricted | | 13,877 |
| Accounts receivable | 2,318,202 | 1,960,995 |
| Prepaid expenses and other current assets | 818,176 | 489,844 |
| Total current assets | 96,606,771 | 52,214,909 |
| Property and equipment, net | 315,470 | 407,738 |
| Long-term investments | | 788,768 |
| Long-term investment restricted | 152,610 | 152,610 |
| Goodwill | 8,982,000 | 8,982,000 |
| Other assets | 56,025 | 67,544 |
| Total assets | $ 106,112,876 | $ 62,613,569 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 2,568,945 | $ 2,349,183 |
| Accrued liabilities | 1,873,842 | 2,007,699 |
| Current portion of long-term debt, net | 4,860,418 | 5,709,985 |
| Total current liabilities | 9,303,205 | 10,066,867 |
| Long-term debt, net | 20,668,112 | 22,589,058 |
| Other long-term liabilities | 148,745 | 174,018 |
| Total liabilities | 30,120,062 | 32,829,943 |
| Commitments | | |
| Stockholders Equity: | | |
| Common stock, $0.01 par value 225,000,000 shares authorized; 129,617,501 shares issued and 128,394,655 shares outstanding at September 30, 2015; 87,253,657 shares issued and 86,030,811 shares outstanding at December 31, 2014 | 1,296,175 | 872,537 |
| Additional paid-in capital | 901,242,489 | 810,001,410 |

| | | |
|---|---|---|
| Treasury stock (at cost, 1,222,846 shares) | (1,524,029) | (1,524,029) |
| Accumulated deficit | (825,075,335) | (779,555,295) |
| Accumulated other comprehensive loss | 53,514 | (10,997) |
| Total stockholders equity | 75,992,814 | 29,783,626 |
| Total liabilities and stockholders equity | $ 106,112,876 | $ 62,613,569 |

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

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**CURIS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues: | | | | |
| Royalties | $ 2,292,608 | $ 1,783,271 | $ 5,997,514 | $ 4,895,454 |
| Research and development, net | (247,641) | (18,407) | (211,711) | (44,672) |
| License fees | | | | 3,000,000 |
| Total revenues | 2,044,967 | 1,764,864 | 5,785,803 | 7,850,782 |
| Costs and Expenses: | | | | |
| Cost of royalty revenues | 116,145 | 89,295 | 303,209 | 246,280 |
| Research and development | 4,001,069 | 3,705,365 | 14,658,017 | 10,180,271 |
| In-process research and development | | | 24,347,815 | |
| General and administrative | 2,771,496 | 2,723,235 | 9,711,470 | 8,475,392 |
| Total costs and expenses | 6,888,710 | 6,517,895 | 49,020,511 | 18,901,943 |
| Loss from operations | (4,843,743) | (4,753,031) | (43,234,708) | (11,051,161) |
| Other Income/(Expense): | | | | |
| Interest income | 127,329 | 38,881 | 251,692 | 129,120 |
| Interest expense | (826,710) | (933,903) | (2,537,024) | (2,834,609) |
| Change in fair value of warrant liability | | 67,910 | | 716,786 |
| Total other expense | (699,381) | (827,112) | (2,285,332) | (1,988,703) |
| Net loss | $ (5,543,124) | $ (5,580,143) | $ (45,520,040) | $ (13,039,864) |
| Net loss per common share (basic and diluted) | $ (0.04) | $ (0.06) | $ (0.37) | $ (0.15) |
| Weighted average common shares (basic and diluted) | 128,392,413 | 86,004,857 | 121,634,415 | 85,962,415 |

| | | | | |
|---|---|---|---|---|
| Total comprehensive loss | $ (5,488,033) | $ (5,584,080) | $ (45,455,529) | $ (13,029,416) |

See accompanying notes to unaudited condensed consolidated financial statements.

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**CURIS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(unaudited)**

| | Nine Months Ended September 30, 2015 | 2014 |
|---|---|---|
| Cash Flows from Operating Activities: | | |
| Net loss | $ (45,520,040) | $ (13,039,864) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 123,056 | 114,058 |
| Stock-based compensation expense | 2,874,585 | 2,245,565 |
| Change in fair value of warrant liability | | (716,786) |
| Non-cash interest expense on investments | 118,674 | 108,511 |
| Amortization of debt issuance costs | 44,296 | 68,716 |
| Issuance of common stock in consideration for rights granted under Aurigene collaboration agreement (see Note 4(b)) | 23,968,183 | |
| Payment-in kind interest on Curis Royalty s debt | | (713,968) |
| Net gain on sale of fixed assets and equipment | (16,545) | (1,750) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (357,207) | (362,131) |
| Prepaid expenses and other assets | (338,526) | (168,343) |
| Accounts payable and accrued liabilities | 75,589 | 345,474 |
| Total adjustments | 26,492,105 | 919,346 |
| Net cash used in operating activities | (19,027,935) | (12,120,518) |
| Cash Flows from Investing Activities: | | |
| Purchase of investments | (95,595,171) | (38,284,246) |
| Sale of investments | 73,521,081 | 49,353,851 |
| Decrease in restricted cash | 13,877 | 13,877 |
| Purchases of property and equipment | (47,985) | (65,764) |
| Proceeds from sale of equipment | 18,785 | 1,750 |
| Net cash (used in)/provided by investing activities | (22,089,413) | 11,019,468 |
| Cash Flows from Financing Activities: | | |
| Proceeds from issuance of common stock associated with offerings, net of issuance costs (see Note 8(a)) | 64,619,407 | |
| Proceeds from issuance of common stock under share-based compensation plans | 202,542 | 256,843 |
| Payment on Curis Royalty s principal obligations | (2,793,096) | (813,810) |
| Net cash provided by/(used in) financing activities | 62,028,853 | (556,967) |

| | | | | |
|---|---|---|---|---|
| Net Increase/(Decrease) in Cash and Cash Equivalents | | 20,911,505 | | (1,658,017) |
| Cash and Cash Equivalents, Beginning of Period | | 7,747,411 | | 9,591,487 |
| Cash and Cash Equivalents, End of Period | $ | 28,658,916 | $ | 7,933,470 |

See accompanying notes to unaudited condensed consolidated financial statements.

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**CURIS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**

## 1. Nature of Business

Curis, Inc. is a biotechnology company seeking to develop and commercialize innovative drug candidates for the treatment of human cancers. As used throughout these condensed 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, an orally-available, small molecule inhibitor of histone deacetylase, or HDAC, and phosphatidylinositol-3-kinase, or PI3K enzymes, that is being investigated in clinical studies in patients with lymphomas 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 (see Note 4(b)). The collaboration is comprised of multiple programs, in which Curis has the option to exclusively license compounds once a development candidate is nominated within each respective program. In October 2015, the Company exercised options to license the first two programs under this collaboration. The first licensed program is focused on the development of orally-available small molecule antagonists of programmed death -1 (PD-1) and V-domain Ig suppressor of T cell activation (VISTA) in the immuno-oncology field. The Company has named CA-170, a PD-L1/VISTA antagonist, as the development candidate from this program. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. In addition, in October 2015 the Company selected a second preclinical program within the immuno-oncology part of the collaboration, the third overall collaboration program, that is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties.

The Company is also party to a collaboration with F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under which Roche and Genentech are commercializing Erivedge® (vismodegib), a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor, in advanced basal cell carcinoma, or BCC. Roche and Genentech are continuing to develop Erivedge in less severe forms of BCC and have communicated plans to develop Erivedge in other non-oncology indications.

The Company s proprietary pipeline also includes CUDC-427, an orally-available, small molecule antagonist of inhibitor of apoptosis, or IAP proteins, and CUDC-305, a Heat Shock Protein 90, or HSP90, inhibitor. The Company currently intends to utilize its available resources for the continued development of CUDC-907 and drug candidates it licenses under the collaboration with Aurigene. As such, the Company is seeking to collaborate with third parties for the further development of CUDC-427 and CUDC-305.

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 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 risk 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 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 reliance on Aurigene to successfully discover and preclinically develop drug candidates under the parties collaboration agreement; 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 corporate 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; Roche and Genentech s ability to successfully

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commercialize Erivedge; positive results in Roche and Genentech s ongoing clinical trials; 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; and the Company s ability to successfully enter into one or more material outlicensing or collaboration agreements for its proprietary drug candidates.

The Company anticipates that existing cash, cash equivalents and investments at September 30, 2015 should enable it to maintain current and planned operations into 2017. The Company s ability to continue funding its planned operations beyond this period is dependent upon, among other things, its ability to control expenses and its ability to raise additional funds through equity or debt financings, the success of its collaboration with Genentech, including its receipt of additional contingent cash payments under this collaboration, new collaborations or other sources of financing. The Company may not be able to successfully raise additional funds or enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations 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, the condensed consolidated financial statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on February 24, 2015.

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, 2015, the results of operations for the three- and nine-month periods ended September 30, 2015 and 2014, and the cash flows for the nine-month periods ended September 30, 2015 and 2014.

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: 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; assumptions used in the Company s valuation of stock-based compensation; and, the value of certain investments and liabilities, including the Company s long-term warrant liability. 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 under which the Company records revenues. The terms of the Company s agreement with Genentech provide for Genentech to make a non-refundable

license fee payment, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its 2014 Annual Report on Form 10-K.

## 4. Collaboration Agreements

*(a) Genentech*

In June 2003, the Company licensed its proprietary Hedgehog signaling 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 signaling 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 Roche in several other countries for the treatment of advanced basal cell carcinoma. Genentech s parent company, Roche, is also conducting additional exploratory Phase 2 studies in patients with less severe forms of basal cell carcinoma.

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Pursuant to the agreement, the Company is eligible to receive up to an aggregate of $115,000,000 in contingent cash milestone payments, exclusive of royalty payments, in connection with the development of Erivedge or another small molecule Hedgehog signaling pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this amount, the Company has received $59,000,000 as of September 30, 2015. In June 2014, Roche filed an investigational new drug application for the use of Erivedge in patients with idiopathic pulmonary fibrosis, a non-oncology indication, resulting in a milestone payment of $3,000,000 to the Company. As a result of this milestone payment, the Company recognized revenue of $3,000,000 during the nine months ended September 30, 2014. No such payments were received during the three and nine months ended September 30, 2015.

In addition to the contingent cash milestone payments, the Company s wholly-owned subsidiary, Curis Royalty, 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% (such that the applicable royalty rate will range from 3% to 5.5%) 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 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 U.S. Food and Drug Administration, or FDA, and the European Medicine Agency s Committee for Medicinal Products for Human Use, or CHMP, approved another Hedgehog signaling pathway inhibitor, sonidegib, which is marketed by Novartis, for use in locally advanced BCC. The Company and Genentech are currently evaluating the impact that these recent approvals will have on the royalty rate that Curis Royalty receives from Genentech.

Future royalty payments related to Erivedge will service the outstanding debt and accrued interest owed by Curis Royalty to BioPharma-II, up to specified quarterly caps for 2015, and thereafter until the debt is fully repaid (see Note 7). The Company recognized royalty revenues from Genentech s net sales of Erivedge of $2,292,608 and $1,783,271 during the three months ended September 30, 2015 and 2014, respectively, and $5,997,514 and $4,895,454 during the nine months ended September 30, 2015 and 2014, respectively. The Company recorded cost of royalty revenues in the costs and expenses section of its Condensed Consolidated Statements of Operations and Comprehensive Loss of $116,145 and $89,295 during the three months ended September 30, 2015 and 2014, respectively, and $303,209 and $246,280 during the nine months ended September 30, 2015 and 2014, respectively. Each of these amounts are comprised of 5% of the Erivedge royalties earned by Curis Royalty, which 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 the specified quarterly cap, until such time as the loan is fully repaid.

The Company recorded research and development revenue of $47,240 and $72,817 during the three months ended September 30, 2015 and 2014, respectively, and research and development revenue of $183,965 and $144,054 during the nine months ended September 30, 2015 and 2014, respectively, related to expenses incurred and paid by the Company on behalf of Genentech, and for which Genentech is obligated to reimburse the Company. Genentech incurred expenses of $296,380 and $94,118 during the three months ended September 30, 2015 and 2014, respectively, and expenses of $410,785 and $233,701 during the nine months ended September 30, 2015 and 2014, respectively, under this collaboration, for which the Company is obligated to reimburse Genentech, and which the Company has recorded as contra-revenues in its Condensed Consolidated Statements of Operations and Comprehensive Loss.

*(b) Aurigene*

*Collaboration Overview.* 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.

In October 2015, the Company exercised options to license the first two programs under this collaboration, resulting in an aggregate one-time payment of $6,000,000 by the Company to Aurigene. The first licensed program is focused on the development of orally-available small molecule antagonists of PD-1

and VISTA in the immuno-oncology field. The Company has named CA-170, a PD-L1/VISTA antagonist, as the development candidate from this program. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000,000 for supplemental research, development and/or manufacturing activities in support of these two programs.

Also in October 2015, the Company named another preclinical program within the immuno-oncology part of the collaboration which is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties. The Company made a $2,000,000 milestone payment to Aurigene during the second quarter of 2015 related to the selection of this program.

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 as many additional programs as feasible in order for Aurigene to initiate or continue the relevant preclinical activities described in each program s written plan. 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.

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. 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.

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.

*Up-front Equity Issuance.* In connection with the collaboration agreement, the Company issued to Aurigene 17,120,131 shares of its common stock in partial consideration for the rights granted to the Company under the collaboration agreement. The shares were issued pursuant to a stock purchase agreement with Aurigene dated

January 18, 2015.

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

- for the PD-1/VISTA and IRAK4 programs: up to $52,500,000 per program, including $3,000,000 for each option exercise, $3,000,000 upon acceptance of each IND filing by the Company and $4,000,000 upon dosing of the fifth patient in the first Phase 1 clinical trial in each program. In addition, Curis is obligated to make specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any;

for the third and fourth programs: up to $50,000,000 per program, including $2,000,000 for a program selection fee that the Company paid in May 2015 for the third program, $3,000,000 for an option exercise fee if the program is licensed and $2,500,000 upon acceptance of an IND filing by the Company. In addition, Curis is obligated to make development milestones, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any; and

for any program thereafter: up to $140,500,000 per program, including up to a total of $53,000,000 for research fees, an option exercise fee, a preclinical milestone and development milestones, as well as specified filing, approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any.

*Royalties on Net Sales by the Company.* The Company has agreed to pay Aurigene tiered royalties on the Company s and its affiliates annual net sales of products at percentage rates ranging from the high single digits up to 10%, subject to specified reductions.

*Amounts that the Company Receives from Sublicensees.* The Company has agreed to make the following payments to Aurigene upon its entry into sublicense agreements on any program(s):

with respect to amounts that the Company and its affiliates receive from sublicensees under a licensed program in the U.S. or the European Union, a declining percentage of non-royalty sublicense revenues, such percentage correlating to the stage of the most advanced product for such licensed program at the time the sublicense is granted (for example, 25% of such amounts following the Company s initiation of Phase 2 clinical study and 15% of such amounts after initiation of the first pivotal study). This sharing will also extend to royalties that the Company receives from sublicensees, subject to minimum royalty percentage rates that the Company is obligated to pay to Aurigene, which generally range from 5-10%;

with respect to amounts that the Company and its affiliates receive from sublicensees under a licensed program in Asia, 50% of such sublicensing revenues (including both non-royalty sublicensee revenues and royalties that the Company receives from sublicensees); and

with respect to amounts that the Company and its affiliates receive from sublicensees under a licensed program outside of the U.S., the European Union and Asia, a percentage of such non-royalty sublicense revenues ranging from 30% to 50%. The Company is also obligated to share 50% of royalties that the Company receives from sublicensees that it receives in these territories.

The Company s royalty payment obligations (including with respect to royalties on sales by sublicensees) under the collaboration agreement will expire on a product-by-product and country-by-country basis on the later of (i) the expiration of the last-to-expire valid claim of the Aurigene patents covering the manufacture, use or sale of such product in such country and (ii) 10 years from the first commercial sale of such product in such country.

*Term and Termination.* The term of the collaboration agreement began upon signing and, unless earlier terminated, will expire upon either: (i) 90 days after the completion by Aurigene of its obligations under all research plans if the Company has not exercised the option with respect to at least one program by such time; or (ii) expiration of the last-to-expire royalty term for any and all products. Upon expiration (but not on earlier termination) of the collaboration agreement, all licenses granted by Aurigene to the Company that were in effect immediately prior to

such expiration shall survive on a non-exclusive, royalty-free, fully paid, irrevocable, perpetual basis.

The collaboration agreement may be terminated, either in its entirety or with respect to a particular program, by either Aurigene or the Company for uncured material breach by the other party, other than an uncured material breach by the other party of its diligence obligations with respect to a program or licensed program. If an uncured material breach other than a diligence breach relates to a particular program or licensed program, the non-breaching party may terminate the collaboration agreement only with respect to that program or licensed program. However, after initiation of the first pivotal clinical trial of a product for a licensed program, Aurigene may not terminate the collaboration agreement with respect to such licensed program for an uncured non-diligence breach by the Company, except in the case of the Company s uncured material breach of its payment obligations with respect to such licensed program, but Aurigene may pursue any and all remedies that may be available to it at law or in equity as a result of such breach. Similarly, after initiation of the first pivotal clinical trial of a product for a licensed program, the Company may not terminate the collaboration agreement with respect to the license the Company has granted Aurigene for the territory or India and Russia for such licensed program for an uncured non-diligence breach by Aurigene, but the Company may pursue any and all remedies that may be available at law or in equity as a result of such breach.

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On a program-by-program basis, the Company may terminate the collaboration agreement as it relates to a program or licensed program for an uncured diligence breach by Aurigene in connection with such program or licensed program, and Aurigene may terminate the collaboration agreement as it relates to a licensed program for an uncured diligence breach by the Company in connection with such licensed program.

In addition, the Company may terminate the collaboration agreement in its entirety or as it relates to a particular program or licensed program or on a country-by-country basis, for any reason or for no reason at any time upon 60 days prior written notice to Aurigene.

In the event of termination of the collaboration agreement in its entirety before the Company has exercised the option for any program, or termination of the collaboration agreement as it relates to any program prior to exercise of the option for such program, all rights and licenses granted by either Aurigene or the Company with respect to such program under the collaboration agreement (including the option for such program) will automatically terminate.

If the royalty term with respect to a product for any licensed program in any country has expired on or before any termination of the collaboration agreement in its entirety or as to such licensed program, the license granted by Aurigene to the Company with respect to such product in such country, as well as the corresponding license granted to Aurigene in its territory, shall survive a termination of the collaboration agreement.

Solely in the event of termination of the collaboration agreement by Aurigene for the Company s uncured breach, or the Company s termination of the collaboration agreement for convenience, the following will apply to any program that was a licensed program immediately prior to such termination:

- the Company s license with respect to any licensed program that is not a terminated program (defined below), either in the Company s entire territory or in countries within our territory outside of the terminated region (defined below), as applicable, shall continue in full force and effect, subject to all terms and conditions of the collaboration agreement, including the Company s payment obligations;

- the Company s license with respect to any terminated program, either in the Company s entire territory or in the terminated region, as applicable, shall terminate and revert to Aurigene;

- the Company will grant Aurigene a perpetual, royalty-free (except for pass-through royalties and milestone payments payable by the Company under licenses to third party patent rights with respect to products developed or commercialized by or on behalf of Aurigene) license, with the right to sublicense, under the Company s relevant patent rights and other technology solely to develop, manufacture and commercialize compounds and products for any terminated program, either in the Company s entire territory or in the terminated region, as applicable. The foregoing license will be non-exclusive with respect to the Company s patent rights and exclusive with respect to its other technology;

- the Company will grant to Aurigene a right of first negotiation, exercisable within 90 days after termination, to obtain an exclusive, royalty-bearing license, with the right to sublicense, under our relevant patent rights solely to develop, manufacture and commercialize compounds and products for any terminated program, either in the Company s entire territory or in the terminated region, as applicable, upon commercially

reasonable terms and conditions to be negotiated in good faith by the parties;

the Company will perform other specified activities and actions reasonably necessary for Aurigene to develop, manufacture and commercialize compounds and products for any terminated program, either in the Company s entire territory or in the terminated region, as applicable; and

the applicable license to Aurigene will survive termination of the collaboration agreement.

For purposes of the foregoing, terminated program means: (i) in the case of termination of the collaboration agreement in its entirety by Aurigene for the Company s uncured non-diligence breach, any program that was a licensed program immediately prior to such termination, but excluding, except in the case of the Company s uncured

material breach of the Company s payment obligations with respect to such licensed program, any such licensed program for which initiation of the first pivotal clinical trial of a product has occurred prior to such termination; (ii) in the case of any termination of the collaboration agreement as to a particular licensed program by Aurigene either for the Company s uncured non-diligence breach (to the extent termination as to such licensed program is permitted) or the Company s uncured diligence breach, such licensed program; (iii) in the case of the Company s termination of the collaboration agreement in its entirety for convenience, any program that was a licensed program immediately prior to such termination; or (iv) in the case of the Company s termination of the collaboration agreement as to a particular licensed program for convenience, such licensed program; provided, however, that, in the case of the preceding clauses (iii) and (iv), if the Company s termination of the collaboration agreement in its entirety or as to a particular licensed program for convenience was with respect only to a particular country or subset of countries within the entire territory (as applicable, a terminated region ), the applicable licensed program(s) shall be considered terminated program(s) only in the terminated region but shall remain licensed program(s) in the rest of the Company s territory.

*Accounting Summary.* Under the terms of this collaboration agreement, the Company issued to Aurigene 17,120,131 shares of its common stock in partial consideration for the rights granted under the collaboration agreement at a value of $23,968,183 based on the closing share price of the Company s common stock on the closing date of the stock purchase agreement, January 20, 2015, which was $1.40 per share. In addition, the Company made a cash payment of $379,632 pursuant to the collaboration agreement. As compounds licensed from Aurigene are in pre-clinical development and require substantial development, regulatory, and marketing approval efforts in order to reach technological feasibility, the Company recognized in-process research and development expense of $24,347,815 within its Consolidated Statement of Operations and Comprehensive Loss for the nine months ended September 30, 2015.

The Company recognized $2,000,000 in research and development expenses within its Consolidated Statement of Operations and Comprehensive Loss for the nine months ended September 30, 2015 related to a payment made to Aurigene in connection with the selection of a preclinical program under this collaboration.

The October 2015 option exercises to in-license the PD-1/VISTA and IRAK4 programs resulted in a payment of $6,000,000 to Aurigene required to be paid during the fourth quarter of 2015. The Company expects that it will record this full amount as a research and development expense within its Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2015.

*(c) Debiopharm International S.A.*

*Termination and Transition Agreement.* In February 2015 and as amended in August 2015, the Company entered into a termination and transition agreement with Debiopharm International S.A., or Debiopharm , to terminate the August 5, 2009 license agreement between the Company and Debiopharm, under which the Company granted Debiopharm an exclusive, worldwide license to Debio 0932, a small molecule inhibitor of Heat Shock Protein 90, or HSP90, as amended.

Under the terms of the termination and transition agreement, the licenses and all other rights granted by the Company related to Debio 0932 terminated and reverted to the Company, effective as of the termination date. Debiopharm ceased enrollment in all clinical trials as of the termination date. In addition, the Company exercised its right, pursuant to the license agreement, to obtain a non-exclusive, worldwide, royalty-bearing license, with the right to sublicense, under intellectual property rights of Debiopharm to develop, make, have made, use, sell, offer for sale, have sold, and import Debio 0932 and any product containing Debio 0932. Debiopharm will also transfer to the Company the U.S. investigational new drug application related to Debio 0932. Debiopharm also assigned to the Company its sole patent

application related to Debio 0932.

Under the terms of the February 2015 transition agreement, Debiopharm transitioned to the Company all ongoing Debio 0932 development and manufacturing activities, manufacturing technology necessary for Debio 0932 manufacture, and all data relating to Debio 0932 generated by or on behalf of Debiopharm.

The Company agreed to make the following payments to Debiopharm under the terms of the termination and transition agreement, as amended in August 2015:

*Up-front drug product payment.* The Company paid $750,000 to Debiopharm, primarily in consideration for Debiopharm providing drug product for use in the Company s future clinical studies, which has been recorded within the research and development line item of its Condensed Consolidated Statements of Operations and Comprehensive Loss during the nine months ended September 30, 2015.

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*Royalties on the Company s net sales.* The Company has agreed to pay to Debiopharm royalties at a rate of 3% of net sales by the Company (excluding sales by the Company s third party sublicensees) of products containing Debio 0932.

*Amounts that the Company receives from sublicensees.* The Company has agreed to pay to Debiopharm the following percentages of amounts that the Company receives from third party sublicensees;

10% of any royalties that the Company receives from third party sublicensees based on such sublicensees net sales of products containing Debio 0932; and

20% of any non-royalty sublicense payments that the Company receives from third party sublicensees up to a maximum of $30,000,000, unless such sublicense payments are attributable to the Company s grant to a third party sublicensee of a license or sublicense to develop or commercialize a topical formulation of Debio 0932 for local, non-systemic delivery for the treatment of psoriasis, in which case there is no such maximum payment.

*(d) The Leukemia & Lymphoma Society Agreement*

*November 2011 Agreement.* In November 2011, the Company entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, agreed to support the Company s ongoing development of CUDC-907 for patients with relapsed or refractory lymphoma and multiple myeloma. Under the agreement, LLS agreed to make milestone payments up to $4,000,000 that were contingent upon the Company s achievement of specified clinical development objectives with CUDC-907. Since the inception of the agreement, the Company has received $1,650,000 from LLS related to milestones achieved under this agreement. The Company did not receive any milestone payments pursuant to the LLS agreement during the three and nine months ended September 30, 2015 or 2014, respectively.

In August 2015, the Company entered into an amendment of the November 2011 agreement with LLS. Under this amendment, LLS agreed to provide advisory services to the Company regarding both CUDC-907 and the IRAK4 program under the Company s collaboration with Aurigene, and LLS will no longer be obligated to make further milestone payments related to the Company s ongoing clinical development of CUDC-907.

The Company has agreed to make up to $1,650,000 in future payments to LLS pursuant to achievement of certain objectives, including a licensing, sale, or other similar transaction, as well as regulatory and commercial objectives, in each case related to the CUDC-907 program. However, if CUDC-907 does not continue to meet its clinical safety endpoints in future clinical trials in the defined field, or fails to obtain necessary regulatory approvals, all funding provided to the Company by LLS will be considered a non-refundable grant.

## 5. Fair Value Measurements

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP also 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.

The Financial Accounting Standards Board, or FASB, Codification Topic 820, *Fair Value Measurements and Disclosures,* requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. 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. The Company s warrant liability was valued using a probability-weighted Black-Scholes model, discussed further in Note 8, and is therefore classified as Level 3.

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In accordance with the fair value hierarchy, the following table shows the fair value as of September 30, 2015 and December 31, 2014 of those financial assets and liabilities that are measured at fair value on a recurring basis, according to the valuation techniques the Company used to determine their fair value. No financial assets or liabilities are measured at fair value on a nonrecurring basis at September 30, 2015 and December 31, 2014.

| | Quoted Prices in Active Markets (Level 1) | Other Observable Inputs (Level 2) | Unobservable Inputs (Level 3) | Fair Value |
|---|---|---|---|---|
| **As of September 30, 2015:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 15,182,706 | $ | $ | $ 15,182,706 |
| Municipal bonds | | 3,499,750 | | 3,499,750 |
| Corporate commercial paper, stock, bonds and notes | | 8,499,825 | | 8,499,825 |
| Short-term investments: | | | | |
| Corporate commercial paper, stock, bonds and notes | 19,021,799 | 45,789,678 | | 64,811,477 |
| Total assets at fair value | $ 34,204,505 | $ 57,789,253 | $ | $ 91,993,758 |

| | Quoted Prices in Active Markets (Level 1) | Other Observable Inputs (Level 2) | Unobservable Inputs (Level 3) | Fair Value |
|---|---|---|---|---|
| **As of December 31, 2014:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 4,419,894 | $ | $ | $ 4,419,894 |
| Municipal bonds | | 1,090,000 | | 1,090,000 |
| Short- and long-term investments: | | | | |
| Corporate commercial paper, stock, bonds and notes | 40,091,800 | 2,699,750 | | 42,791,550 |
| Total assets at fair value | $ 44,511,694 | $ 3,789,750 | $ | $ 48,301,444 |

During the nine months ended September 30, 2015, four investments with an aggregate fair value of $3,223,151 at September 30, 2015 were transferred from Level 1 to Level 2 due to a change in the level of trading activity during the reporting period.

## 6. Investments

The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of September 30, 2015 are as follows:

| | | Amortized Cost | Unrealized Gain | Unrealized Loss | Fair Value |
|---|---|---|---|---|---|
| Corporate bonds and notes | short-term | $ 64,761,846 | $ 50,805 | $ (1,174) | $ 64,811,477 |
| Total investments | | $ 64,761,846 | $ 50,805 | $ (1,174) | $ 64,811,477 |

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Short-term investments have maturities ranging from one and twelve months with a weighted average maturity of 3.2 months at September 30, 2015.

The amortized cost, unrealized gains and losses and fair value of investments available-for-sale as of December 31, 2014 are as follows:

| | | Amortized Cost | Unrealized Gain | Unrealized Loss | Fair Value |
|---|---|---|---|---|---|
| Corporate bonds and notes | short-term | $ 42,011,286 | $ 4,883 | $ (13,387) | $ 42,002,782 |
| Corporate bonds and notes | long-term | 791,261 | | (2,493) | 788,768 |
| Total investments | | $ 42,802,547 | $ 4,883 | $ (15,880) | $ 42,791,550 |

Short-term investments have maturities ranging from one and twelve months with a weighted average maturity of 4.1 months at December 31, 2014. Long-term investments have maturities ranging from January 2016 to May 2016 with a weighted average maturity of 13.8 months.

## 7. Debt

In December 2012, Curis wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II. In connection with the loan, Curis transferred to Curis Royalty its right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that it may 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 intended to be 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 academic institutions, (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, subject to caps of $3,000,000 per quarter in 2015, will be applied first to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive the remaining royalty amounts above the caps, if any, and 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. 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 month ended September 30, 2015, the Company made payments totaling $5,288,152, of which $2,793,096 has been applied to the principal portion of the debt with the remainder applied to accrued interest. As of September 30, 2015, the Company recorded short- and long-term debt of $4,860,418 and $20,668,112, respectively (net of unamortized issuance costs of $14,351 and $76,869, respectively), and at December 31, 2014, the Company recorded short- and long-term debt of $5,709,985 and $22,589,058, respectively (net of unamortized issuance costs of $38,074 and $75,729, respectively), related to the loan, with such amounts recorded within the Company s Consolidated Balance Sheets. In addition, the Company recorded related accrued interest on the debt of $283,748 and $286,075 as of September 30, 2015 and December 31, 2014, respectively, with such amounts included in the Company s accrued liabilities section of its Consolidated Balance Sheets. For the three and nine months ended September 30, 2015, the Company recognized interest expense related to the loan with BioPharma-II of $826,710 and $2,537,024, respectively. For the three and nine months ended September 30, 2014, the Company recognized interest expense related to the loan with BioPharma-II of $933,903 and $2,834,609, respectively.

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Because the repayment of the term loan is contingent upon the level of Erivedge royalties received, the short- and long-term classification is based on the Company s estimate of the timing of amounts to be repaid. The Company currently estimates that the loan would be repaid in 2019; however, this estimate is impacted by numerous factors, some of which are beyond the Company s control. Accordingly, the Company s estimate may not be predictive of when this loan would actually be repaid. The repayment term may be shortened or extended depending on the actual level of Erivedge royalties. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, the 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 due to 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.

Curis Royalty is currently entitled to a royalty that escalates from 5% to 7.5% based on worldwide annual net sales of Erivedge ranging from less than $150 million to over $600 million. The royalty rate applicable to Erivedge may be decreased by 2% (such that the applicable royalty rate will range from 3% to 5.5%) 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 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 Hedgehog signaling pathway inhibitor sonidegib, marketed by Novartis, for use in locally advanced BCC. The Company is currently evaluating, with Genentech, the future impact of these recent approvals on the royalty rate paid to Curis Royalty by Genentech.

At September 30, 2015, the fair value of the principal portion of the debt is estimated as $26,330,000. Due to the assumptions required in estimating future Erivedge royalties, the expected repayment period and weighting of various royalty projection scenarios, determining the fair value of the debt required application of Level 3 inputs.

## 8. Common Stock and Warrant Liability

*(a) 2015 Public Offering of Common Stock*

On February 25, 2015, the Company entered into an underwriting agreement with Cowen and Company, LLC, or Cowen, acting for itself and as representative of the named underwriters, relating to an underwritten public offering of 21,818,181 shares of the Company s common stock. The offering price to the public was $2.75 per share, and the underwriters agreed to purchase the shares from the Company pursuant to the underwriting agreement at a price of $2.585 per share. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 3,272,727 shares of common stock at the public offering price per share less the underwriting discounts and commissions. The underwriters exercised this option in full on February 25, 2015. On March 2, 2015, the Company completed the public offering of 25,090,908 shares of common stock. The Company received net proceeds from the sale of the shares, after deducting the underwriting discounts and commissions and estimated offering expenses, of $64,619,407.

*(b) 2010 Registered Direct Offering*

On January 27, 2010, the Company completed a registered direct offering of 6,449,288 units with each unit consisting of (i) one share of the Company s common stock and (ii) one warrant to purchase 0.25 of one share of common stock at a purchase price of $2.52 per unit. The Company received net proceeds from the sale of the units, after deducting offering expenses, of approximately $14,942,000.

In connection with this offering, the Company issued warrants to purchase an aggregate of 1,612,322 shares of common stock. As of December 31, 2014, warrants to purchase 238,805 shares of the Company s common stock had been exercised, and warrants to purchase an aggregate of 1,373,517 shares of common stock were outstanding. All outstanding warrants expired on January 27, 2015 pursuant to the terms of the warrants. Due to the original terms, the warrants were deemed to be a liability and the Company revalued the warrants at each reporting period, with change in fair value of the warrant liability recognized in the Consolidated Statement of Operations and Comprehensive Loss. The Company recorded other income of $67,910 and $716,786 for the three and nine months ended September 30, 2014, respectively. The Company did not recognize any other income or expense associated with these warrants during the three and nine months ended September 30, 2015.

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*(c) 2015 Sales Agreement*

On July 2, 2015, the Company entered into a sales agreement with Cowen, pursuant to which the Company may sell from time to time up to $30,000,000 of the Company s 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. In addition, with the Company s prior written approval, Cowen may also sell the common stock by any other method permitted by law, including in negotiated transactions. Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market to sell on the Company s behalf all of the shares requested to be sold by the Company. The Company has no obligation to sell any of the common stock under the sales agreement. Either the Company or Cowen may at any time suspend solicitations and offers under the sales agreement upon notice to the other party. The sales agreement may be terminated at any time by either the Company or Cowen upon written notice to the other party as specified in the sales agreement. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. In addition, the Company has agreed to reimburse a portion of the expenses of Cowen in connection with the offering of $16,000. Each party has agreed in the sales agreement to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, subject to the terms of the sales agreement. The shares 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 that the Company filed with the Securities and Exchange Commission on July 2, 2015. The Company did not sell any shares of common stock under this sales agreement during the three or nine months ended September 30, 2015.

## 9. Accrued Liabilities

Accrued liabilities consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Accrued compensation | $ 1,213,549 | $ 1,386,226 |
| Professional fees | 189,875 | 122,850 |
| Accrued interest on debt (see Note 7) | 283,748 | 286,075 |
| Other | 186,670 | 212,548 |
| Total | $ 1,873,842 | $ 2,007,699 |

## 10. Accounting for Stock-Based Compensation

As of September 30, 2015, the Company had two shareholder-approved, share-based compensation plans: (i) the Amended and Restated 2010 Stock Incentive Plan, or the 2010 Plan, adopted by the Board of Directors in March 2015 and approved by shareholders in May 2015 and (ii) the 2010 Employee Stock Purchase Plan, or the ESPP, adopted by the Board of Directors in April 2010 and approved by shareholders in June 2010. The Company can issue up to 19,000,000 shares of its common stock pursuant to awards granted under the Amended and Restated 2010 Plan. For a

complete discussion of the Company s share-based compensation plans, see Note 4, Stock Plans and Stock Based Compensation in the notes to the Company s consolidated financial statements included in Item 8 of Part II of the Company s Annual Report. As of September 30, 2015, 8,876,502 shares remained available for grant under the 2010 Plan.

During the nine months ended September 30, 2015, the Company s board of directors granted options to purchase 2,526,250 shares of the Company s common stock to officers and employees of the Company under the 2010 Plan. Of these options, 1,466,250 shares vest and become exercisable as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period, and are exercisable at a price equal to the closing price of the Company s common stock on the NASDAQ Global Market on the grant dates. The Company s board of directors

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granted the remaining 1,060,000 shares of the Company s common stock to its officers in February 2015. Such stock options have an exercise price equal to $2.39 per share, the closing price of the Company s common stock on the NASDAQ Global Market on the date of grant, and will vest and become exercisable as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period; provided that such awards will terminate and be forfeited if the Company s stockholders did not approve an amendment to the 2010 Plan to increase the number of shares authorized for issuance thereunder within 12 months of the grant date; and further provided that such options shall not be exercisable and no common stock shall be issued thereunder, before the approval of such stock incentive plan amendment by the Company s stockholders. As mentioned above, the shareholders approved such amendment in May 2015 and options to purchase an aggregate of 1,060,000 shares of common stock were awarded to the Company s officers.

During the nine months ended September 30, 2015, the Company s board of directors also granted options to its non-employee directors to purchase 260,000 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 exercise prices price of $1.94 per share, which equals to 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, 2015 and 2014 based on the assumptions noted in the following table:

| | For the nine months ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Expected term (years) - Employees | 6 | 6 |
| Expected term (years) Officers and Directors | 7 | 7 |
| Risk-free interest rate | 1.5-1.9% | 1.85-2.2% |
| Volatility | 68-70% | 70-71% |
| 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 stock price volatility and expected terms 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.

The aggregate intrinsic value of employee options outstanding at September 30, 2015 was $2,600,000, of which $2,349,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2015 and 2014 were $1.71 and $1.79, respectively. As of September 30, 2015, there was approximately $6,540,000, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the Company s 2010 Plan that is expected to be recognized as expense over a weighted average period of 2.53 years. The intrinsic values of employee stock options exercised during the nine months ended September 30, 2015 and 2014 were $81,000 and $105,000, respectively.

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*Vesting Tied to Market Conditions*

Monte Carlo simulation models were used to value stock options to purchase an aggregate of 1,040,000 shares of common stock granted to the Company s officers during the year ended December 31, 2014. Of this amount, options to purchase 640,000 shares of common stock were granted in February 2014 with an exercise price of $3.09 and options to purchase 400,000 shares of common stock were granted in June 2014 with an exercise price of $1.75 per share that contained specific market conditions. The key assumptions used in these Monte Carlo simulation models and resulting valuations are noted in the following table:

| | Market Condition Options Granted February 18, 2014 | Market Condition Options Granted June 2, 2014 |
|---|---|---|
| Expected life (years) officers | 6 | 6 |
| Risk-free interest rate | 1.9% | 2.1% |
| Volatility | 70% | 65% |
| Dividends | None | None |
| Number of options granted | 640,000 | 400,000 |
| Fair value per share | $ 1.20 | $ 0.34 |

Based on the above, the Monte Carlo simulation models calculated an aggregate fair value of $905,000, excluding forfeitures, related to these grants that are being recognized on a straight-line basis over the estimated vesting periods of the separate tranches. These awards accounted for $106,677 and $348,332 of the employee stock-based compensation expense recorded by the Company for the three and nine months ended September 30, 2015, respectively, and $118,284 and $274,661 of the employee stock-based compensation expense recorded by the Company for the three and nine months ended September 30, 2014. As of September 30, 2015, none of the options with market conditions had vested.

*Employee Stock-Based Compensation Expense*

The Company recorded $994,402 and $2,720,475 in compensation expense for the three and nine months ended September 30, 2015, respectively, and the Company recorded $855,511 and $2,337,538 in compensation expense for the three and nine months ended September 30, 2014, respectively, related to employee and director stock option grants. The total fair values of vested stock options for the nine months ended September 30, 2015 and 2014 were $2,124,000 and $2,213,000, 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 reversed expense of $93,519 and recognized expense related to non-employee stock options of $154,110 during the three and nine months ended September 30, 2015, respectively, and reversed expense of $37,211 and of $91,973, for the three and nine months ended September 30, 2014, respectively.

**Total Stock-Based Compensation Expense**

For the three and nine months ended September 30, 2015 and 2014, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations:

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Research and development expenses | $ 169,548 | $ 195,670 | $ 771,040 | $ 496,418 |
| General and administrative expenses | 731,335 | 622,630 | 2,103,545 | 1,749,147 |
| Total stock-based compensation expense | $ 900,883 | $ 818,300 | $ 2,874,585 | $ 2,245,565 |

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## 11. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss) as of September 30, 2015 and 2014:

| | Unrealized Losses on Securities Available-for-Sale | |
|---|---|---|
| Balance, as of December 31, 2014 | $ | (10,997) |
| Other comprehensive gain before reclassifications | | 64,511 |
| Amounts reclassified from accumulated other comprehensive income (loss) | | |
| Net current period other comprehensive loss | | 64,511 |
| Balance, as of September 30, 2015 | $ | 53,514 |

The above amounts do not reflect a tax effect as the Company expects to retain a net loss position for 2015.

| | Unrealized Gains/Losses on Securities Available-for-Sale | |
|---|---|---|
| Balance, as of December 31, 2013 | $ | (6,984) |
| Other comprehensive gain before reclassifications | | 10,448 |
| Amounts reclassified from accumulated other comprehensive income (loss) | | |
| Net current period other comprehensive gain | | 10,448 |
| Balance, as of September 30, 2014 | $ | 3,464 |

## 12. Loss Per Common Share

The Company applies ASC Topic 260 - *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted loss per common share is computed using the weighted-average number of 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, 2015 and 2014, as the effect of the potential common stock equivalents is antidilutive due to the Company s net loss position for these periods. Antidilutive securities consist of stock options and warrants outstanding as of the respective reporting period as follows:

| | For the three and nine months ended September 30, 2015 | For the three and nine months ended September 30, 2014 |
|---|---|---|
| Stock options outstanding | 13,678,899 | 11,364,119 |
| Warrants outstanding | | 1,373,517 |
| Total antidilutive securities | 13,678,899 | 12,737,636 |

**13. Related Party Transaction**

On June 2, 2014, Daniel R. Passeri resigned as Chief Executive Officer of the Company and 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. Pursuant to the terms of the consulting agreement, Mr. Passeri agreed to provide 120 hours per month of consulting services to the Company on intellectual property, corporate and strategic matters. In consideration for the services rendered by Mr. Passeri to the Company, the Company agreed to pay Mr. Passeri $32,500 per month until June 1, 2015, provided that if at any time during the consultation period Mr. Passeri obtained full time employment with a third party, then Mr. Passeri and the Company would negotiate a good faith reduction in the number of hours that Mr. Passeri would consult, and thereafter Mr. Passeri would be paid an hourly fee, in lieu of the monthly retainer, for services rendered under the consulting agreement. On December 1, 2014, Mr. Passeri obtained full time employment with a third party. From December 1, 2014 through June 30, 2015, Mr. Passeri was compensated an hourly fee in lieu of a monthly retainer for services rendered to the company.

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On June 1, 2015, the Company and Mr. Passeri renewed the agreement for a period of six months. On June 30, 2015, Mr. Passeri resigned from his full-time employment with a third party and, thereafter, the Company requested that Mr. Passeri begin providing 120 hours per month of consulting services for the remainder of the consulting term in exchange for monthly payments of $30,000. Pursuant to the terms of the consulting agreement, the Company recognized expenses of $90,000 and $114,300 during the three and nine month periods ending September 30, 2015, respectively, and expenses of $97,500 and $127,833 during the three and nine months ended September 30, 2014, respectively.

**14. Recent Accounting Pronouncements**

In April 2015, the FASB updated the guidance related to the presentation of debt issuance costs. The new standard requires debt issuance costs, related to a recognized debt liability, be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. The update requires the guidance to be applied retrospectively. The update is effective for fiscal years beginning after December 15, 2015 and the Company does not expect adoption of this guidance will have a material impact on its financial statements.

In January 2015, the FASB issued new guidance to eliminate the concept of extraordinary items as part of its initiative to reduce complexity in accounting standards. The guidance is effective for annual and interim periods beginning after December 15, 2015 and may be applied prospectively or retrospectively. The Company does not expect adoption of this standard will have a material impact on its financial statements.

In May 2014, the FASB issued new revenue recognition guidance for entities which provides a single comprehensive model to account for revenue arising from contracts with customers, and will supersede most current revenue recognition guidance. The new standard also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity s nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The guidance is anticipated to be effective for the Company in 2018. Early adoption is permitted in 2017. The Company is currently evaluating the impact the standard will have on its consolidated financial statements.

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## Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes appearing elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled Risk Factors in Part II, Item 1A of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used throughout this report, the terms the Company, we, us, and our refer to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term Curis refers to Curis, Inc.

### Overview

We are a biotechnology company seeking to develop and commercialize innovative drug candidates for the treatment of human 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. We are currently investigating this molecule in two studies, including in a Phase 1 clinical study in patients with relapsed, refractory lymphoma, as well as in a Phase 1 study in patients with solid tumors. We anticipate initiating a Phase 2 trial of CUDC-907 for treatment of patients with relapsed or refractory diffuse large B cell lymphoma, or DLBCL, by the end of 2015.

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 PD-1 and VISTA in the immuno-oncology field, including the development candidate designated CA-170, which is a PD-L1/VISTA antagonist. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. In addition, in October 2015 we selected a second preclinical program within the immuno-oncology field, the third overall collaboration program, that is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties. We expect to file an IND and initiate Phase 1 clinical testing of CA-170 during the first half of 2016. We also expect to file an IND for development of the IRAK4 inhibitor within the first half of 2016.

Our other collaborators, F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, are commercializing Erivedge® (vismodegib), a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor, in advanced basal cell carcinoma, or BCC. Roche and Genentech are also continuing Erivedge s clinical development in less severe forms of BCC, and have communicated plans for development in other non-oncology indications.

Our proprietary pipeline also includes CUDC-427, an orally-available, small molecule antagonist of inhibitor of apoptosis, or IAP proteins. We recently completed dose escalation and expansion arms of CUDC-427 in a Phase 1 clinical trial in patients with solid tumors or lymphoma. We also regained rights to our Heat Shock Protein 90, or HSP90, inhibitor CUDC-305 from Debiopharm International S.A., or Debiopharm earlier this year. We recently re-evaluated our clinical development plans for these molecules and determined that we would preserve our available resources for the continued development of CUDC-907 and drug candidates under our collaboration with Aurigene, including CA-170. We are currently seeking to collaborate with third parties for further development of CUDC-427

and CUDC-305.

*CUDC-907*. We are conducting a Phase 1 clinical study of CUDC-907 in patients with relapsed or refractory lymphomas or multiple myeloma. In the fourth quarter of 2014, we initiated enrollment of patients with diffuse large B-cell lymphoma, or DLBCL, Hodgkin s lymphoma, or multiple myeloma in the expansion stage of this Phase 1 study and in the second quarter of 2015 we initiated enrollment and treatment of patients with DLBCL using CUDC-907 in combination with rituximab in a separate expansion arm of the Phase 1 study. During the second quarter of 2015, interim data from the dose escalation and monotherapy expansion stages of the ongoing Phase 1 study were presented at the Annual Meeting of American Society of Clinical Oncology (ASCO), the 20th Congress of the European Hematology Association (EHA), as well as at the 13th International Congress on Malignant Lymphoma (ICML). At the time of these presentations, amongst 10 response-evaluable, heavily pre-treated patients with relapsed/ refractory DLBCL, two achieved complete responses, or CRs, and four experienced partial responses, or PRs. Three of these objective responses (one CR and two PRs) occurred in patients with transformed follicular lymphoma or t-FL/DLBCL, a difficult to treat subset of DLBCL. Among 12 response-evaluable patients with Hodgkin s lymphoma, one achieved a PR. In addition, stable disease was reported in 25 of 44

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response-evaluable patients across various lymphomas and multiple myeloma. A total of four dose limiting toxicities were reported across all schedules tested, occurring in three patients, and consisting of diarrhea (two cases) and hyperglycemia (two cases). The most commonly occurring drug-related side effects included diarrhea, fatigue, nausea, thrombocytopenia and neutrophil decrease. The recommended Phase 2 dose of CUDC-907 was determined to be 60 mg, on a 5-days on / 2 days off schedule, in 21-day cycles. No dose limiting toxicities have occurred on this dose and schedule, which is currently undergoing further examination in the expansion phase of the trial in patients with relapsed refractory DLBCL.

Additionally, we have initiated testing of CUDC-907 in conjunction with rituximab in patients with relapsed/ refractory DLBCL in the ongoing Phase 1 clinical study in order to assess tolerability and preliminary efficacy of the combination. We anticipate initiating a Phase 2 clinical trial of CUDC-907 for treatment of patients with relapsed/refractory DLBCL by the end of 2015. In light of substantial unmet need for more effective therapies, in April 2015 the U.S. Food & Drug Administration, or FDA, granted CUDC-907 orphan drug designation for the treatment of relapsed, refractory DLBCL. We expect to present additional data from the Phase 1 study of CUDC-907 in patients with relapsed/ refractory DLBCL at a medical meeting later this year. In the fourth quarter of 2014, we initiated a second Phase 1 trial to investigate CUDC-907 in patients with advanced solid tumors, including those with advanced hormone receptor positive breast cancer or with NUT midline carcinoma. We anticipate presenting data from this solid tumor study during 2016.

*Aurigene*. In January 2015, we entered into an exclusive, multi-year collaboration with Aurigene that is focused on discovery, development and commercialization of drug candidates in the fields of immuno-oncology and precision oncology. As part of the agreement, Aurigene has granted to us the option to exclusively license multiple compounds including the designated development candidates discovered using their small molecule technology that address molecular targets within the scope of the collaboration. Within the collaboration, Aurigene is responsible for conducting all discovery and preclinical activities, including IND-enabling studies and providing Phase 1 clinical trial supply of the investigational agent, and we are responsible for all clinical development, regulatory and commercialization efforts worldwide, excluding India and Russia, for each candidate for which we exercise an option to obtain a license. We will also make specified payments to Aurigene, including option exercise fees, pre-IND milestones for the first four programs, as well as milestone payments and royalties on any products that we successfully commercialize under the collaboration.

Currently, there are three programs under this collaboration, including two targeting immune checkpoints and one targeting the IRAK4 kinase. 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 PD-1 and VISTA in the immuno-oncology field, which development candidate is designated as CA-170. The second licensed program is focused on orally-available small molecule inhibitors of IRAK4 in the precision oncology field. In addition, in October 2015 we named another preclinical program under this collaboration that is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties. Because Aurigene is primarily responsible for preclinical development of all program compounds, we expect that a majority of our collaborator-related costs related to these first three programs will be related to option exercise fees and pre-IND milestones. In addition, in October 2015, we agreed to invest an aggregate of $2,000,000 for supplemental research, development and/or manufacturing activities in support of these two licensed programs.

For each of the PD-1/VISTA and IRAK4 programs, we paid Aurigene $3,000,000 for each option exercise in October 2015, $3,000,000 per program upon acceptance of an IND by the FDA and $4,000,000 per program upon our dosing of the fifth patient in the first Phase 1 clinical trial. For the PD-1/TIM-3 program, our payments to Aurigene include $2,000,000 that we paid for program selection, $3,000,000 for an option exercise fee if the program is licensed and

$2,500,000 upon acceptance of an IND filing by the FDA. Our collaborator-related costs subsequent to these initial milestones will be largely directed toward further clinical development expenses for the respective program, with the next milestone for each program incurred upon the first regulatory approval in a major market.

*Erivedge*. Erivedge is an FDA approved medicine for the treatment of metastatic or locally advanced basal cell carcinoma, or BCC, and is being developed and commercialized by Roche and Genentech under a collaboration agreement between Curis and Genentech. In January 2012, the FDA approved Erivedge for the treatment of adults with BCC that has spread to other parts of the body, that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation, collectively considered as advanced BCC. In May 2013, Australia s Therapeutic Goods Administration, or TGA, approved Erivedge and in July 2013, the European Commission granted conditional approval for the marketing of Erivedge in all 28 European Union member states. Erivedge s approval in the United States, Europe, Australia and several other countries is based on positive clinical data from the ERIVANCE BCC/SHH4476g trial, a pivotal Phase 2 study of Erivedge in patients with advanced BCC. Under the provisions of the conditional approval in Europe, Roche is expected to provide additional data on Erivedge in advanced BCC from the ongoing global safety study, known as STEVIE, which is an international, single-arm, open-label multicenter trial in patients with advanced forms of BCC. The

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STEVIE trial has completed enrollment of approximately 1,200 patients and interim analyses from the study confirmed a safety profile similar to that observed in previous studies of Erivedge in BCC patients. Roche and Genentech are also continuing Erivedge s clinical development in less severe forms of BCC as well as communicating its potential development in other non-oncology indications, including in idiopathic pulmonary fibrosis and myelofibrosis.

*CUDC-427 and CUDC-305*. In 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427. Under the terms of the license agreement, we have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. In the fourth quarter of 2014, we completed the amended dose escalation stage of a Phase 1 study in which consecutive cohorts of patients according to the standard 3+3 design were treated with CUDC-427 at dose levels of 100, 200 and 300 mg daily on a 14 days on, 7 days off schedule. No dose limiting toxicities occurred on this dose and schedule.

In February 2015, we entered into a termination and transition agreement with Debiopharm pursuant to which we regained the worldwide rights to all future development and commercialization to the compound that we have re-designated as CUDC-305 (formerly Debio 0932). During the fourth quarter of 2014, Debiopharm determined that it would not advance the compound to the Phase 2 stage of the HALO, or HSP90 inhibition And Lung cancer Outcomes, study. Debiopharm determined that the results from the Phase 1 portion of the HALO lung cancer study were inconclusive although safety observations were generally consistent with the previously observed side effects of the compound and/or the respective chemotherapeutic regimens administered in the trial. We currently intend to utilize our available resources for the continued development of CUDC-907 and drug candidates under our collaboration with Aurigene, including CA-170, and as such we do not anticipate initiating any new clinical trials testing CUDC-427 and CUDC-305 on our own. We are currently seeking to collaborate with third parties for further development of CUDC-427 and CUDC-305.

***Our Collaborations***

Our current collaborations and license agreements are summarized as follows:

***Aurigene***

*Collaboration Overview.* 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. Under the collaboration agreement, Aurigene has granted us 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 with the exception of India and Russia. Upon exercise of the option for a particular program, Aurigene will grant us the royalty-bearing license described above for such program, and we will grant Aurigene an exclusive, royalty-free, fully paid license under our relevant technology to develop, manufacture and commercialize compounds from such program and products containing such compounds in India and Russia.

There are currently three programs under this collaboration, including two programs targeting immune checkpoint regulators and one program targeting the IRAK4 kinase. 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 PD-1/VISTA in the immuno-oncology field and the second licensed program is focused on orally-available small molecule inhibitors of IRAK4 in the precision oncology field. We expect to progress these

molecules to Investigational New Drug, or IND, application filings the first half of 2016.

In addition, in October 2015 we named another preclinical program within the immuno-oncology field that is focused on evaluating small molecule antagonists with dual PD-1 and TIM-3 targeting properties.

*Up-front Equity Issuance*. In connection with the collaboration agreement, we issued to Aurigene 17,120,131 shares of our common stock valued at $23,968,000 in partial consideration for the rights granted to us under the collaboration agreement, which we recognized as expense during the nine months ended September 30, 2015. The shares were issued pursuant to a stock purchase agreement with Aurigene dated January 18, 2015.

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*Research Payments, Option Exercise Fees and Milestone Payments*. We have agreed to make the following research, option exercise fees and milestone payments to Aurigene:

- for each of the PD-1/VISTA and IRAK4 programs: up to $52,500,000 per program, including $3,000,000 for each option exercise, $3,000,000 upon acceptance of each IND filing and $4,000,000 upon our dosing of the fifth patient in the first Phase 1 clinical trial for each program; as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000,000 for supplemental research, development and/or manufacturing activities in support of these two programs;

- for the third and fourth programs: up to $50,000,000 per program, including $2,000,000 for a program selection fee selection fee that we paid in May 2015 for the third program $3,000,000 for an option exercise fee if the program is licensed and $2,500,000 upon acceptance of an IND filing, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any; and

- for any program thereafter: up to $140,500,000 per program, including up to a total of $53,000,000 for research fees, an option exercise fee, a preclinical milestone and development milestones, as well as specified filing, approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any.

*Royalties on Net Sales by Curis*. We have agreed to pay Aurigene tiered royalties on our and our affiliates annual net sales of products at percentage rates ranging from the high single digits up to 10%, subject to specified reductions.

*Amounts that we receive from Sublicensees*. We have agreed to make the following payments to Aurigene upon our entry into sublicense agreements on any program(s):

- with respect to amounts that we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program in the U.S. or the European Union, a declining percentage of non-royalty sublicense revenues that is dependent on the stage of the most advanced product for such licensed program at the time the sublicense is granted, including, for example 25% of such amounts following our initiation of Phase 2 clinical study and 15% of such amounts after initiation of the first pivotal study. This sharing will also extend to royalties that we receive from sublicensees, subject to minimum royalty percentage rates that we are obligated to pay to Aurigene, which generally range from mid-to-high single-digit royalty percentage rates up to 10%;

- with respect to sublicensing revenues we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program in Asia, 50% of such sublicensing revenues, including both non-royalty sublicensee revenues and royalties that we receive from sublicensees; and

with respect to non-royalty sublicensing revenues we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program outside of the U.S., the European Union and Asia, a percentage of such non-royalty sublicense revenues ranging from 30% to 50%. We are also obligated to share 50% of royalties that we receive from sublicensees that we receive in these territories.

Our royalty payment obligations (including with respect to royalties on sales by sublicensees) under the collaboration agreement with respect to a product in a country will expire on a product-by-product and country-by-country basis on the later of (i) expiration of the last-to-expire valid claim of the Aurigene patents covering the manufacture, use or sale of such product in such country and (ii) 10 years from the first commercial sale of such product in such country.

***Genentech***

*Genentech Hedgehog Signaling Pathway Inhibitor Collaboration.* Under the terms of our collaboration agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog signaling pathway inhibitors. The lead drug candidate under this program is Erivedge. Genentech subsequently granted a sublicense to Roche for non-U.S. rights to Erivedge, other than in Japan where such rights are held by Chugai. Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing.

We are eligible to receive up to $115,000,000 in contingent cash payments for the development of Erivedge or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which we have received $59,000,000 to date. In addition to the contingent cash milestone payments, our wholly-owned subsidiary, Curis Royalty, is entitled to a royalty on net sales of Erivedge that ranges from 5% to 7.5% based upon global Erivedge sales by Roche and Genentech, subject to reduction under specified circumstances. The royalty rate applicable to Erivedge may be decreased by 2% (such that the applicable royalty rate will range from 3% to 5.5%) 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 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 sonidegib, marketed by Novartis for the treatment of adults with locally advanced BCC. We are currently evaluating the future impact of these recent approvals on the royalty paid to Curis Royalty by Genentech.

We recognized $5,998,000 of royalty revenue from Genentech s net sales of Erivedge during the nine months ended September 30, 2015 and have recognized an aggregate of $18,227,000 in royalty revenues since Erivedge was approved. In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan from 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 will be repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis. As of September 30, 2015, Curis Royalty owed BioPharma-II a total of $25,903,000, gross, which was comprised of principal and accrued interest. Future royalty payments related to Erivedge will service the outstanding debt and accrued interest to BioPharma-II, up to the quarterly caps for 2015, and until the debt is fully repaid thereafter. Because the repayment of the term loan is contingent upon the level of Erivedge royalties received, the short- and long-term classification is based on our estimate of the timing of amounts to be repaid. We currently estimate that the loan would be repaid in 2019; however, this estimate is impacted by numerous factors, some of which are beyond our control. Accordingly, our estimate may not be predictive of when this loan would actually be repaid. The repayment term may be shortened or extended depending on the actual level of Erivedge royalties. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, the unpaid interest outstanding will be added to the principal on a quarterly basis. The length of the actual repayment period could vary materially from the to the extent that royalty payments Curis Royalty receives are lower than our current estimates, which could arise due to factors beyond our control, such as due to 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.

As a result of our licensing agreements with various universities, we are also obligated to make payments to these university licensors when we receive certain payments from Genentech. We are obligated to make payments to university licensors on royalties that Curis Royalty earns in all territories other than Australia in an amount that is equal to 5% of the royalty payments that Curis Royalty receives from Genentech. This obligation is for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that Curis Royalty earns 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 expiration of the Australian patent in April 2019, after which the amount will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. Cost of royalty revenues were $303,000 during the nine months ended September 30, 2015. As of September 30, 2015, we have paid an aggregate of $1,016,000 to university licensors upon receipt of royalties since Erivedge was approved.

*Genentech IAP Inhibitor License Agreement.* In November 2012, we licensed from Genentech the exclusive, worldwide rights for the development and commercialization of CUDC-427, a small molecule that is designed to promote cancer cell death by antagonizing IAP proteins. Under the terms of the license agreement, we and/or our sublicensees have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. Genentech is entitled to receive milestone payments upon the first commercial sale of CUDC-427 in certain territories and tiered single-digit royalties on net sales of CUDC-427. We

are currently seeking a collaborator for the further development of CUDC-427.

***The Leukemia & Lymphoma Society***

In November 2011, we entered into an agreement with LLS, pursuant to which LLS agreed to support up to $4,000,000 of the direct costs of the development of CUDC-907, through milestone payments related to our achievement of specified development objectives with patients having relapsed or refractory lymphomas and multiple myeloma. As of September 30, 2015, we have received $1,650,000 under our agreement with LLS. Under this agreement, we will be obligated to make future contingent payments, including potential royalty payments, upon our successful entry into a collaboration agreement for CUDC-907 or upon the achievement of certain regulatory and commercial objectives. Such future payments are capped at 2.5 times the funding payments that we receive from LLS under the agreement.

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In August 2015, we entered into an amendment of our November 2011 agreement with LLS. Under this amendment, LLS has agreed to provide advisory services to us regarding both CUDC-907 and our IRAK4 program under the collaboration with Aurigene, and in turn, LLS will no longer be obligated to make further milestone payments related to our ongoing clinical development of CUDC-907.

We have agreed to make up to $1,650,000 in future payments to LLS across certain objectives, including a licensing, sale or other similar transaction, as well as regulatory and commercial objectives, in each case related to the CUDC-907 program. However, if CUDC-907 does not continue to meet its clinical safety endpoints in future clinical trials in the defined field or fails to obtain necessary regulatory approvals, all funding provided us by LLS will be considered a non-refundable grant.

***Debiopharm***

In August 2009, we granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell our HSP90 inhibitor technology, including Debio 0932, to Debiopharm. Debiopharm completed Phase 1 testing of this drug candidate and in August 2012, Debiopharm initiated the HSP90 inhibition And Lung cancer Outcomes, or HALO, Phase 1/2 clinical trial of Debio 0932 in combination with various chemotherapy regimens in patients with stage IIIb or IV non-small cell lung cancer, or NSCLC. Debiopharm reviewed data from the Phase 1 portion of the HALO study and determined that the results from the Phase 1 portion of the HALO study were inconclusive, although safety observations were generally consistent with previously observed side effects of Debio 0932 and/or the respective chemotherapeutic regimens administered in the trial.

In February 2015, as amended in August 2015, we entered into a termination and transition agreement with Debiopharm to terminate our August 2009 license agreement, effective February 5, 2015. We redesignated the molecule as CUDC-305. We do not expect to initiate any additional clinical trials of CUDC-305 on our own and are seeking collaborative opportunities for the molecule s further development. Under the terms of this termination and transition agreement, as amended, the licenses and all other rights granted by us related to CUDC-305 terminated and reverted to Curis effective as of the termination date. Debiopharm ceased enrollment in all clinical trials as of the termination date. In addition, we exercised our right, pursuant to the license agreement, to obtain a non-exclusive, worldwide, royalty-bearing license, with the right to sublicense, under other intellectual property rights of Debiopharm to develop, make, have made, use, sell, offer for sale, have sold and import CUDC-305. Debiopharm also assigned its sole patent application related to CUDC-305 to us. Debiopharm transitioned ongoing CUDC-305 development and manufacturing activities to us and has made available all necessary information generated by or on behalf of Debiopharm to pursue the manufacturing of CUDC-305.

During the nine months ended September 30, 2015, we paid $750,000 to Debiopharm, primarily in consideration for Debiopharm providing drug product.

We have agreed to pay to Debiopharm royalties at a rate of 3% of net sales by us (excluding sales by our third party sublicensees) of products containing CUDC-305 and to pay Debiopharm the following percentages of amounts that we receive from third party sublicensees: (i) 10% of any royalties that we receive from third party sublicensees based on such sublicensees net sales of products containing CUDC-305; and (ii) 20% of any non-royalty sublicense payments that we receive from third party sublicensees, provided that the maximum aggregate amount payable by us to Debiopharm with respect to non-royalty sublicense payments is $30,000,000.

***Liquidity***

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, private and public placements of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable on an annual basis and have an accumulated deficit of $825,075,000 as of September 30, 2015.

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, 2015 should enable us to maintain current and planned operations into 2017. Our ability to continue funding our planned operations into and beyond this point is dependent on a number of factors, including our ability to manage our expenses, and 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, or establishing additional corporate collaborations or from other sources of financing.

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***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 asset, CUDC-907, as well as for such clinical trials to generate favorable data;
- our and Aurigene s ability to successfully advance CA-170 through IND-enabling studies and for us to then finance and complete planned Phase 1 clinical trials;
- our and Aurigene s ability to complete preclinical development and IND-enabling studies for IRAK4 inhibitors and for us to then finance and complete planned Phase 1 clinical trials;
- Aurigene s ability to advance its preclinical immuno-oncology and precision oncology drug candidates, and our ability to further progress these programs clinically;
- Our ability to enter into at least one collaboration for one of our proprietary programs;
- 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 of additional clinical studies of Erivedge, including in non-oncology indications such as a potential Phase 2 study in idiopathic pulmonary fibrosis.

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 and the magnitude of payments from our current and potential corporate collaborators. 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, the timing of our entry into new collaborations, if any, and the timing of the receipt of payments, if any, from new or existing collaborators. We anticipate that existing capital resources as of September 30, 2015 should enable us to maintain current and planned operations into 2017.

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

*Debt.* In December 2012, our wholly-owned subsidiary, Curis Royalty, entered into a $30,000,000 debt transaction with BioPharma-II, which holds an annual interest rate of 12.25% and is collateralized by certain future Erivedge royalty and royalty-related payment streams.

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 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 intended to be 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 academic institutions, (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, subject to caps of $3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive the remaining amounts above the caps, if any, and we remain entitled to receive any contingent payments upon achievement of clinical development objectives. In 2016, there are no 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, and 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, 2015, the outstanding principal and interest due under the loan is $25,903,000.

*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, subject to quarterly caps in 2015, 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 from our estimate to the extent that royalty payments we receive are lower than our current estimates, which could arise due to factors beyond our control, such as due to 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, up-front license payments, and funded research and development that we may receive under new collaboration agreements, if any, and contingent cash payments for the achievement of clinical, development and regulatory objectives, if any, are met, under new collaborations or our existing collaboration with Genentech. Our ability to enter into new collaborations and our receipt of additional payments under our existing collaboration with Genentech cannot be assured, nor can we predict the timing of any such arrangements or 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 in the Revenues section of 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. For royalties that Curis Royalty receives from Roche s sales of Erivedge in Australia, we will be obligated to make payments to university licenses of 2% of Roche s direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

*Research and Development.* Research and development expense consists of costs incurred to develop our drug candidates. These expenses consist primarily of: salaries and related expenses for personnel including stock-based compensation expense, costs of conducting clinical trials, including amounts paid to clinical centers, clinical research organizations and consultants, among others, other outside service costs including costs of contract manufacturing, sublicense payments, the costs of supplies and reagents, consulting, and occupancy and depreciation charges. Research and development expenses also include certain payments that we make to Aurigene under our January 2015

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

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| Drug Candidate | Primary Disease | Collaborator/Licensee | Status |
|---|---|---|---|
| ***Dual HDAC and PI3K Inhibitor*** | | | |
| -CUDC-907 | Relapsed, refractory DLBCL | Internal development | Phase 1 Expansion |
| | Solid tumors including breast cancer and NUT midline carcinoma | Internal development | Phase 1 |
| ***Aurigene Immuno-Oncology*** | | | |
| -CA-170 (PD-L1/VISTA antagonist) | Cancers | Aurigene | Pre-IND |
| -PD-1/TIM-3 antagonists | Cancers | Aurigene | Preclinical* |
| ***Aurigene Precision Oncology*** | | | |
| -IRAK4 Inhibitors | Hematological cancers | Aurigene | Preclinical |
| ***Antagonist of IAP Proteins*** | | | |
| -CUDC-427 | Advanced solid tumor & lymphomas | Seeking collaborator | Completed Phase 1 |
| ***HSP90 Inhibitor*** | | | |
| -CUDC-305 | Cancers | Seeking collaborator | Completed Phase 1 |
| ***Hedgehog Signaling Pathway Inhibitor*** | | | |
| -Erivedge | Advanced BCC | Genentech (Roche) | Approved in US, Australia and others and conditional approval in the EU; regulatory submissions made in additional territories |
| -Erivedge | Preceding excision and multiple BCC | Roche | Phase 2 |
| -Erivedge | Idiopathic Pulmonary Fibrosis | Roche | Phase 2; patient enrollment currently suspended to allow for protocol amendment |
| -Erivedge | Myelofibrosis | Roche | Phase 1b |

* (1) We have an option to exclusively license molecules under the terms of our agreement with Aurigene.

With the exception of Erivedge approved in advanced BCC, our programs are in early stages of clinical or in 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.

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

*In-process Research and Development.* We recognized in-process research and development expenses of $24,348,000 during the nine months ended September 30, 2015 in partial consideration for the rights granted to us under the collaboration agreement with Aurigene.

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*General and Administrative.* General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by us. We expect that our general and administration expenses will increase in future periods related to an increase in employee-related costs due to increased stock-based compensation and other personnel costs.

**Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with GAAP 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 collectability of receivables, 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, including our long-term warrant liability. 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 judgments related to the carrying value of assets and liabilities that are not readily apparent from other sources. Changes to the probabilities underlying the assumptions used in valuing our warrant liability could materially impact our financial statements. 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, 2014, or the Annual Report, which was filed with the SEC on February 24, 2015.

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**Results of Operations**

***Three-Month Periods Ended September 30, 2015 and September 30, 2014***

*Revenues.* Total revenues are summarized as follows:

| | For the Three Months Ended September 30, 2015 | 2014 | Percentage Increase/ (Decrease) |
|---|---|---|---|
| **REVENUES:** | | | |
| Royalty revenues from Genentech | $ 2,293,000 | $ 1,783,000 | 29% |
| Research and development, net | (248,000) | (18,000) | (1,278%) |
| Total revenues | $ 2,045,000 | $ 1,765,000 | 16% |

Total revenues increased by $280,000, or 16%, to $2,045,000 for the three months ended September 30, 2015 as compared to $1,765,000 for the same period in 2014, primarily related to an increase in our royalty revenues recognized from Genentech and Roche s net sales of Erivedge during the third quarter of 2015 as compared to the same period in 2014. In addition, our research and development revenues decreased by $230,000 related to an increase in contra-revenues of $202,000 recorded during the three months ended September 30, 2015 as compared to the prior year period recorded as charges against revenues related to patent expenses incurred by Genentech that we are obligated to reimburse Genentech.

*Cost of Royalty Revenues.* Cost of royalty revenues increased to $116,000 from $89,000 for the quarters ended September 30, 2015 and 2014, respectively, as a result of an increase in Erivedge royalties. 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.* Research and development expenses are summarized as follows:

| Research and Development Program | For the Three Months Ended September 30, 2015 | 2014 | Percentage Increase/ (Decrease) |
|---|---|---|---|
| CUDC-907 | $ 2,776,000 | $ 2,128,000 | 30% |
| CUDC-427 | 254,000 | 1,032,000 | (75%) |
| CUDC-305 | 29,000 | 5,000 | 480% |
| Translational and preclinical | 723,000 | 110,000 | 557% |
| Other | 49,000 | 234,000 | (79%) |
| Stock-based compensation | 170,000 | 196,000 | (13%) |
| Total research and development expense | $ 4,001,000 | $ 3,705,000 | 8% |

Our research and development expenses increased by $296,000, or 8%, to $4,001,000 for the three months ended September 30, 2015, as compared to $3,705,000 for the same period in 2014. Our research and development expenses

increased primarily due to increases in spending on CUDC-907 and preclinical programs under our collaboration with Aurigene. These increases were partially offset by decreases in spending on CUDC-427.

Spending on CUDC-907 increased by $648,000 to $2,776,000 during the three months ended September 30, 2015, as compared to $2,128,000 in the prior year period. These increased costs primarily related to clinical site, patient, CRO, formulation and consulting costs for two of our ongoing Phase 1 clinical trials of CUDC-907, for which enrollment has increased, as well as costs related to the initiation of our anticipated Phase 2 clinical trial in DLBCL patients. Internal resource costs, primarily personnel costs, supporting the development of CUDC-907 also increased over the prior year period. Spending on our preclinical research programs increased $613,000 for the three months ended September 30, 2015 includes costs to support the development programs under our Aurigene collaboration, primarily consisting of personnel costs.

Offsetting these increases, spending on CUDC-427 decreased by $778,000 during the three months ended September 30, 2015 as compared to the prior year period, primarily related to decreases in consulting, outside services and employee-related costs. The last patient treated in the Phase 1 trial of CUDC-427 completed dosing in March 2015 and earlier in 2015 we decided to discontinue investments in the further clinical development of CUDC-427.

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We expect that a majority of our research and development expenses for the foreseeable future will be incurred in support of our efforts to advance CUDC-907 and any development programs resulting from our collaboration with Aurigene, including option exercise fees and potential milestone payments upon achievement of objectives in certain territories, if any.

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

| | For the Three Months Ended September 30, | | Percentage Increase/ (Decrease) |
|---|---|---|---|
| | 2015 | 2014 | |
| Personnel | $ 784,000 | $ 842,000 | (7%) |
| Occupancy and depreciation | 99,000 | 95,000 | 4% |
| Legal services | 267,000 | 447,000 | (40%) |
| Consulting and professional services | 553,000 | 460,000 | 20% |
| Insurance costs | 98,000 | 94,000 | 4% |
| Other general and administrative expenses | 239,000 | 162,000 | 48% |
| Stock-based compensation | 731,000 | 623,000 | 17% |
| Total general and administrative expenses | $ 2,771,000 | $ 2,723,000 | 2% |

General and administrative expenses increased $48,000, or 2%, to $2,771,000 for the three months ended September 30, 2015 as compared to $2,723,000 for the prior year period. Increased spending on consulting and professional services (including audit-related expenses), and stock-based compensation resulting from an increase in the number of options granted during 2015 when compared to the same prior year period were offset by a decrease in legal fees related to foreign patent matters.

*Change in Fair Value of Warrant Liability.* In connection with our January 2010 registered direct offering, we issued warrants to purchase an aggregate of 1,612,322 shares of common stock which became exercisable as of the closing of the transaction. The warrants had an initial exercise price of $3.55 per share and a five year term, and the fair value of the warrants is recorded as a long-term liability. The fair value of the warrants was estimated using a Black-Scholes option pricing model. Historically, the warrants were revalued at each reporting period, with updated assumptions and the resulting gains and losses recorded as the change in fair value of warrant liability in the income statement. Expected volatilities used in the models were based on our historical volatility commensurate with the term of the warrants.

All of our outstanding warrants at December 31, 2014 expired unexercised on January 27, 2015 in accordance with the warrant terms; therefore, no amounts were recognized during the quarter ended September 30, 2015 related to the change in fair value of the warrants. We estimated that the fair value of the warrants at September 30, 2014 was zero using this model with the following assumptions: expected volatility of 50%, risk free interest rate of 0%, expected life of 0.3 years and no dividends. We recorded income of $68,000 for the quarter ended September 30, 2014, primarily related to the change in our stock price during the period.

*Other Expense (Income).* For the three months ended September 30, 2015 and 2014, interest expense was $827,000 and $934,000, respectively, related to interest accrued on Curis Royalty s outstanding debt with the BioPharma-II. Interest income was $127,000 and $39,000 for the three month periods ended September 30, 2015 and 2014, respectively.

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***Nine-Month Periods Ended September 30, 2015 and September 30, 2014***

*Revenues.* Total revenues are summarized as follows:

| | For the Nine Months Ended September 30, 2015 | 2014 | Percentage Increase/ (Decrease) |
|---|---|---|---|
| **REVENUES:** | | | |
| Royalty revenues from Genentech | $ 5,998,000 | $ 4,895,000 | 23% |
| Research and development, net | (212,000) | (44,000) | (382%) |
| License fees | | 3,000,000 | (100%) |
| Total revenues | $ 5,786,000 | $ 7,851,000 | (26%) |

Total revenues decreased by $2,065,000, or 26%, to $5,786,000 for the nine months ended September 30, 2015 as compared to $7,851,000 for the same period in 2014, primarily related to a decrease of $3,000,000 in our license fees revenues related to our Genentech collaboration. We did not receive any such payments from Genentech during the nine months ended September 30, 2015. In addition, during the nine months ended September 30, 2015 and 2014, our research and development revenues were net of contra-revenues of $411,000 and 234,000, respectively, that we recorded related to patent expenses incurred by Genentech that we are obligated to reimburse.

Offsetting these decreases, royalty revenues recognized from Genentech and Roche s net sales of Erivedge increased $1,103,000 to $5,998,000 during the nine months ended September 30, 2015 as compared to $4,895,000 during the same period in 2014, a 23% increase over the prior year period.

*Cost of Royalty Revenues.* Cost of royalty revenues, which we are required to pay to two university licensors, increased during the nine months ended September 30, 2015 as compared to the prior year period as a result of an increase in the royalties that we earned with respect to Erivedge during the nine months ended September 30, 2015 as compared to the prior year period.

*Research and Development Expenses.* Research and development expenses are summarized as follows:

| Research and Development Program | For the Nine Months Ended September 30, 2015 | 2014 | Percentage Increase/ (Decrease) |
|---|---|---|---|
| CUDC-907 | $ 8,167,000 | $ 4,936,000 | 65% |
| CUDC-427 | 1,395,000 | 3,593,000 | (61%) |
| CUDC-305 | 872,000 | 18,000 | 4,744% |
| Translational and preclinical | 3,314,000 | 294,000 | 1,027% |
| Sublicense fees incurred on development and regulatory milestones under our Genentech collaboration | | 150,000 | (100%) |
| Other | 139,000 | 693,000 | (80%) |

| | | | |
|---|---|---|---|
| Stock-based compensation | 771,000 | 496,000 | 55% |
| Total research and development expense | $ 14,658,000 | $ 10,180,000 | 44% |

Our research and development expenses increased by $4,478,000, or 44%, to $14,658,000 for the nine months ended September 30, 2015, as compared to $10,180,000 for the same period in 2014. Our research and development expenses increased primarily due to increases in spending on our clinical development programs, CUDC-907 and CUDC-305, and preclinical programs under our collaboration with Aurigene. These increases were partially offset by decreases in spending on CUDC-427 and our other programs, including CUDC-101.

Spending on CUDC-907 increased $3,231,000 during the nine months ended September 30, 2015 as compared to the prior year period primarily related to clinical site, patient, CRO, formulation and consulting costs, for our ongoing Phase 1 clinical trials of CUDC-907. Internal resource costs, primarily personnel costs, supporting the development of CUDC-907 also increased over the prior year period. Spending on CUDC-305 increased by $854,000, primarily due to the $750,000

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payment we made to Debiopharm for drug product upon termination of that agreement. Increased spending of $3,020,000 on our preclinical research programs for the nine months ended September 30, 2015 includes a $2,000,000 milestone payment to Aurigene for selection of a third research program under that collaboration and also includes costs to support these planned development programs. Stock-based compensation also increased $275,000 for the nine months ended September 30, 2015 as compared to the prior year period related to unvested non-employee stock options that are marked-to-market at each quarterly reporting period as well as an increase in the number of options granted during the nine months ended September 30, 2015 when compared to the prior year period.

Offsetting these increases, spending on CUDC-427 decreased by $2,198,000 during the nine months ended September 30, 2015 as compared to the prior year period, primarily related to decreases in consulting, outside services and employee-related costs. In addition, spending related to other programs, primarily our CUDC-101 program, decreased by $554,000.

We recorded in-process research and development expenses of $24,348,000 for the nine months ended September 30, 2015, which represents the partial consideration for the rights granted to us under the collaboration agreement with Aurigene in January 2015.

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

| | For the Nine Months Ended September 30, | | Percentage Increase/ (Decrease) |
|---|---|---|---|
| | 2015 | 2014 | |
| Personnel | $ 2,825,000 | $ 2,899,000 | (3%) |
| Occupancy and depreciation | 294,000 | 277,000 | 6% |
| Legal services | 1,690,000 | 1,109,000 | 52% |
| Consulting and professional services | 1,717,000 | 1,442,000 | 19% |
| Insurance costs | 271,000 | 273,000 | (1%) |
| Other general and administrative expenses | 810,000 | 726,000 | 12% |
| Stock-based compensation | 2,104,000 | 1,749,000 | 20% |
| Total general and administrative expenses | $ 9,711,000 | $ 8,475,000 | 15% |

General and administrative expenses increased by $1,236,000, or 15%, for the nine months ended September 30, 2015, as compared to the prior year period, primarily due to an increase in legal, professional and consulting services related to the Aurigene transaction, various business development and corporate matters, as well legal costs associated with the maintenance of our intellectual property. In addition, stock-based compensation increased $355,000 over the prior year period as a result of an increase in the number of options issued during the nine months ended September 30, 2015 as compared to the prior year period.

*Change in fair value of warrant liability.* As a result of revaluing the warrants issued in January 2010, we recorded other income of $717,000 for the nine months ended September 30, 2014. Because the warrants expired in January 2015, no amounts were recognized for the nine months ended September 30, 2015.

*Other Expense (Income).* For the nine months ended September 30, 2015 and 2014, interest expense was $2,537,000 and $2,835,000, respectively, related to interest accrued on Curis Royalty s outstanding debt with the BioPharma-II.

Interest income was $252,000 and $129,000 for the nine-month periods ended September 30, 2015 and 2014, respectively.

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**Liquidity and Capital Resources**

*Sources of Liquidity*

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

On February 25, 2015, we entered into an underwriting agreement with Cowen acting both for itself and as representative of the named underwriters, relating to an underwritten public offering of 21,818,181 shares of our common stock. The underwriters agreed to purchase the shares pursuant to the underwriting agreement at a price of $2.585 per share, and the offering price to the public was $2.75 per share. Under the terms of the underwriting agreement, we granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 3,272,727 shares of common stock at the public offering price per share, less the underwriting discounts and commissions. On March 2, 2015, we completed the public offering of 25,090,908 shares of common stock, including underwriters full exercise of their option. After deducting underwriting discounts and commissions and estimated offering expenses, proceeds from the sale totaled approximately $64,619,000.

On July 2, 2015, we entered into a new sales agreement with Cowen, pursuant to which we may sell from time to time up to $30,000,000 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. In addition, with our prior written approval, Cowen may also sell the common stock by any other method permitted by law, including in negotiated transactions. Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market to sell on our behalf all of the shares requested to be sold by us. We have no obligation to sell any of the common stock under the 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 Cowen or us upon written notice to the other party as specified in the sales agreement. The aggregate compensation payable to Cowen will be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. In addition, we have agreed to reimburse a portion of Cowen s expenses in connection with the offering, of $16,000. Each party has agreed to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, pursuant to the terms of 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 that we filed with the Securities and Exchange Commission on July 2, 2015. Through September 30, 2015, we have not sold any shares of common stock pursuant to this sales agreement.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 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 will be repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be 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, 2015 totaled $5,288,000, of which $2,793,000 has been applied to the principal portion of the debt with the remainder paying interest. As of September 30, 2015, Curis

Royalty owed a total of $25,903,000, gross of issuance costs, to BioPharma-II comprised of principal and accrued interest.

We have received aggregate milestone payments totaling $59,000,000 under our collaboration with Genentech. In addition, we began receiving royalty revenues in 2012 in connection with Genentech s net sales of Erivedge in the U.S. and Roche s net sales of Erivedge outside of the U.S. Erivedge royalty revenues received subsequent to December 2012 are being used to repay Curis Royalty s outstanding principal and interest under the loan due to BioPharma-II, subject to specified quarterly caps. Curis Royalty will be entitled to receive and distribute to Curis remaining royalty and royalty-related amounts in excess of the foregoing caps, if any. 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 receiving any such payments, as well as on royalties that are received in any territory other than Australia, we are required to make payments to certain university licensors totaling 5% of these amounts. For royalties that Curis Royalty receives from Roche s sales of Erivedge in Australia, we will be obligated to make payments to university licenses of 2% of Roche s direct

net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022.

At September 30, 2015, our principal sources of liquidity consisted of cash, cash equivalents, and investments of $93,470,000, excluding our restricted investments of $153,000. In October 2015, we paid Aurigene $6,000,000 in option exercise fees for the first two programs under that collaboration. 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*

The use of our cash flows for operations has primarily consisted of 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 $19,028,000 during the nine-month period ended September 30, 2015 was primarily the result of our net loss for the period of $45,520,000, 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 $27,112,000. In addition, accounts receivable increased $357,000 related to an increase in Erivedge royalties and prepaid assets increased $339,000 related to deposits made with vendors.

Net cash used in operating activities of $12,121,000 during the nine-month period ended September 30, 2014 was primarily the result of our net loss for the period of $13,040,000 and repayments of capitalized interest on our debt of $714,000. These decreases in cash were offset by non-cash charges consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense and depreciation which totaled $1,818,000. Changes in certain operating assets and liabilities had offsetting impacts on operating cash during the nine months ended September 30, 2014.

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

Investing activities accounted for cash expenditures of $22,089,000 and provided cash of $11,019,000 for the nine-month periods ended September 30, 2015 and 2014, respectively, resulting primarily from net investment activity from purchases and investment maturities for the respective periods. The increase in purchases of investments during the nine-month periods ended September 30, 2015 resulted from the reinvestment of the net proceeds received from the public offering of our common stock.

Financing activities provided cash of $62,029,000 for the nine-month period ended September 30, 2015. We received $64,619,000 in net proceeds from our underwritten public offering of common stock, and we also received proceeds of $203,000 from the exercise of stock options during the same nine-month period. These proceeds were offset by the principal payments on Curis Royalty s loan with BioPharma-II of $2,793,000. Financing activities used cash of $557,000 for the nine-month period ended September 30, 2014, as a result of principal payments on Curis Royalty s

loan with BioPharma-II of $814,000, offset by $257,000 in proceeds from the exercise of stock options.

*Funding Requirements*

We have incurred significant losses since our inception. As of September 30, 2015, we had an accumulated deficit of approximately $825,075,000. 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 as well as for potential programs under our collaboration with Aurigene, and to fund our general and administrative costs and expenses.

In January 2015, we entered into an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets with Aurigene. 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. There

are currently three programs under this collaboration, including two programs targeting immune checkpoints and one program targeting the IRAK4 kinase. 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 PD-1 and VISTA in the immuno-oncology field. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. We expect to progress these molecules to Investigational New Drug, or IND, application filings the first half of 2016.

In addition, in October 2015 we selected another preclinical program within the immuno-oncology field that is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties.

For the PD-1/VISTA and IRAK4 programs we are obligated to make up to $52,500,000 in payments to Aurigene per program, including $3,000,000 for the option exercise fee for each program that we paid in October 2015, $3,000,000 upon acceptance of each IND filing and $4,000,000 upon our dosing of the fifth patient in the first Phase 1 clinical trial in each program. In addition, we are obligated to make specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000,000 for supplemental research, development and/or manufacturing activities in support of these two programs.

For the PD-1/TIM-3 program we are obligated to make up to $50,000,000 in payments to Aurigene per program, including $2,000,000 for a program selection fee, which we paid for the third program in May 2015, $3,000,000 for an option exercise fee if the program is licensed and $2,500,000 upon acceptance of an IND filing, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any.

We have historically derived a substantial 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 our collaboration with Genentech. Our ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge (subject to Curis Royalty s obligation to remit certain royalties to BioPharma-II). We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding, which we expect to receive if we successfully enter into new collaboration agreements;
- contingent cash payments, which we expect to receive for the achievement of development objectives under any new collaborations, or pursuant to our existing collaboration with Genentech; and
- royalty payments that are contingent upon the successful commercialization of products based upon such collaborations, including royalties on sales of Erivedge in advanced BCC by Genentech, subject to Curis Royalty s obligation to remit certain royalties to BioPharma-II.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of our receipt of payments thereunder is highly uncertain. In addition, for the foreseeable future, we will

only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty s obligation to remit such royalties to BioPharma-II in repayment of the loan between the parties. We currently estimate that all royalties that we receive from Genentech will be remitted to BioPharma-II until the loan is fully repaid.

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.

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We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at September 30, 2015, should enable us to maintain current and planned operations into 2017. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates and maintaining compliance with regulatory requirements;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- 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;
- 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 also expect to 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.

**New Accounting Pronouncements**

In April 2015, the FASB updated the guidance related to the presentation of debt issuance costs. The new standard requires debt issuance costs, related to a recognized debt liability, be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. The update requires the guidance to be applied retrospectively. The update is effective for fiscal years beginning after December 15, 2015 and we do not expect adoption of this guidance will have a material impact on our financial statements.

In January 2015, the FASB issued new guidance to eliminate the concept of extraordinary items as part of its initiative to reduce complexity in accounting standards. The guidance is effective for annual and interim periods beginning after December 15, 2015, and may be applied prospectively or retrospectively. We do not expect that adopting this standard will have a material impact on our financial statements.

In May 2014, the FASB issued new revenue recognition guidance for entities which provides a single comprehensive model to account for revenue arising from contracts with customers, and will supersede most current revenue recognition guidance. The new standard also requires significantly expanded disclosures regarding the qualitative and quantitative information of an entity s nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The guidance is anticipated to be effective in 2018. Early adoption is permitted in 2017. We are currently evaluating the impact the standard will have on its consolidated financial statements.

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**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of September 30, 2015.

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## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our current cash balances in excess of operating requirements are invested in cash equivalents, short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, government obligations with an average maturity of less than one year and long-term investments. All marketable securities and long-term investments are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the ongoing 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 or long-term investments since September 30, 2015, 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 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, 2015. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or 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, 2015, 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 quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II OTHER INFORMATION

### Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q and in other documents we file with the SEC, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede-, the risk factors previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2014.

### 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 losses since our inception. As of September 30, 2015, we had an accumulated deficit of approximately $825,075,000. We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to support our current and planned research and development activities for CUDC-907 as well as to fund programs we have licensed and expect to develop under our collaboration with Aurigene, which we expect will require substantial additional capital, and to fund our general and administrative costs and expenses.

We have historically derived a substantial portion of our operating cash flow from the receipt of milestone payments and research funding revenues under our collaboration agreements with third parties. However, we have no current research funding revenue under these agreements and there can be no assurance that we will receive any future milestone payments under these agreements. Our ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge (subject to Curis Royalty s obligation to remit royalties to BioPharma-II). We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaboration with Genentech; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations, including royalties on sales of Erivedge in advanced BCC by Genentech, subject to Curis Royalty s obligation to remit royalties to BioPharma-II.

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 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, sonidegib, marketed by Novartis, for the treatment of adults with locally advanced BCC. We are currently evaluating, with Genentech, the future impact of these recent approvals on the royalty rate paid to Curis Royalty by Genentech. We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of our receiving payments under such collaborations is highly uncertain. In addition, for the foreseeable future, we will only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty s obligation to remit such royalties to BioPharma-II in repayment of the loan. We currently estimate that all royalties that we receive from Genentech will be remitted to BioPharma-II until the loan is fully repaid.

To become and remain profitable, either alone or with collaborators we must develop and eventually commercialize one or more drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling those drugs for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. Other than Erivedge, which is being commercialized by Genentech and Roche, our most advanced drug candidates are currently only in early clinical testing.

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

**We will require substantial additional capital, which may be difficult to obtain.**

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 substantial working capital to support our research and development activities for CUDC-907 as well as development candidates we have and may continue to license under our collaboration with Aurigene, including those obtained through our October 2015 option exercises to license two programs under this collaboration. 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 will impose significant potential financial obligations on us. The collaboration provides for inclusion of multiple programs, and we have the option to exclusively license compounds once a development candidate is nominated within each respective program.

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

We anticipate that existing cash, cash equivalents, investments and working capital at June 30, 2015 should enable us to maintain current and planned operations into 2017. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and accelerate our need for additional working capital, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates and maintaining compliance with regulatory requirements;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- 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 not the responsibility of one of our collaborators, 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 also expect to 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.

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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 $30,000,000 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 intended to be 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 under the credit agreement to repay the loan may be accelerated, 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 as 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.

**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;

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- the status of, and level of expenses incurred in connection with, our programs, including development costs relating to CUDC-907 as well as to fund 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 fluctuations resulting from the impact of future sales of competing products, including Hedgehog signaling pathway inhibitor sonidegib, marketed by Novartis, that was approved in the US and in Europe for the treatment of locally advanced BCC;

- 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.

**Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.**

Our general business strategy and prospects may be adversely affected by the uncertain economic conditions, volatile business environment and continued unpredictable and unstable market conditions, both domestically and abroad. If equity and credit markets are unfavorable, it is likely to make future debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon research and development plans.

At September 30, 2015, we had $93,470,000 of cash, cash equivalents and investments consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. Any deterioration in conditions of the global credit and financial markets could negatively impact our current portfolio of cash equivalents and marketable securities and our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and liquidity of marketable securities owned by us.

There is a possibility that our stock price may decline due to the volatility of the stock market in recent years.

## RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

**We depend heavily on the success of our most advanced product candidates. 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 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 from specified programs and in October 2015, we exercised options to exclusively license two programs under this agreement and also named a third program. We expect to file IND applications for a development candidate from each licensed program during the first half of 2016. 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;
- 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;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;

- acceptance of the medicines, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies;
- continuing acceptable safety profile for the medicines following approval;
- enforcing and defending intellectual property rights and claims; and
- achieving desirable medicinal properties for the intended indications.

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.

**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.**

In January 2012, Erivedge became an FDA-approved medicine for people with advanced BCC. Since 2012, Erivedge has also been 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. Roche and Genentech are also continuing development of Erivedge in less severe forms of BCC as well as pursuing its potential development in other non-oncology indications. 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 for the treatment of advanced BCC is no longer accepted as safe, efficacious, cost-effective and preferable 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 STEVIE trial;

- 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 or Genentech and/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 any and all regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;

- competing products are approved for the same indications as Erivedge, for example, during the third quarter of 2015, the FDA and CHMP approved another Hedgehog signaling pathway inhibitor, called sonidegib, marketed by Novartisfor 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, for the foreseeable future, we expect that all royalties that Curis Royalty receives under our collaboration agreement with Genentech will be remitted to BioPharma-II in repayment of our loan until the loan is fully repaid.

**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 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 checkpoints 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 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 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 forego or delay 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 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.**

We currently have a collaboration with Genentech pursuant to which 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 its collaboration with us, 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 its collaboration with us. For example, Genentech/ Roche is involved in the commercialization of many cancer medicines and is 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 are focused 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

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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 its collaboration with us.

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 in the United States, European Union and several other countries of Erivedge for the treatment of advanced BCC. 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 either 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 omissions.

**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 continue to 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 expertise, such as additional clinical, regulatory, sales and marketing expertise, for which we have not budgeted;

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- 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.

**If preclinical studies and clinical trials of our drug candidates are not successful then our future profitability and success could be adversely affected.**

In order to obtain regulatory approval for the commercial sale of our drug candidates, we and any current or potential future collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our drug candidates are safe and effective for each indication for which approval is sought.

Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Preclinical testing and clinical trials of our drug candidates may not be successful. 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 cannot be certain that we will not face similar setbacks. We, and our collaborators, could experience delays or failures in preclinical testing or clinical trials of any of our drug candidates for a number of reasons including, for example:

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results;
- we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular drug candidate;
- the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- preclinical and early clinical data are often susceptible to varying interpretations and analyses and even if we, or our collaborators, believe that the results of clinical trials for our product candidates to be successful, regulatory authorities may disagree with our interpretations and analyses;
- we may encounter difficulties or delays in manufacturing sufficient quantities of the drug candidate used in any preclinical study or clinical trial;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;

the timing and completion of clinical trials of our drug candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining trial participants may result in increased costs, program delays or program termination;

our products under development may not be effective in treating cancer or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

we, our clinical investigators, or our current or potential future collaborators and subcontractors, may fail to comply with applicable regulatory requirements, including good clinical practices and requirements regarding the disclosure of clinical trial information;

institutional review boards, regulators, including the FDA or its foreign equivalents, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and

we, along with any of our current or potential future collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities, nor may we or any of our current or potential future collaborators or subcontractors use disqualified clinical investigators or institutions to perform clinical trials of our drug candidates. Employment or use of such a debarred or disqualified person or institution may result in delays in the FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s) or institution(s).

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

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended or with labeling that highlights undesirable safety risks;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for use of the product.

If any of the above were to occur, our reputation and our ability to raise additional capital will be materially impaired and our stock price is likely to decline.

**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 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, may result in increased development costs for our drug candidates, which could cause the value of our stock price to decline. Moreover, our inability to enroll a sufficient number of patients for any of our current or future clinical trials, and/or the reporting of adverse events by companies with competing drug candidates, could result in significant delays or may require us to abandon one or more clinical trials altogether.

**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 substantially 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 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 to 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 that we do not control does not relieve us of these responsibilities and requirements. If any of the third party contractors on whom we rely 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.

**If we or Genentech and/ or Roche do not obtain, or if there are delays in obtaining, necessary regulatory approvals, then we will not be able to commercialize our drug candidates, our business will be materially impaired and the market price of our common stock could substantially decline.**

We and Genentech and/or Roche will be required to obtain regulatory approval in order to successfully advance drug candidates through the clinic and prior to marketing and selling such products. We have limited experience in filing and prosecuting applications to obtain marketing approval. The process of obtaining required regulatory approvals is expensive and the time required for these approvals is uncertain and typically takes a number of years, depending on the type, complexity and novelty of the product. During the course of this process, the FDA or a foreign equivalent may determine that a drug candidate is not effective, or is only moderately effective, or has undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude our obtaining marketing approval. With respect to our internal programs, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the approved indicated uses for which we or our collaborative partners may market the product, to labeling that highlights undesirable safety risks, or to distribution and use restrictions or other requirements under a Risk Evaluation and Mitigation Strategy, or REMS. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We and Genentech and/or Roche are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of potential future products outside of the U.S. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA or a foreign equivalent does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition, regulatory agencies may change existing requirements or adopt new requirements or policies. We and Genentech and/or Roche may be slow to adapt or may not be able to adapt to these changes or new requirements.

As a result of these factors, we and Genentech and/or Roche may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell drug candidates in the time periods estimated, if at all. Moreover, if we or Genentech and/or Roche incur costs and delay development programs or fail to successfully develop and commercialize products based upon our technologies, our ability to generate revenues will be materially impaired and our stock price could decline.

**Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with such products.**

Even if we or any collaborators obtain regulatory approval of a drug candidate, such product, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual 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, cGMP 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.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the requirement to implement a risk evaluation and mitigation strategy. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for, among other things, off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion or manufacturing of prescription products may lead to investigations by the FDA, Department of Justice, and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

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

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

**Our current and future relationships with customers and third-party payors in the U.S. and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.**

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include:

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

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires 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 Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians, and teaching hospitals with data collection, requirements for manufacturers to submit reports to CMS on the 90th day of each calendar year, and disclosure of such information to be made by CMS on a publicly available website beginning in September 2014; and

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analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

**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 EU, 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 our 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 materially harmed.

**If we or any of our collaborators fail to achieve market acceptance for any approved products, our future revenue and ability to achieve profitability may be adversely affected.**

Our future products, including those developed under collaborations with third parties such as Aurigene, may not gain commercial acceptance among physicians, patients and third-party payors, even if necessary marketing approvals have been obtained. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- efficacy and potential advantages compared to alternative treatments;
- the price we charge for our drugs;

- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to successfully develop companion diagnostics that effectively identify patient populations likely to benefit from treatment with our therapeutic products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

The potential market opportunities for our product candidates are difficult to precisely estimate. Our estimates of the potential market opportunities are predicated on many assumptions including industry knowledge and publications, third party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

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**We may not receive Fast Track designation for our product candidates from the FDA, or Fast Track designation may not actually lead to a faster development or regulatory review or approval process.**

We intend to seek Fast Track designation for some or all of our product candidates. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot guarantee that the FDA will grant it. Even if our product candidates receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

## RISKS RELATING TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

**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 without limitation 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 us and our current and potential future collaborators and the uncertainties inherent 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.

**We face substantial competition, which may result in our competitors discovering, developing or commercializing 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 five 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, Pfizer Inc. and Novartis.

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. We are currently evaluating, with Genentech, the future impact of these recent approvals on the royalty rate paid to Curis Royalty by Genentech.

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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 HDAC or PI3K and there are multiple companies testing HDAC or PI3K inhibitors that are in various stages of clinical development. In addition, Debiopharm, Novartis and TetraLogic are all developing antagonists of IAP proteins and several companies are investigating HSP90 inhibitors.

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 PD-1 and VISTA 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 two approved drugs on the market that target PD-1/PD-L1 interactions (Bristol-Myer Squibb s Opdivo™ and Merck & Co. s Keytruda™) and a number of drug candidates in various stages of development that target the similar interactions such as Roche s MPDL3280A, Merck KGaA s avelumab (collaborator: Pfizer), AstraZeneca/ MedImmune s MEDI4736 and MEDI0680, Curetech/ Medivation s pidilizumab and others.

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.

**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. 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 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. Product liability insurance is expensive and may be difficult to retain. As such, it is possible that we will not be able to retain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims.

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**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. We do not maintain key man life insurance on any of these officers. Replacing 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 research, develop and successfully commercialize products in our areas of core competency.

Our ability to operate successfully depends on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

**We may seek to acquire complementary businesses and technologies or otherwise seek to expand our operations to 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 without limitation 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.

**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.**

We have a subsidiary in China, Curis Shanghai, which is currently licensed to conduct business but is not operational.

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, or 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.

**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, the value of certain liabilities, including the fair value of our warrant liability, 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 the assumptions underlying them, 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.

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

Despite the implementation of security measures, our internal computer systems and those of our current and future collaborators, other contractors, or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations or those of our collaboration partners could result in a material disruption of our product development programs or those of our collaboration partners. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and continued development of our drug candidates may be delayed. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party contract manufacturers) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

**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 of which are outside 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.

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## 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 third-party 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, we do not control the 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 the 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.

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**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 these third parties or to obtain a judgment that our drug candidates do not infringe the 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 Asia 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 license 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. 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 will impair our intellectual property rights and may harm our business, prospects and reputation.

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**If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.**

We rely significantly 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 for licenses to us 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 licenses to us of 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 patented 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 competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or 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 MANUFACTURING AND SALES

**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 manufacturing capabilities and we lack the resources and the capability to 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 poor or 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 at a time that is costly 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 corresponding 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, failure of regulatory authorities to grant marketing approval of 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 biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and prospects.

**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 to 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.

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We may seek to independently market and sell products that are not already subject to agreements with other parties. If we determine 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.

**Even if we successfully commercialize any products under development, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could adversely affect the commercial success of our drug candidates.**

Our ability to collect significant revenues from sales of our products, if commercialized successfully, may depend on our ability, and the ability of any current or potential future collaboration partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies; and
- other healthcare-related organizations.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third party payers are increasingly challenging the prices charged for medical products and services. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or a foreign equivalent. 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. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the US. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any product candidate that we develop, restrict or regulate post-approval activities and affect our ability to profitably sell profitably or commercialize any product candidate for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. 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 receive for any approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors.

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In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively PPACA. Among the provisions of PPACA of importance to our potential products are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the 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 of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer s Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report product 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 PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law 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 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, or in-licensed products, if any, may be.

## 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 adversely affect 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 November 5, 2015. 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:

- 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;
- the 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.

**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.

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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 $30,000,000 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, 2015, 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.**

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future.

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

As of September 30, 2015, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 48.6% of our outstanding common stock. As a result, these stockholders, if acting together, will be able to exert influence over the management and affairs of our company and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. 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 analysts publish negative evaluations of our stock, the price of our stock could decline.**

If one or more of the analysts covering our business downgrade their evaluation of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price 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 lower 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.

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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 transaction.

**Item 6. Exhibits**

(a) Exhibits.

See exhibit index.

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**SIGNATURE**

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

CURIS, INC.

Dated: November 9, 2015

By: /s/ MICHAEL P. GRAY
**Michael P. Gray**

Chief Financial and Business Officer

(Principal Financial and Accounting Officer)

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## EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 31.1 | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 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 |